

Correspondence between ISO13485:2016 and MHLW MO 169 Chapter 2, as revised in 2021

MHLW MO 169 Chapter 2 Basic Requirements Regarding Manufacturing Control and Quality Control of Medical Devices	ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes	Note for understanding the requirements of MHLW MO 169 Chapter 2, as amended in 2021
Section 1 General Rules	1 Scope	
4	1, paragraph 4 and 5	Scope of the requirements of this chapter is explained in this Article. Article 4.1 specifies that Class 1 medical devices are exempted from the requirements of design and development, Article 30 to Article 36- 2. Article 4.2 and 4.3 specifies the rule of exclusion and non-application of the requirements. These articles are identical to the description of ISO13485:2016 clause 1, paragraph 4 and 5.
Section 2 Quality Management System	4. Quality management system	
5-1	4.1.1	Roles undertaken by the organization are Marketing Authorization Holder provided by Article 23-2.1 of PMD Act, Registered Manufacturing Site provided by Article 23-2-3.1 and 23-2-4.1 of PMD Act, Seller of pharmaceutical products provided by Article 24.1 of PMD Act, Seller and Leaser of specially-controlled medical devices provided by Article 39.1 of PMD Act, Repairer of medical devices provided by Article 40-2.1 of PMD Act, or Seller and Leaser of controlled medical devices provided by Article 39-3.1 of PMD Act.
5-2	4.1.2	
5-3	4.1.3	
5-4	4.1.4	
5-5	4.1.5	
5-6	4.1.6	
6	4.2.1	
7-1	4.2.2	
7-2	4.2.3	
8	4.2.4	The retention period of obsolete documents required by the ordinance is specified by Article 67.
9	4.2.5	The record retention period required by the ordinance is specified by Article 68.
Section 3 Management responsibility	5. Management responsibility	
10	5.1	
11	5.2	
12	5.3	
13	5.4.1	
14	5.4.2	

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15	5.5.1	
16	5.5.2	
17	5.5.3	
18	5.6.1	
19	5.6.2	The organization is not required to input “reporting to regulatory authorities”, the item specified in ISO13485:2016 5.6.2 c), to management review, when the organization is the person operating the registered manufacturing site.
20	5.6.3	
Section 4 Resource Management	6. Resource Management	
21	6.1	
22	6.2, paragraph 1 and 2	
23	6.2, paragraph 3	
24	6.3	
25-1	6.4.1	
25-2	6.4.2	
Section 5 Product realization	7. Product realization	
26	7.1	
27	7.2.1	
28	7.2.2	
29	7.2.3	
30	7.3.1, 7.3.2	
31	7.3.3	
32	7.3.4	
33	7.3.5	
34	7.3.6	
35-1	7.3.7	Clinical evaluations and/or evaluation of performance of the medical devices are required to be implemented as part of design and development validation, in the case that the medical device is designated by 23-2-5.3 or 23-2-9.4 of PMD Act.
35-2	7.3.8	
36-1	7.3.9	
36-2	7.3.10	
37	7.4.1	
38	7.4.2	
39	7.4.3	
40	7.5.1	
41	7.5.2	

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42	7.5.3	
43	7.5.4	
44	7.5.5	
45	7.5.6	
46	7.5.7	
47	7.5.8	
48	7.5.9.1	
49	7.5.9.2	The requirements of Article 49.2 and Article 49.3, which are identical to the requirements of ISO13485:2016 7.5.9.2 paragraph 2 and 3, are not applied, when the organization is the person operating the registered manufacturing site.
51	7.5.10	
52	7.5.11	
53	7.6	
Section 6 Measurement, analysis and improvement	8 Measurement, analysis and improvement	
54	8.1	
55-1	8.2.1	
55-2	8.2.2	This article is identical to the requirement of ISO13485:2016 8.2.2. However, it should be noted that the organization is required to determine the need to report the information to the Marketing Authorization Holder instead of the regulatory authorities, when the organization is the person operating the registered manufacturing site.
55-3	8.2.3	This article is identical to the requirement of ISO13485:2016 8.2.3. However, it should be noted that the organization is required to notify the information to the Marketing Authorization Holder instead of the regulatory authorities, when the organization is the person operating the registered manufacturing site. Record of the notification shall also be maintained.
56	8.2.4	
57	8.2.5	
58	8.2.6, paragraph 1-3	
59	8.2.6, paragraph 4	
60-1	8.3.1	
60-2	8.3.2	
60-3	8.3.3	
60-4	8.3.4	
61	8.4	
62	8.5.1	
63	8.5.2	

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64	8.5.3	
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## **Tentative translation of MHLW MO 169 Chapter 3, as revised in 2021**

Note:

- 1) This English document is only for reference purpose. In case of any discrepancies, the Japanese text shall prevail.
- 2) The requirements of MHLW MO 169 are applied to both the Marketing Authorization Holder etc. and the person operating the Registered Manufacturing Site (hereafter RMS). In this document the requirements are stipulated as the requirements for the Marketing Authorization Holder etc. Meanwhile, the requirements must be paraphrased as appropriate, when they are applied to RMS.
- 3) Article 69 to Article 72-3 are applied only to the Marketing Authorization Holder etc. (These requirements are not applied to RMS.).
- 4) Article 65, which was included in the chapter 3 of the previous version of the ordinance, is deleted in this version. Hence, there is no “Article 65” in this version.

Chapter 3 Additional Requirements Regarding Manufacturing Control and Quality Control of Medical Devices, etc.

(Additional Requirements Regarding Quality Management System)

Article 66

- (1) The Marketing Authorization Holder etc. shall establish, document, implement the quality management system pursuant to the provisions of Chapter 3 to Chapter 5-2 inclusive (limited to the provisions that shall apply pursuant to the provisions of Article 3, hereinafter the same in this article) as well as the provisions of Chapter 2 and also maintain its effectiveness.
- (2) The Marketing Authorization Holder etc. shall manage processes pursuant to the provisions of Chapter 3 to Chapter 5-2 inclusive, as well as the provisions of Chapter 2.
- (3) The Marketing Authorization Holder etc. shall describe the procedures and records (specified in each item of Article 6 as well as Chapter 3 to Chapter 5-2) in the documents related to the quality management system.

(Retention Period of Quality Management System Documents)

Article 67

- (1) The Marketing Authorization Holder etc. shall retain the quality management system documents or their copies for the following periods (5 years for the documents for training) from the date of obsolete (see Article 8(4))

Proviso: This provision shall not apply to the quality management documents used for the manufacturing or testing of the products when they are maintained to be available for the period

specified in the Article 68.

- (i) 15 years for the specially designated maintenance control required medical devices [one year plus the shelf life for the products of which the shelf life or the expiry date (hereinafter simply referred to as the "shelf life") plus one year exceeds 15 years]
- (ii) 5 years for the medical devices, etc. other than the specially designated maintenance control required medical devices (one year plus the shelf life for the products of which the shelf life plus one year exceeds 5 years).

(Retention Period of Records)

#### Article 68

- (1) The Marketing Authorization Holder etc. shall retain the records specified under Article 9(1) or in this chapter for the following periods (5 years for the records of the training) from the date of creation.
  - (i) 15 years for the specially designated maintenance control required medical devices (one year plus the shelf life for the products of which the shelf life plus one year exceeds 15 years)
  - (ii) 5 years for the medical devices, etc. other than the specially designated maintenance control required medical devices (one year plus the shelf life for the products of which the shelf life plus one year exceeds 5 years).

(Reporting Adverse Events, etc.)

#### Article 69

The Marketing Authorization Holder etc. shall make all the facilities and the relevant registered manufacturing sites pursuant to the provisions of Article 23-2-3(1) or Article 23-2-4(1) of the PMDA Act (hereinafter referred to as the "Registered Manufacturing Site"), document the procedure to notify The Marketing Authorization Holder etc. of the matters specified in the items of Article 228-20(1) and 228-20(2) of the Enforcement Regulations concerning the products when the facilities and relevant Registered Manufacturing Sites recognize the matters concerned.

(Relationship with Good Vigilance Practice (GVP))

#### Article 70

The Marketing Authorization Holder etc. shall perform the duties related to post-marketing safety control of the products pursuant to the provision of the Ordinance on the Standards for Post-Marketing Safety Control of Drug, Quasi-Drug, Cosmetics and Medical Devices and Regenerative and Cellular Therapy Products, Gene Therapy Products etc. [MHLW Ministerial Ordinance No. 135, 2004 (hereinafter referred to as the "Good Vigilance Practice (GVP)"]], supplementary to the provisions of this Ministerial Ordinance.

(Duties of General Manager Responsible for Manufacturing and Sales of Medical Devices, etc.)

#### Article 71

- (1) The Marketing Authorization Holder etc. shall have the General Manager Responsible for Manufacturing and Sales of Medical Devices, etc. specified in Article 23-2-14(2) of the PMD Act (hereinafter referred to as the "General Manager Responsible for Manufacturing and Sales of Medical Devices, etc.") perform the following duties.
- (i) To supervise the duties of the manufacturing control and quality control such as decision of release of the products and to bear a responsibility for the duties.
  - (ii) When it is deemed necessary to fairly and properly perform the duties, to give a necessary opinion in writing to The Marketing Authorization Holder etc., the top management and other persons responsible for the duties concerned and to retain its copy for 5 years.
  - (iii) To supervise the Domestic Quality Assurance Manager specified in Article 72(1) (excluding cases where the General Manager Responsible for Manufacturing and Sales of Medical Devices, etc. also serves as the Domestic Quality Assurance Manager pursuant to the provision of the Article 71(2)).
  - (iv) To respect the opinions of the management representative and the Domestic Quality Assurance Manager specified in Article 72(1).
  - (v) To have the units related to the manufacturing control or quality control and the Safety Control General Division specified in Article 4(1) of the Good Vigilance Practice (GVP) (hereinafter referred to as the "Safety Control General Division" in Article 72(2)(ix) closely collaborate with each other.
- (2) The General Manager Responsible for Manufacturing and Sales of Medical Devices, etc. may also serve as the top management, the management representative or the Domestic Quality Assurance Manager specified in Article 72(1).

(Domestic Quality Assurance Manager)

#### Article 72

- (1) The Marketing Authorization Holder etc. shall provide the facilities located in Japan with the Domestic Quality Assurance Manager who satisfies the following requirements as a responsible person for the duties of controlling quality of the domestic products performed pursuant to the provision of this Ministerial Ordinance (hereinafter referred to as the "quality control duties").
- (i) To be a responsible person of the Quality Assurance Division in The Marketing Authorization Holder etc.
  - (ii) To be the person who was engaged in the quality control duties or equivalent duties for 3 years or longer
  - (iii) To be the person who has competence for proper and smooth conduct of the quality control duties in Japan
  - (iv) To be the person who does not belong to the units related to sales of medical devices, etc. and other than above, to be the person who is not suspected to bring about obstacles to proper and smooth conduct of the quality control duties in Japan.
- (2) The Marketing Authorization Holder etc. shall have the Domestic Quality Assurance Manager perform the following duties based on the procedures, etc. prepared pursuant to the provision of this

Ministerial Ordinance.

- (i) To supervise the quality control duties in Japan
  - (ii) To verify that the quality control duties in Japan are properly and smoothly performed
  - (iii) For the products that are distributed in Japan, to decide release to market by lot (by manufacturing number or manufacturing code for medical devices, etc. which do not constitute a lot) and to prepare records of the decision result and release to market such as destination (when having the person appointed beforehand decide release to market pursuant to the provision of Article 72(3), to appropriately comprehend condition of deciding release of the products to market).
  - (iv) For the products that are distributed in Japan, when the change in manufacturing method or testing method, etc. that may affect quality of the products is made, to collect information on the change from domestic and abroad and to comprehend the information. When the change concerned might seriously affect the quality of the products, to rapidly report in writing to the management representative and the General Manager Responsible for Manufacturing and Sales of Medical Devices, etc. and to make necessary and appropriate measures be taken.
  - (v) For the products that are distributed in Japan, to collect information on quality, etc. of the products (including information on inferior quality or potential inferior quality) from domestic and abroad. When the information concerned is obtained, to rapidly report in writing to the management representative and the General Manager Responsible for Manufacturing and Sales of Medical Devices, etc., to record and to make necessary and appropriate measures be taken.
  - (vi) When the products distributed in Japan are recalled, to perform the following duties.
    - A. The medical devices, etc. recalled shall be segregated, stored for a certain period and properly handled.
    - B. The record describing content of recall shall be prepared and to report to the management representative and the General Manager Responsible for Manufacturing and Sales of Medical Devices, etc. in writing.
  - (vii) Other than those specified in Article 72(2)(iv) to 72(2)(vi), to report to the management representative and the General Manager Responsible for Manufacturing and Sales of Medical Devices, etc. in writing when it is deemed necessary for performing the quality control duties in Japan.
  - (viii) When performing the quality control duties in Japan, to give a written notice or instruction to the person operating the Registered Manufacturing Site, retailers, proprietors of a pharmacy, proprietors of a hospital or a clinic and other involved parties.
  - (ix) When recognizing the information on the safety assurance measures specified in Article 2(2) of the Good Vigilance Practice (GVP), to supply the Safety Control General Division with the information in writing without delay.
- (3) Release to market specified in Article 72(2)(iii) may be decided by the person who is appointed beforehand by the Domestic Quality Assurance Manager [limited to the personnel of the Quality Assurance Division or the Personnel of the Registered Manufacturing Site (limited to the sites which performs release of the products to market) who has competence for proper and smooth conduct of the

duties concerned].

(4) The person who decided release to market pursuant to the provisions of Article 72(3) shall prepare records of the result and release to market such as destination and shall report in writing to the Domestic Quality Assurance Manager.

(5) The Domestic Quality Assurance Manager may also serve as the management representative.

(Other Items to be Complied)

#### Article 72-2

(1) The Marketing Authorization Holder etc. shall consolidate necessary systems also based on relationship with the duties performed pursuant to the provisions of Article 55 so that collection of information pursuant to the provisions of Article 72(2)(iv) and 72(2)(v) is not interfered and also shall make and document the agreement on necessary and sufficient matters between relevant facilities and the Registered Manufacturing Site, respectively.

(2) The Marketing Authorization Holder etc. shall document the procedures for the following matters.

- (i) Response to notices from repairers of medical devices
- (ii) Ensuring quality in retailers or leasers of medical devices
- (iii) Response to notices from retailers or leasers of used medical devices

(Duties of Appointed Marketing Authorization Holders for Foreign Manufacturers of Medical Devices, etc.)

#### Article 72-3

(1) The restrictive approval holders of foreign manufactured medical devices, etc. shall have the Appointed Marketing Authorization Holders for foreign manufacturers of medical devices, etc. perform the following duties among the duties performed pursuant to the provision of this Ministerial Ordinance.

- (i) Of the duties performed pursuant to the provisions of Article 7, those related to domestic duties
- (ii) Of the duties performed pursuant to the provisions of Article 17, those related to domestic duties
- (iii) Of the duties performed pursuant to the provisions of Article 29, those related to domestic duties
- (iv) Of the duties performed pursuant to the provisions of Article 43, those related to domestic duties
- (v) Of the duties performed pursuant to the provisions of Article 48 and Article 49, those related to domestic duties
- (vi) Of the duties performed pursuant to the provisions of Article 55 and Article 55-2, those related to domestic duties
- (vii) Of the duties performed pursuant to the provisions of Article 60 to Article 60-4, those related to domestic duties
- (viii) Recall handling related to domestic products
- (ix) Duties related to post-marketing safety control of domestic products
- (x) Duties to make necessary cooperation with the Restrictive Authorization Holders of foreign

manufactured medical devices, etc. for making necessary reports to and transfer of information and appropriately performing other duties concerned with the top management and the management representative of the Restrictive Authorization Holders of foreign manufactured medical devices, etc. and other relevant persons concerning the duties performed as the Appointed Marketing Authorization Holders for foreign manufacturers of medical devices, etc.

(xi) Control of documents and records related to the duties performed as the Appointed Marketing Authorization Holders for foreign manufacturers of medical devices, etc.

(2) For the foreign manufacturers of designated specially controlled medical devices, the provisions of the Article 72-3(1) shall apply mutatis mutandis. In such cases, the "Appointed Marketing Authorization Holders for foreign manufacturers of medical devices, etc." shall read the "Appointed Marketing Authorization Holders for foreign manufacturers of specially controlled medical devices, etc."

(3) For the Appointed Marketing Authorization Holders for foreign manufacturers of medical devices, etc. or the Appointed Marketing Authorization Holders for foreign manufacturers of specially controlled medical devices, etc., the provisions from Article 70 to 72 (excluding Article 72(5) shall apply mutatis mutandis. In such cases, "other" in Article 71(1)(i) shall read "performed as other Appointed Marketing Authorization Holders for foreign manufacturers of medical devices, etc. or the Appointed Marketing Authorization Holders for foreign manufacturers of specially controlled medical devices, etc.", "The Marketing Authorization Holder etc., the top management" in Article 71(1)(ii) shall read "the Appointed Marketing Authorization Holders for foreign manufacturers of medical devices, etc. or the Appointed Marketing Authorization Holders for foreign manufacturers of specially controlled medical devices, etc.", "the management representative and Article 71(1)" in Article 71(1)(iv) shall read " Article 71(1)", "opinion of " shall read "opinion of", "the top management or the management representative or Article 72(1)" in Article 71(2) shall read " Article 72(1)", "pursuant to" in Article 72(1) shall read "as the Appointed Marketing Authorization Holders for foreign manufacturers of medical devices, etc. or the Appointed Marketing Authorization Holders for foreign manufacturers of specially controlled medical devices, etc. pursuant to", "the management representative and the General Marketing Supervisor of medical devices, etc." in Article 72(2)(iv) shall read "the General Marketing Supervisor of medical devices, etc." and "the management representative and the General Marketing Supervisor of medical devices, etc." in Article 72(2)(v), 72(2)(vi)-B and 72(2)(vii) shall read the "General Marketing Supervisor of medical devices, etc. "

## **Tentative translation of MHLW MO 169 revised in 2021, Chapter 4**

(Note)

- 1) This English document is only for reference purpose. In case of any discrepancy, the Japanese text shall prevail.
- 2) The requirements of MHLW MO 169 are applied to both the Marketing Authorization Holder and the person operating the Registered Manufacturing Site. In this document the requirements are stipulated as the requirements for the Marketing Authorization Holder. Meanwhile, when they are applied to the Registered Manufacturing Site, the requirements must be paraphrased, as appropriate.

### **Chapter 4. Manufacturing control and quality control of biological medical devices, etc.**

(Infrastructure for operation at a manufacturing site of a marketing authorization holder, etc. of specified biological medical devices, etc.)

Article 73 Marketing authorization holders, etc. (hereinafter referred to as "marketing authorization holders, etc. of specified biological medical devices, etc.") of products related to medical devices and cell/tissue-based medical devices (hereinafter referred to as "specified biological medical devices, etc." in this chapter), such as medical devices, etc. as specified biological products, designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Paragraph 2, Article 43 of the Act shall satisfy the following requirements as an infrastructure for operation at manufacturing sites that manufacture the said products (excluding manufacturing sites that only perform packaging, labeling, storage, or design; the same shall apply in this chapter).

[1] Facilities supplying distilled water, etc. necessary for manufacturing products shall have a structure necessary for preventing contamination of distilled water, etc. by foreign matters or microorganisms (including viruses; the same shall apply hereinafter in this chapter and Chapter 6).

[2] Workplaces (places where manufacturing operations are performed; the same shall apply in this chapter and through Chapter 6) shall conform to the following requirements.

A. Work rooms or controlled work areas should have structures and facilities that can maintain and control appropriate temperature, humidity, and cleanliness according to the manufacturing process.

B. Work rooms for weighing of raw materials or materials or cleaning of containers should have a well-closed structure for dust prevention.

C. Work rooms for drying or sterilization of containers after cleaning should be dedicated.

This does not apply if there is no risk of contamination of cleaned containers.

D. Clean areas (work areas where weighing and preparation of parts, etc. are performed and where products, etc. are exposed to the air in the work areas after cleaning; the same shall apply hereinafter in this chapter and Chapter 6) and aseptic areas (work areas where sterilized products, parts, etc., or sterilized containers are exposed to the air in the work areas, areas where closure of containers is performed, and areas where aseptic operations, such as sterility testing, are performed; hereinafter the same in this chapter.) shall conform to the following requirements.

- (1) The surfaces of ceilings, walls, and floors are smooth and free from cracks and do not cause dust.
- (2) Drainage facilities have an appropriate structure to prevent contamination by harmful drainage.

E. Do not install drainage ports in clean areas. This shall not apply to the following cases.

- (1) Drainage ports are equipped with traps that are easy to clean and devices to prevent backflow of drainage.
- (2) Traps have a structure to allow disinfection.
- (3) A ditch of the floor is shallow and easy to clean and connected to the outside of manufacturing areas (places where culture, extraction, and purification, weighing and preparation of parts, etc., cleaning and drying of containers, closure and packaging of containers, and gowning are performed) through drainage ports.

F. Aseptic areas shall conform to the following requirements.

- (1) Do not install drainage ports.
- (2) Do not install sinks.

G. Areas where tests using animals or microorganisms are performed and areas where animal tissues or microorganisms not necessary for manufacturing products related to specified biological medical devices, etc. are handled shall be clearly separated from the other areas where the said products are manufactured, and an air-handling system shall be separated.

H. Areas for aseptic operations shall be provided with clean air treated with filters and have a structure and facilities necessary for appropriate differential pressure control.

I. Areas, where pathogenic microorganisms, etc. are handled, shall have a structure and facilities necessary for appropriate negative pressure control.

J. Areas, where infectious microorganisms, etc. are handled, shall have facilities for cleaning, disinfection, and sterilization of apparatuses used in the areas and facilities for treatment of waste fluids, etc.

K. The following facilities shall be installed in rooms that are clearly separated from others,

excluding facilities that are considered unnecessary for manufacturing of the products depending on the type and manufacturing method, etc. of the products.

(1) Storage facilities for microorganisms

(2) Facilities to control animals inoculated with microorganisms for use in manufacturing or testing

(3) Facilities for treating animals for use in manufacturing or testing

(4) Facilities for inoculating microorganisms into culture media, etc.

(5) Facilities for culturing microorganisms

(6) Facilities for collecting, inactivating, and sterilizing cultured microorganisms

(7) Facilities to disinfect apparatuses and instruments, etc. used for manufacturing or testing

L. The surfaces of the ceilings, walls, and floors of the rooms with facilities listed in (2) to (4) and (6) of K shall be structured so that they can be cleaned and disinfected.

M. Rooms having facilities listed in (4) and (6) of K and rooms having facilities for sterility testing among those necessary for testing of products, etc. shall meet the following requirements.

(1) They shall be aseptic rooms. This does not apply to cases where work rooms are equipped with facilities that can perform aseptic operation without hindrance according to the type of product and manufacturing method, etc.

(2) The aseptic rooms in (1) shall have a dedicated anteroom and structure so that a work room can normally be entered only through the anteroom, and a doorway of the anteroom does not face the outside.

N. In addition to the facilities listed in K, facilities listed below shall be provided.

(1) Facilities necessary for breeding control of animals for use in manufacturing or testing

(2) Facilities for preparation of culture media and diluent

(3) Facilities necessary for cleaning, drying, sterilization, and storage of apparatuses, instruments, and containers, etc. for use in manufacturing or testing

(4) Facilities for container closure

(5) Facilities to properly dispose of animal carcasses and other dirt and to purify polluted water

O. Storage facilities shall be equipped with a thermostat, self-recording thermometer, and other necessary instruments.

P. An air-handling system shall conform to the following requirements.

(1) The structure should be appropriate to prevent contamination of products, etc. by microorganisms, etc.

(2) When pathogenic microorganisms, etc. are handled, the structure should be appropriate to prevent air diffusion of the microorganisms, etc.

(3) The structure should be such that the air emitted from areas, where pathogenic microorganisms, etc. are handled, is emitted after removal of the microorganisms, etc. by high performance air filters.

(4) The structure should be such that the air emitted from work rooms, where pathogenic microorganisms, etc. may leak, is not re-circulated. This does not apply if the microorganisms, etc. have been sufficiently removed by the structure specified in (3) and if re-circulation is considered inevitable.

(5) A separate line should be used for each work room where necessary.

Q. Pipes, valves, and vent filters shall have a structure that can be easily cleaned or sterilized according to the intended use.

R. The following testing facilities and apparatuses are provided. This does not apply to cases where testing is performed by using other testing institutions of a marketing authorization holder, etc. of specified biological medical devices, etc. on their own responsibility without any problem.

(1) Facilities and apparatuses for sealing inspection if it is necessary to perform the sealing inspection

(2) Facilities and apparatuses for foreign substance inspection

(3) Facilities and apparatuses for physicochemical tests of products, process agents, and materials

(4) Facilities and apparatuses for sterility testing

(5) Facilities and apparatuses for pyrogen tests if it is necessary to perform the pyrogen tests

(6) Facilities and apparatuses for biological tests if it is necessary to perform the biological tests

[3] Work areas for products related to cell/tissue-based medical devices shall conform to the following requirements.

A. Areas for receiving and processing raw materials or materials and storage of products, etc. shall be separated from the other areas for manufacturing products related to cell/tissue-based medical devices.

B. Areas for receiving and processing raw materials or materials and storage of products, etc. shall have a structure and facilities necessary for these operations.

[4] Areas for manufacturing products using human blood or plasma as raw materials or materials should be clearly separated from the other areas, and there should be facilities and apparatuses exclusively for use in manufacturing. This shall not apply to manufacturing processes after a process to inactivate or remove viruses.

[5] Facilities used to control animals for use in manufacturing or testing (donor animals [including animals providing cells or tissues that become raw materials or materials of

cell/tissue-based medical devices; the same shall apply in this chapter]; hereinafter referred to as "animals used") shall meet the following requirements.

- A. An area for inspection of animals used shall be separated from the other areas.
- B. There should be a storage facility for feed with no risk of intrusion of pests.
- C. There should be a housing room for animals for use in manufacturing and housing room for animals for use in testing.
- D. The housing rooms for animals used have a different line of the air-handling system from those of the other areas. This does not apply to animals that are considered appropriate to be kept outside.
- E. When animals used are inoculated with antigens, etc., there should be an inoculation room separated from a necropsy room for animals.

(Documents related to manufacturing control and quality control)

Article 74 Marketing authorization holders, etc. of products related to biological medical devices, etc. (hereinafter referred to as "marketing authorization holders, etc. of biological medical devices, etc.") shall, when handling products related to biological medical devices, etc., describe the following matters in a product master formula in addition to those specified in Article 7-2.

- [1] Names, nature, properties, ingredients and their contents, and other specifications of materials obtained from humans, animals, plants, or microorganisms, which are used as parts, etc.
- [2] Specifications of animals used (including a method of breeding control)
- [3] Other necessary matters

(Process control)

Article 75 Marketing authorization holders, etc. of biological medical devices, etc. shall, when handling products related to biological medical devices, etc., appropriately control operations related to process control of products related to biological medical devices, etc. listed below and document the procedures based on a product master formula in addition to the operations described in the preceding article.

- [1] Instruct a person designated beforehand to conduct the following operations according to the details of the operations.
  - A. When biological raw materials (raw materials or materials which are derived from organisms [excluding plants] and used for manufacturing biological medical devices, etc.; the same shall apply hereinafter) and microorganisms, etc. contained in products, etc. are inactivated or removed in the manufacturing process, take measures necessary to prevent

contamination by raw materials, materials, or products, etc. that have not undergone inactivation or removal.

B. When biochemical technologies, such as fermentation, are used in the manufacturing process, items, such as temperature and hydrogen ion index, necessary for controlling the manufacturing process shall be continuously measured.

C. If a column chromatography device, etc. is used in the manufacturing process, take necessary measures to prevent contamination of the device by microorganisms, etc., and measure endotoxin where necessary.

D. If a culture system is used in the manufacturing process to continuously supply culture media to a culture vessel and continuously discharge culture fluid, take necessary measures to maintain culture conditions in the culture vessel during the culture period.

E. In the following cases, perform validation, and prepare and retain the records.

(1) When manufacturing of products related to biological medical devices, etc. is newly started at the manufacturing site

(2) When there is a change in manufacturing procedures, etc., which has a significant impact on the quality of products related to biological medical devices, etc.

(3) Other cases where it is deemed necessary for proper conduct of manufacturing control and quality control of products related to biological medical devices, etc.

F. Access to work areas by persons other than those engaged in manufacturing operations should be restricted as much as possible.

G. Implement hygiene control of members in accordance with the following provisions.

(1) Restrict entry of members to clean areas or aseptic areas where operations are being conducted as much as possible.

(2) Members engaged in manufacturing operations shall not be engaged in operations related to control of animals used (excluding those currently used in the manufacturing process).

H. Implement hygiene control of members engaged in operations in clean areas or aseptic areas in accordance with the following requirements.

(1) Persons engaged in manufacturing operations shall wear disinfected work clothes, shoes, caps, and masks.

(2) Medical check-ups shall be given periodically members to confirm that they do not suffer from diseases that may contaminate products, etc. with microorganisms, etc.

(3) If members are in a health condition that may cause contamination of products, etc. by microorganisms, etc. (including skin or hair infection, cold, injury, or symptoms, such as diarrhea or fever of unknown cause; the same shall apply hereinafter), they shall report it.

I. Animals used (limited to those used for manufacturing; the same shall apply hereinafter in

this item) should be bred under proper control at all times, and their health should be monitored so that animals with infectious disease and other animals unsuitable for use would not be used.

J. All goods contaminated by microorganisms (limited to those contaminated in the manufacturing process) and carcasses of animals used should be treated so as not to cause hazards to the public health and hygiene.

K. Prepare and retain records on the following matters concerning the handling of strains of microorganisms used for manufacturing.

- (1) Name of microorganism and number assigned to each container
- (2) Date of receipt and name and address of the other party (name and address in the case of a corporation)
- (3) Biological properties and date of inspection
- (4) Status of subculture

L. Verify that biological raw materials are appropriate based on a product master formula of the products concerned, and prepare and retain records on the results of the verification.

M. For biological raw materials for use in manufacturing of biological medical devices, etc., records shall be prepared and retained as specified by the Minister of Health, Labour and Welfare. An agreement shall be concluded with the relevant collector, etc. of raw materials or materials falling under the category of the biological raw materials concerned (hereinafter referred to as "raw material collector, etc.") to store them appropriately at the raw material collector.

[2] Prepare and retain records of E, L, and M of the preceding item for each lot.

2. Marketing authorization holders, etc. of biological medical devices, etc. shall, when handling products related to cell/tissue-based medical devices, appropriately control operations related to process control of products related to cell/tissue-based medical devices listed below at a manufacturing site of the products in question and document the procedures based on a product master formula in addition to the operations described in the preceding paragraph.

[1] Instruct a person designated beforehand to conduct the following operations according to the details of the operations.

A. When handling cells or tissues collected from different donors (persons providing cells or tissues as raw materials or materials of cell/tissue-based medical devices [excluding those related to bodies of brain-dead persons specified in Paragraph 2, Article 6 of the Act on Organ Transplantation <Act No. 104 of 1997>]; the same shall apply in this chapter) or donor animals, take necessary measures to prevent mix-up and cross-contamination of the cells or tissues.

B. At the time of receipt of cells or tissues as raw materials or materials, verify that they are appropriate based on a product master formula of the products and records of the following matters, and prepare records on the results.

(1) Site where the cells or tissues were collected

(2) Date of collection of the cells or tissues

(3) Status of donor screening (a diagnosis of a donor is made through history taking or tests, etc., and whether the donor is fully eligible to provide cells or tissues that become raw materials or materials of products related to cell/tissue-based medical devices is judged by history taking and tests, etc.) if the cells or tissues are derived from humans

(4) Acceptance status of donor animals and status of donor screening (testing and rearing management are performed for donor animals, and whether the donors are fully eligible as providers of cells or tissues that become raw materials or materials of products related to cell/tissue-based medical devices is judged by the testing and breeding control) if the cells or tissues are derived from animals

(5) Process of operations to collect the cells or tissues

(6) In addition to those listed in (1) to (5), matters necessary for ensuring the quality of products related to cell/tissue-based medical devices

C. When collecting cells or tissues as raw materials or materials from donor animals, take necessary measures to prevent contamination by microorganisms, etc. in the process of collection, and prepare records of such measures.

D. When any of the following is applicable to a member, do not allow the member to engage in operations in a clean area or aseptic area.

(1) He/she is in a health condition that may cause contamination of products by microorganisms, etc.

(2) Microorganisms, etc. that may contaminate cells or tissues are handled immediately before collection or processing of cells or tissues.

E. Know the name of a business office to which products are released, date of release, and lot for each product, and prepare records thereof.

F. Take measures necessary to ensure the quality of products for distribution, and prepare records of such measures.

G. Prepare records on breeding control after receipt of donor animals.

[2] Prepare and retain records of B, C, F, and G in the preceding item for each lot and records of E in the same item for each product.

3. Marketing authorization holders, etc. of biological medical devices, etc. shall store records of the preceding two paragraphs so that a series of records from biological raw materials used in manufacturing to products manufactured by using the biological raw materials can

be checked appropriately.

(Testing)

Article 76 Marketing authorization holders, etc. of biological medical devices, etc. shall, when handling products related to biological medical devices, etc., appropriately control operations related to testing of products related to biological medical devices, etc. listed below at a manufacturing site of the products and document the procedures based on a product master formula in addition to the operations described in the preceding article.

[1] In order to prevent mix-up and cross-contamination of samples, samples should be separated by appropriate identification labeling.

[2] Testing that is important for quality control and cannot be performed with finished products should be conducted at an appropriate stage in the manufacturing process.

[3] Animals used (limited to those used for testing; the same shall apply hereinafter in this item) should be bred under proper control at all times, and their health should be monitored so that animals with infectious disease and other animals unsuitable for use would not be used.

[4] All goods contaminated by microorganisms (limited to those contaminated in the testing process) and carcasses of animals used should be treated so as not to cause hazards to the public health and hygiene.

[5] Prepare and retain records on the following matters concerning the handling of strains of microorganisms used for testing.

- A. Name of microorganism and number assigned to each container
- B. Date of receipt and name and address of the other party (name and address in the case of a corporation)
- C. Biological properties and date of inspection
- D. Status of subculture

[6] For each lot (biological raw materials used for manufacturing of products related to medical devices, etc. as specified biological products not constituting a lot: For each manufacturing number of the products or for each lot of the biological raw materials) of products related to specified biological medical devices, etc., reference samples in an amount of at least twice the quantity necessary for specified tests shall be stored under appropriate storage conditions for an appropriate period from the date of manufacturing (shelf life plus 10 years if medical devices related to the products are medical devices, etc. as specified biological products). This does not apply to products related to medical devices, etc. as specified biological products, not constituting a lot, for which reference samples are stored by a raw material collector, etc. for the relevant period as specified by operating

procedures agreed by the raw material collector, etc., and to products related to medical devices or cell/tissue-based medical devices designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Paragraph 2, Article 43 of the Act, which do not constitute a lot. For products related to medical devices, etc. as specified biological products that constitute a lot, storage of biological raw materials used for manufacturing of the products may be substituted for storage of products after a period of the shelf life of the products plus one year.

2. Marketing authorization holders, etc. of biological medical devices, etc. shall, when handling products related to cell/tissue-based medical devices, appropriately control operations related to testing of products related to cell/tissue-based medical devices listed in each of the following items at a manufacturing site of the products in question and establish/document the procedures based on a product master formula in addition to the operations described in the preceding paragraph.

[1] Instruct a person designated according to the details of operations beforehand to conduct testing at the time of receipt and after receipt of donor animals and other necessary operations.

[2] Prepare and retain records of the operations specified in the preceding item.

3. Marketing authorization holders, etc. of biological medical devices, etc. shall store records of the preceding two paragraphs so that a series of records from biological raw materials used in manufacturing to products manufactured by using the biological raw materials can be checked appropriately.

#### (Education and training)

Article 77 Marketing authorization holders, etc. of biological medical devices, etc. shall, when handling products related to biological medical devices, etc., document procedures for the following operations in addition to those specified in Article 23.

[1] Provide education and training related to microbiology, medicine, and veterinary medicine, etc. to members engaged in manufacturing or testing of products related to biological medical devices, etc.

[2] Provide education and training on measures necessary for prevention of microbial contamination to members engaged in operations in aseptic areas, areas handling pathogenic microorganisms, and so forth.

2. Marketing authorization holders, etc. of biological medical devices, etc. shall prepare and retain records on the education and training in the preceding paragraph.

#### (Management of documents and records)

Article 78 Marketing authorization holders, etc. of biological medical devices, etc. shall retain documents specified in this chapter or at least one copy of the documents for the periods listed in the following items (5 years for those related to education and training) from the date of abolition of the documents. However, for documents used for manufacturing or testing of products, it is enough to store those documents so that they can be used during storage of records related to the products specified in the following paragraph.

[1] Shelf life plus 30 years for products related to medical devices, etc. as specified biological products, etc. or biological medical devices, etc. manufactured using human blood as raw materials (origin of raw materials or materials used in manufacturing [including those used in the manufacturing process; the same shall apply hereinafter]; the same shall apply hereinafter)

[2] Shelf life plus 10 years for products related to biological medical devices, etc. (excluding those listed in the preceding item)

2. Marketing authorization holders, etc. of biological medical devices, etc. shall retain records specified in this chapter for the period specified in Item 1 or Item 2 of the preceding paragraph from the date of preparation (5 years for those related to education and training).

(Exceptions for retention of records)

Article 79 Marketing authorization holders, etc. of biological medical devices, etc. shall, notwithstanding the provisions of this chapter, retain records specified in this chapter for products related to biological medical devices, etc. designated by the Minister of Health, Labour and Welfare for the period designated by the Minister. This does not apply to cases where an agreement is concluded with a raw material collector, etc. and the raw material collector, etc. stores them appropriately for the said period.

## **Tentative translation of MHLW MO 169 revised in 2021, Chapter 5**

(Note)

- 1) This English document is only for reference purpose. In case of any discrepancy, the Japanese text shall prevail.
- 2) The requirements of MHLW MO 169 are applied to both the Marketing Authorization Holder and the person operating the Registered Manufacturing Site. In this document the requirements are stipulated as the requirements for the Marketing Authorization Holder. Meanwhile, when they are applied to the Registered Manufacturing Site, the requirements must be paraphrased, as appropriate.

### **Chapter 5. Manufacturing control and quality control of radioactive *in vitro* diagnostics**

(Infrastructure for operation at a registered manufacturing site of radioactive *in vitro* diagnostics)

Article 80 Marketing authorization holders, etc. of products related to radioactive *in vitro* diagnostics shall meet the following requirements as an infrastructure for operation at a registered manufacturing site (excluding registered manufacturing sites where only design is performed; the same shall apply in this chapter) of the products (for a registered manufacturing site where only packaging, labeling, or storage of containers or wrappers specified in the proviso of Item 1, Paragraph 3, Article 2 of the Regulations for Manufacturing and Handling of Radiopharmaceuticals is conducted, provisions related to work rooms in E of Item 2 and D of Item 4 shall be excluded, and provisions related to testing rooms in E of Item 2 and D of Item 4 are excluded if such testing is conducted on its own responsibility by using other testing facilities of the registered manufacturing site or other testing institutions and if it is found that there is no problem).

[1] It should be installed in a place where there is less risk of a landslide and flood.

[2] Work areas for products related to radioactive *in vitro* diagnostics shall conform to the following requirements.

A. They should be clearly separated from the other facilities.

B. A main structure, etc. is fireproof or made of non-combustible materials (non-combustible materials specified in Item 9, Article 2 of the Building Standards Act [Act No. 201 of 1950]; the same shall apply hereinafter).

C. Shielding walls or other shielding materials necessary to control the following doses at or below the dose limit specified by the Minister of Health, Labour and Welfare are installed.

(1) Radiation dose to which people may be exposed in a place where people in a registered

manufacturing site always enter

(2) Radiation dose at the boundary of a registered manufacturing site and in an area where people in a registered manufacturing site inhabit

D. There shall be only one entrance/exit site, where people enter/leave on a routine basis.

E. There should be work rooms and testing rooms (including animal testing rooms if animal testing is performed; the same shall apply hereinafter) conforming to the following requirements.

(1) Internal walls, floors, and other parts that may be contaminated by radioactive substances (radioactive substances specified in Item 2, Article 1 of the Regulations for Manufacturing and Handling of Radiopharmaceuticals; the same shall apply hereinafter) shall have a structure with few gaps, such as protrusions, dents, and joint of finishing materials.

(2) The surfaces of inner walls, floors, and other parts that may be contaminated by radioactive substances shall be flat and smooth and finished with materials that are difficult to be penetrated and corroded by gases or liquids.

(3) There should be disposal containers that are free from risk of scattering, leaking, seepage, or flow of radioactive substances or those contaminated by radioactive substances and can be used for transportation and disposal safely.

(4) A device, such as a hood and glove box, connected to exhaust facilities shall be provided to prevent the spread of air contaminated by gaseous radioactive substances or radioactive substances.

F. There should be a contamination inspection room conforming to the following requirements (room for inspection and removal of contamination by radioactive substances on the surface of human body or objects worn on human body such as work clothes, shoes, and protective equipment; the same shall apply hereinafter). This does not apply to handling of radioactive substances in quantity or concentration at or below the levels specified by the Minister of Health, Labour and Welfare.

(1) It is installed in the most appropriate place for inspection and removal of contamination by radioactive substances (e.g., near the entrance of work area where people always enter and leave).

(2) The requirements of (1) and (2) of E shall be met.

(3) Cleaning facilities and gowning facilities are provided, and radiation measuring instruments for inspection of contamination and equipment necessary for removal of contamination are provided.

(4) The drainage pipes of the cleaning facilities specified in (3) are connected to drainage facilities.

[3] Storage facilities conforming to the following requirements shall be provided.

- A. A main structure, etc. is fireproof, and a storage room with a fire door or storage box with a fireproof structure is provided at the opening.
  - B. Shielding walls and other shielding items conforming to the standards of C of the preceding item are provided.
  - C. There shall be only one entrance/exit site, where people enter/leave on a routine basis.
  - D. There should be a key or other facility or apparatus for closure at a part, such as a door and lid, leading to the outside.
  - E. There should be a lockable facility or apparatus for storing radiopharmaceuticals separately from the other goods.
  - F. There should be containers for radioactive substances conforming to the following requirements.
    - (1) Containers for radioactive substances that may contaminate the air outside the containers should have an airtight structure.
    - (2) Containers of liquid radioactive substances should have a structure to prevent liquid spill and be made of materials that are unlikely to be penetrated by liquid.
    - (3) For containers of liquid or solid radioactive substances, which may cause accidents, such as cracks and breakage, trays, absorbent materials, and other facilities or apparatuses shall be provided to prevent the spread of contamination by radioactive substances.
- [4] A disposal facility conforming to the following requirements shall be provided.
- A. They should be clearly separated from the other facilities.
  - B. A main structure, etc. is fireproof or made of non-combustible materials.
  - C. Shielding walls and other shielding items conforming to the standards of C of Item 2 are provided.
  - D. Exhaust facilities conforming to the following requirements shall be provided. This does not apply to cases where radioactive substances are handled in quantity or concentration at or below the levels specified by the Minister of Health, Labour and Welfare or cases where establishment of exhaust facilities significantly hinders the purpose of use or is difficult due to the nature of operations and there is no risk that gaseous radioactive substances are generated or that the air is contaminated by the radioactive substances.
    - (1) It is capable of keeping the concentration of radioactive substances in exhaust air at an exhaust port at or below the concentration limit specified by the Minister of Health, Labour and Welfare, or it is capable of keeping the concentration of radioactive substances in the air outside at the boundary (boundary of an area if measures are taken to prevent people from entering the area adjacent to the boundary of the registered manufacturing site without reason; the same shall apply hereinafter in this item) of a registered manufacturing site at or below the concentration limit specified by the Minister of Health, Labour and Welfare by

installing an exhaust air monitoring system and monitoring the concentration of radioactive substances in the exhaust air. This does not apply to the following case: It is significantly difficult to install exhaust facilities with such capability, and the exhaust facilities have the capability of keeping the dose, to which persons outside the boundary of a registered manufacturing site, at or below the dose limit specified by the Minister of Health, Labour and Welfare. The capability has to be approved by the Minister of Health, Labour and Welfare.

- (2) The structure prevents gas leakage, and corrosion-resistant materials are used.
- (3) There should be facilities that can prevent the spread of air contaminated by radioactive substances quickly in case of malfunction.
- (4) It is capable of keeping the concentration of radioactive substances in the air in areas, where people enter on a routine basis, in work rooms, testing rooms, or disposal rooms (rooms where incineration residues of radioactive substances or materials contaminated by radioactive substances are taken out from an incinerator or solidified with concrete or other solidifying materials [including treatment for solidification; the same shall apply hereinafter]; the same shall apply hereinafter) at or below the concentration limit specified by the Minister of Health, Labour and Welfare.

E. In cases where liquid radioactive substances or solutions contaminated by radioactive substances are cleaned or discharged, drainage facilities conforming to the following requirements shall be installed.

- (1) It is capable of keeping the concentration of radioactive substances in drainage at a drainage port at or below the concentration limit specified by the Minister of Health, Labour and Welfare, or it is capable of keeping the concentration of radioactive substances in drainage at the boundary of a registered manufacturing site at or below the concentration limit specified by the Minister of Health, Labour and Welfare by installing a wastewater monitoring system and monitoring the concentration of radioactive substances in drainage. This does not apply to the following case: It is significantly difficult to install drainage facilities with such capability, and the drainage facilities have the capability of keeping the dose, to which persons outside the boundary of a registered manufacturing site, at or below the dose limit specified by the Minister of Health, Labour and Welfare. The capability has to be approved by the Minister of Health, Labour and Welfare.

- (2) The structure prevents leakage of drainage, and materials that prevent penetration of drainage and that are corrosion-resistant are used.
- (3) A wastewater-purifier tank shall have a structure capable of collecting drainage or measuring the concentration of radioactive substances in the drainage and be equipped with a device to control the outflow of drainage.
- (4) The opening at the top of the wastewater-purifier tank shall have a structure with a lid or

have a fence around it or other facilities to prevent unauthorized entry.

F. If radioactive substances or materials contaminated by radioactive substances are incinerated, exhaust facilities meeting the provisions of D, disposal room meeting the provisions of (1), (2), and (4) of E of Item 2, contamination inspection room meeting the provisions of (1) to (3) of F of the same item, and incinerator meeting the following requirements shall be provided.

(1) The structure should prevent gas leakage and ash scattering.

(2) It is connected to exhaust facilities.

(3) The outlet for incineration residue is connected to a disposal room.

G. If radioactive substances or materials contaminated by radioactive substances are solidified using concrete or other solidifying materials, exhaust facilities meeting the provisions of D, disposal room meeting the provisions of (1), (2), and (4) of E of Item 2, contamination inspection room meeting the provisions of (1) to (3) of F of the same item, and solidifying facilities meeting the following requirements shall be provided.

(1) The structure should prevent leakage or spill of radioactive substances or materials contaminated by radioactive substances and dispersion of dust.

(2) Materials that prevent penetration of liquid and corrosion are used.

H. If radioactive substances or materials contaminated by radioactive substances are stored and disposed of, storage and disposal facilities conforming to the following requirements shall be installed.

(1) The structure shall be separated from the outside.

(2) There should be a key or other facility or apparatus for closure at a part, such as a door and lid, leading to the outside.

(3) Containers (those with fireproof structure only) conforming to the provisions of the preceding item are provided.

[5] At the boundary of controlled areas specified in Item 3, Article 1 of the Regulations for Manufacturing and Handling of Radiopharmaceuticals, facilities, such as fences, shall be provided to prevent unauthorized entry by other persons.

2. If exhaust facilities or drainage facilities approved based on D (1) or E (1) of Item 4 of the preceding paragraph are no longer considered to have the capability to be approved, the Minister of Health, Labour and Welfare may revoke the approval.

3. The provisions of Item 1, B to E of Item 2, A to D and F of Item 3, Item 4, and Item 5 of the preceding paragraph shall not apply to cases where only radioactive substances are handled in amount or concentration at or below the levels specified by the Minister of Health, Labour and Welfare.

(Compliance with regulations for manufacturing and handling of radioactive *in vitro* diagnostics)

Article 81 In addition to the provisions of the preceding article, marketing authorization holders, etc. of products related to radioactive *in vitro* diagnostics shall verify that registered manufacturing sites are conducting operations based on the provisions of the Regulations for Manufacturing and Handling of Radiopharmaceuticals.

## **Tentative translation of MHLW MO 169 revised in 2021, Chapter 5-2**

### (Note)

- 1) This English document is only for reference purpose. In case of any discrepancy, the Japanese text shall prevail.
- 2) The requirements of MHLW MO 169 are applied to both the Marketing Authorization Holder and the person operating the Registered Manufacturing Site. In this document the requirements are stipulated as the requirements for the Marketing Authorization Holder. Meanwhile, when they are applied to the Registered Manufacturing Site, the requirements must be paraphrased, as appropriate.

### (Definition)

#### Article 2

27. The term, "re-manufactured single-use medical devices," in this MHLW Ordinance means medical devices for single use (medical devices that can be used only once; hereinafter the same), which have been re-manufactured (inspection, disassembly, cleaning, sterilization, and other necessary processing for the purpose of newly manufacturing and marketing single-use medical devices after use; hereinafter the same).

28. In this Ordinance, "recycled parts" refer to all or part of single-use medical devices used in medical institutions among parts, etc. specified in Paragraph 3 and are supplied for re-manufacturing.

### (Scope of application)

#### Article 3

4. Marketing authorization holders, etc. shall implement manufacturing control and quality control for products related to re-manufactured single-use medical devices in accordance with the provisions of Chapter 2 and Chapter 3 as well as the provisions of Chapter 5-2.

## **Chapter 5-2. Manufacturing control and quality control of re-manufactured single-use medical devices**

(Infrastructure for operation at a registered manufacturing site of a marketing authorization holder, etc. of re-manufactured single-use medical devices)

Article 81-2 Marketing authorization holders, etc. of products related to re-manufactured single-use medical devices (hereinafter referred to as "marketing authorization holders, etc. of re-manufactured single-use medical devices") shall meet the following requirements as an infrastructure for operation at a registered manufacturing site (excluding registered manufacturing sites that only design in the manufacturing process or store finished products in Japan; the same shall apply hereinafter in this chapter) that manufactures the products.

[1] Work areas shall conform to the following requirements.

B. Re-manufacturing clean areas (work areas where recycled parts are exposed to the air in the work areas after pathogenic microorganisms and other causes of diseases are inactivated or removed; the same shall apply in this chapter) shall have a drainage facility conforming to the following requirements.

(1) The facility shall have an appropriate structure to prevent contamination by harmful drainage.

(2) The facility shall have a structure that can be easily cleaned or disinfected

B. There should be facilities listed below. This shall not apply if it is considered obviously unnecessary.

(1) Areas where recycled parts contaminated by pathogenic microorganisms or other causes of diseases are handled: Facilities for cleaning, drying, and sterilization of recycled parts, facilities for cleaning, disinfection, and sterilization of apparatuses used in the areas, and facilities for treatment of waste fluids, etc.

(2) Facilities necessary for cleaning, disinfection, drying, and storage (including drainage facilities to prevent contamination by harmful drainage) of transportation containers (containers for transporting single-use medical devices used in medical institutions, which have not been cleaned or sterilized; the same shall apply hereinafter in this chapter)

C. The following testing facilities and apparatuses are provided. This does not apply to cases where testing is performed by using other testing institutions of a marketing authorization holder, etc. of re-manufactured single-use medical devices on their own responsibility without any problem.

(1) Facilities and apparatuses to verify that recycled parts which have undergone inactivation or removal of pathogenic microorganisms and other causes of diseases are not contaminated by the microorganisms

(2) Other facilities and apparatuses necessary for testing

[2] Areas, where recycled parts contaminated by pathogenic microorganisms or other causes of diseases are handled, shall be clearly separated from the other areas and have dedicated facilities and apparatuses to conduct the manufacturing. In the manufacturing process after the process to inactivate or remove pathogenic microorganisms and other causes of diseases, there should be facilities and apparatuses necessary for manufacturing.

(Process control)

Article 81-2-2 Marketing authorization holders, etc. of re-manufactured single-use medical devices shall, when handling products related to re-manufactured single-use medical devices, appropriately control the following operations related to process control of products related to re-manufactured single-use medical devices based on a product master formula and establish/document procedures of the operations.

[1] Instruct a person designated beforehand to conduct the following operations according to the details of the operations.

A. Marketing authorization holders, etc. of re-manufactured single-use medical devices shall

evaluate and select medical institutions as suppliers of recycled parts that meet the following requirements.

(1) A system for supplying recycled parts conforming to the standards specified by the Minister of Health, Labour and Welfare has been established.

(2) Recycled parts are stored separately so that they are not damaged, deteriorated, or contaminated by pathogenic microorganisms or other causes of diseases that cannot be inactivated or removed in the manufacturing process.

B. For reusing transportation containers used when marketing authorization holders, etc. of re-manufactured single-use medical devices receive recycled parts contaminated by pathogenic microorganisms or other causes of diseases, the transportation containers should be cleaned and disinfected where necessary.

C. Take necessary measures to prevent contamination by recycled parts that have not undergone inactivation or removal when pathogenic microorganisms or other causes of diseases adhering to the recycled parts are inactivated or removed in the manufacturing process.

D. When handling multiple recycled parts, take measures necessary to prevent mix-up among recycled parts and among recycled parts and parts, etc. other than the recycled parts as well as cross-contamination by pathogenic microorganisms and other causes of diseases.

E. If manufacturing facilities, etc. are contaminated by recycled parts, to which pathogenic microorganisms or other causes of diseases have adhered, in the manufacturing process, take necessary measures to remove such contamination.

F. In the following cases, perform validation of cleaning process and other necessary validation, and prepare and retain the records.

(1) When manufacturing of products related to re-manufactured single-use medical devices is newly started at the manufacturing site

(2) When there is a change in manufacturing procedures, etc., which has a significant impact on the quality of products related to re-manufactured single-use medical devices

(3) When there are any changes in the quality, performance, or specifications of the original medical device

(4) Other cases where it is deemed necessary to appropriately conduct manufacturing control and quality control for products related to re-manufactured single-use medical devices

G. Restrict entry of persons other than those engaged in operations in a re-manufacturing clean area to the re-manufacturing clean area as much as possible.

H. Do not bring recycled parts with pathogenic microorganisms or other causes of diseases into a re-manufacturing clean area.

I. For parts, etc. used for manufacturing of re-manufactured single-use medical devices, verify that the parts, etc. are appropriate based on a product master formula of the products, and prepare/retain records of the results for each serial number, etc. (unique numbers, symbols, and other signs to identify individual re-manufactured single-use medical devices; the same shall apply hereinafter) of re-manufactured single-use medical devices.

J. For recycled parts, prepare and retain records of matters to be recorded pursuant to the provisions specified by the Minister of Health, Labour and Welfare.

[2] Know the name of a business office to which products are released and date of release for each serial number, etc. of re-manufactured single-use medical devices, and prepare/retain the records.

2. Marketing authorization holders, etc. of re-manufactured single-use medical devices shall store records of the preceding paragraph for each serial number, etc. so that a series of records from recycled parts used in manufacturing to products manufactured by using the recycled parts can be checked appropriately.

(Testing)

Article 81-2-3 Marketing authorization holders, etc. of re-manufactured single-use medical devices shall, when handling products related to re-manufactured single-use medical devices, appropriately control operations related to testing of parts, etc. and products related to re-manufactured single-use medical devices by appropriate identification labeling of samples for separation to prevent mix-up and cross-contamination of samples at a manufacturing site of the products based on a product master formula and establish/document procedures of the operations in addition to the operations of the previous article.

(Education and training)

Article 81-2-4 Marketing authorization holders, etc. of re-manufactured single-use medical devices shall, when handling products related to re-manufactured single-use medical devices, establish and implement procedures for education and training related to microbiology, medicine, and veterinary medicine, etc. for members engaged in manufacturing or testing of the products in addition to the operations specified in Article 23 and document the procedures.

2. Marketing authorization holders, etc. of re-manufactured single-use medical devices, etc. shall prepare and retain records on the education and training in the preceding paragraph.

(Management of documents and records)

Article 81-2-5 Marketing authorization holders, etc. of re-manufactured single-use medical devices shall retain documents specified in this chapter or at least one copy of the documents for a period of the shelf life of products related to re-manufactured single-use medical devices plus 5 years (5 years for those related to education and training) from the date of abolition of the documents. However, for documents used for manufacturing or testing of products, it is enough to store those documents so that they can be used during storage of records related to the products specified in the following paragraph.

2. Marketing authorization holders, etc. of re-manufactured single-use medical devices shall retain records specified in this chapter for a period of the shelf life of products related to re-manufactured single-use medical devices plus 5 years from the date of preparation (5 years for those related to education and training).

(Ensuring traceability of products related to re-manufactured single-use medical devices)

Article 81-2-6 Marketing authorization holders, etc. of re-manufactured single-use medical devices shall secure the traceability of records related to all of parts, etc. and conditions of work environment if there is a risk that products related to re-manufactured single-use medical devices may not conform to product requirements depending on the parts, etc. or conditions of work environment.

2. In order to ensure the traceability of products related to re-manufactured single-use medical devices after release, marketing authorization holders, etc. of re-manufactured single-use medical devices shall instruct distributors, etc. handling such products (distributors or loaners of specially-controlled medical devices or controlled medical devices; the same shall apply in the following paragraph) to prepare and retain records of distribution of the products concerned.
3. If marketing authorization holders, etc. of re-manufactured single-use medical devices have received an inspection pursuant to the provisions of Paragraph 6 or Paragraph 8, Article 23-2-5 of the Act or on-spot inspection, etc. pursuant to the provisions of Paragraph 1 or Paragraph 4, Article 69 of the Act for the said products and if it is requested by the Minister of Health, Labour and Welfare, prefectural governor, or implementer of compliance inspection of medical devices, etc. stipulated in Article 37-23 of the MHLW Ordinance, distributors, etc. shall be instructed to retain the records of the preceding paragraph so that the records can be presented.

This English document is only for reference purpose. In case of any discrepancy, the Japanese text shall prevail.

## Tentative translation of MHLW MO 1 for Remanufactured Single-Use Devices

### **Regulations for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (MHW Ordinance No. 1, 1961)**

(Matters to be observed by marketing authorization holders of medical devices or *in vitro* diagnostics)

Article 114-54 Matters to be observed by marketing authorization holders of medical devices or *in vitro* diagnostics specified in Paragraph 1, Article 23-2-15 of the Act are as follows.

[4] A person with bacteriological knowledge shall be appointed as an assistant to the Marketing Supervisor-general of medical devices, etc. if none of the Marketing Supervisor-general of medical devices, etc., Domestic Quality Operation Manager, and Safety Management Supervisor of medical devices, etc. of a marketing authorization holder of biological products (limited to medical devices) or re-manufactured single-use medical devices has bacteriological knowledge.

[9] Marketing authorization holders of re-manufactured single-use medical devices shall continuously check for any changes in raw materials of the original medical devices (single-use medical devices intended for re-manufacturing, which have not been re-manufactured yet; the same shall apply hereinafter) and any of the other changes that may affect the quality, effectiveness, and safety of re-manufactured single-use medical devices and take necessary measures, such as changes in design, to ensure the quality, effectiveness, and safety of re-manufactured single-use medical devices if such changes occur.

[10] Marketing authorization holders of re-manufactured single-use medical devices shall continuously collect information on malfunctions and recalls of the original medical devices and other information on the quality, effectiveness, and safety of the devices, examine the impact on the quality, effectiveness, and safety of the re-manufactured single-use medical devices based on the collected information, and take measures necessary to prevent the occurrence or spread of hazards to the public health and hygiene.

[11] Marketing authorization holders of re-manufactured single-use medical devices shall promptly provide the following information to marketing authorization holders of original medical devices, emergency approval holders of foreign manufactured medical devices, etc., or foreign manufacturers of designated specially-controlled medical devices, etc.

A. Approval under Paragraph 1 or Paragraph 15, Article 23-2-5 of the Act for re-manufactured single-use medical devices (cases where a designated marketing

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authorization holder of foreign manufactured medical devices, etc. is provided with information under Item 1, Paragraph 1, Article 114-76 for re-manufactured single-use medical devices) if granted

B. Information on disposal, recall, discontinuation of marketing, provision of information, and other necessary measures taken for re-manufactured single-use medical devices due to quality-related reasons, etc. (excluding cases where the conduct of such measures is obviously attributable to re-manufacturing of the re-manufactured single-use medical devices) if implemented

C. Information on planning and implementation of disposal, recall, discontinuation of marketing, revision of precautions, etc. (matters listed in each item of Paragraph 2, Article 63-2 of the Act or information on precautions, etc. specified in Paragraph 2, Article 68-2 of the Act) or other safety assurance measures considered to require provision of information to marketing authorization holders of original medical devices, emergency approval holders of foreign manufactured medical devices, etc., or foreign manufacturers of designated specially-controlled medical devices, etc. as well as safety management information examined in planning

[12] When marketing authorization holders of re-manufactured single-use medical devices transport single-use medical devices used in medical institutions, which have not been cleaned and sterilized yet (excluding transportation by a vessel or airplane; the same shall apply hereinafter in this item), the following items shall be met.

A. When transporting, enclose devices in containers.

B. The containers specified in the preceding item shall meet the following criteria.

(1) They can be handled easily and safely.

(2) There is no risk of cracking and damage, etc. due to vibration and changes in temperature and internal pressure, etc. expected during transportation.

(3) Measures, such as attaching a seal that does not break easily, are taken to prevent the containers from being opened without a reason.

(4) The containers shall have sufficient strength and water resistance not to cause leakage of the contents.

(5) When they are used repeatedly, it shall be easy to remove contamination by microorganisms, etc. which may be pathogenic.

(6) The containers shall be labeled to indicate that single-use medical devices used in medical institutions are enclosed.

C. Loading of cargoes onto vehicles, etc. shall be done so that safety will not be compromised by movement, turnover, and falling, etc. during transportation.

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- D. They shall be separated from the other cargoes during transportation to prevent them from being mixed with the other cargoes.
- E. A document that describes a method for handling cargoes, measures to be taken in the event of an accident, and other matters to be considered for transportation shall be carried out.
- F. If any contamination by microorganisms, etc. that may be pathogenic is caused by cargoes, the spread of the contamination should be promptly prevented, and decontamination should be performed.
- G. The date and method of transportation, consignee or consignor, and person who carries out the transportation, shall be recorded. The records should be retained for 5 years.
- H. When transportation is outsourced to a third party, the third party shall carry out the transportation by a method conforming to the following matters.
  - (1) Do not subcontract.
  - (2) A contract acceptor shall transport by a method conforming to the matters described in A to G. In addition, necessary matters for this shall be arranged and retained in writing.

(Matters to be observed by manufacturers of medical devices)

Article 114-54-2 Regarding matters to be observed by manufacturers of medical devices specified in Paragraph 3, Article 23-2-15 of the Act (including cases where it is applied mutatis mutandis pursuant to Article 23-2-19 of the Act), if the Medical Device Responsible Engineer Manager at a manufacturing site that manufactures re-manufactured single-use medical devices (excluding manufacturing sites related to manufacturing processes specified in E, Item 4, Paragraph 1, Article 114-8) is not a physician or has no bacteriological knowledge or expertise in sterilization of medical devices, a physician or person with such knowledge shall be appointed as an assistant to the Medical Device Responsible Engineer Manager.

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## Tentative translation of MHLW MA 261

### ○ Standards for Re-manufactured Single-use Medical Devices

(July 31, 2017)

(Ministerial Announcement No. 261 of the Ministry of Health, Labour and Welfare)

Based on the provisions of Paragraph 2, Article 42 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960), the Standards for Re-manufactured Single-use Medical Devices were established as follows and implemented starting from July 31, 2017.

#### Standards for Re-manufactured Single-use Medical Devices

##### Part 1 Definitions

- 1 A "recycled part" is the whole or part of a single-use medical device, which is used at a medical institution and provided for re-manufacturing.
- 2 A "replacement part" means a newly manufactured part constituting a re-manufactured single-use medical device.
- 3 A "serial number, etc." means a unique number, symbol, or other sign to identify an individual re-manufactured single-use medical device.

##### Part 2 Scope

These standards apply to re-manufactured single-use medical devices specified in Item 4, Article 114-8 of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (MHW Ordinance No. 1, 1961).

##### Part 3 Shape and structure

- 1 Recycled parts
  - (1) The shape and structure of recycled parts shall be able to inactivate or remove pathogenic microorganisms and other disease-causing agents by validated methods during remanufacturing processes.
- 2 Replacement parts
  - (1) The shape and structure of replacement parts shall be equivalent to those of the original medical device.
- 3 Re-manufactured single-use medical devices
  - (1) The shape and structure of re-manufactured single-use medical devices shall be equivalent to those of the original medical device.

##### Part 4 Performance and safety

- 1 Raw materials (recycled and replacement parts)
  - (1) Recycled parts shall have been used at medical institutions in Japan.
  - (2) Recycled parts shall not come into contact with the brain, spinal cord, dura mater, cerebral ganglion, spinal ganglion, retina, or optic nerve.
  - (3) Recycled parts shall not be implanted in the human body.
  - (4) Recycled parts shall not be used for treatment and testing, etc. of patients with Class I, II, III, or IV infection, infection such as pandemic influenza, designated infection, or new infectious disease specified in Article 6 of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998) or persons specified in Paragraphs 1 to 3, Article 8 of the said Act.
  - (5) Recycled parts shall be received from a medical institution by a marketing authorization holder of re-manufactured single-use medical devices in accordance with the method described in an approval certificate issued at the time of marketing

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- approval of a re-manufactured single-use medical device (hereinafter referred to as "approval certificate").
- (6) Recycled parts shall be stored separately at a medical institution to prevent them from being damaged, deteriorated, or contaminated by pathogenic microorganisms or other causes of diseases that cannot be inactivated or removed in the manufacturing process.
  - (7) For recycled parts, marketing authorization holders of re-manufactured single-use medical devices or emergency approval holders of foreign manufactured medical devices, etc. (hereinafter referred to as "marketing authorization holders, etc.") shall confirm that the matters listed in (5) and (6) have been performed appropriately.
  - (8) Recycled parts shall be examined appropriately in light of the latest findings on infectious diseases to confirm that they are not contaminated by pathogenic microorganisms or other causes of diseases that cannot be inactivated or removed in the manufacturing process.
  - (9) Recycled parts shall not be provided for re-manufacturing more than the number of times specified in an approval certificate of a re-manufactured single-use medical device manufactured using the parts.
  - (10) Recycled parts shall be received from medical institutions and transported by a marketing authorization holder of re-manufactured single-use medical devices in a sealed, dedicated container designed to prevent breakage, deterioration, or contamination by pathogenic microorganisms or other causes of diseases that cannot be inactivated or removed in the manufacturing process.
  - (11) Recycled parts and replacement parts shall have the quality, performance, and safety described in an approval certificate.
  - (12) In addition to the items from (1) to (11), the requirements for securing the quality, performance, and safety of recycled parts and replacement parts described in an approval certificate shall be met.
- 2 Performance and safety (recycled parts, replacement parts, and re-manufactured single-use medical devices)
- (1) Recycled parts
    - A Recycled parts shall have the quality, performance, and safety required to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices in consideration of deterioration, etc. in characteristics and performance, which may occur due to re-manufacturing.
    - B Recycled parts shall satisfy the following requirements.
      - (a) Marketing authorization holders, etc. of re-manufactured single-use medical devices continuously check the presence or absence of changes in raw materials of the original medical device and other changes that may affect the quality, efficacy, and safety of re-manufactured single-use medical devices, and if such changes occur, measures, such as changes in the re-manufacturing method of recycled parts, necessary to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices have been taken.
      - (b) Information on defects and recalls of the original medical device and other information on the quality, efficacy, and safety have been continuously collected by a marketing authorization holder, etc. of re-manufactured single-use medical devices, and based on the collected information, changes in the re-manufacturing method of recycled parts necessary to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices and other measures have been taken.
  - (2) Replacement parts
    - A Replacement parts shall have the quality, performance, and safety required to ensure the quality, efficacy, and safety of re-manufactured single-use medical

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devices.

- B Replacement parts shall satisfy the following requirements.
- (a) Marketing authorization holders, etc. of re-manufactured single-use medical devices continuously check the presence or absence of changes in raw materials of the original medical device and other changes that may affect the quality, efficacy, and safety of re-manufactured single-use medical devices, and if such changes occur, measures, such as changes in the design of replacement parts, necessary to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices have been taken.
  - (b) Information on defects and recalls of the original medical device and other information on the quality, efficacy, and safety have been continuously collected by a marketing authorization holder, etc. of re-manufactured single-use medical devices, and based on the collected information, changes in the design of replacement parts necessary to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices and other measures have been taken.
- (3) Re-manufactured single-use medical devices
- A The intended use or effects of re-manufactured single-use medical devices shall not exceed the scope of the intended use or effects of the original medical device.
  - B Re-manufactured single-use medical devices shall have the quality, efficacy, and safety equivalent to those of the original medical device in consideration of deterioration, etc. in characteristics and performance, which may occur due to re-manufacturing.
  - C Re-manufactured single-use medical devices shall satisfy the following requirements.
    - (a) Marketing authorization holders, etc. of re-manufactured single-use medical devices continuously check the presence or absence of changes in raw materials of the original medical device and other changes that may affect the quality, efficacy, and safety of products, and if such changes occur, measures, such as changes in the design, necessary to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices have been taken.
    - (b) Information on defects and recalls of the original medical device and other information on the quality, efficacy, and safety have been continuously collected by a marketing authorization holder, etc. of re-manufactured single-use medical devices, and based on the collected information, changes in the design necessary to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices and other measures have been taken.

## Part 5 Manufacturing method

- (1) Recycled parts shall be re-manufactured so that pathogenic microorganisms and other causes of diseases can be inactivated or removed by validated methods.
- (2) Re-manufactured single-use medical devices shall be re-manufactured to have the quality, efficacy, and safety equivalent to those of the original medical device.

## Part 6 Labeling, etc.

### 1 Labeling on medical devices

- (1) For re-manufactured single-use medical devices, a serial number, etc. shall be assigned and indicated on the main body to secure the traceability (history, application, or location; the same shall apply hereinafter) to the matters specified in 3 (2) of Part 6.
- (2) Re-manufactured single-use medical devices shall be identifiable as re-manufactured devices by an appropriate method, such as indicating "re-manufactured" on the body, to prevent confusion with the original medical device.

### 2 Information shown on immediate containers, etc.

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- (1) "Re-manufactured" shall be indicated on an immediate container or wrapper of a re-manufactured single-use medical device.
- (2) Information, such as precautions for re-manufactured single-use medical devices, or documents attached to the re-manufactured single-use medical devices shall include the following information.
  - A Word, "re-manufactured"
  - B Name of the original medical device
  - C Approval number and date of approval of the original medical device, certification number and date of certification of the original medical device, or notification number and date of notification of the original medical device
  - D Name of the marketing authorization holder of the original medical device, names of the emergency approval holder of foreign manufactured medical devices, etc. and designated marketing authorization holder of foreign manufactured medical devices, etc., or names of the foreign manufacturer of designated specially controlled medical devices and designated marketing authorization holder of designated foreign manufactured specially controlled medical devices

### 3 Records and storage

- (1) The following items related to recycled parts shall be recorded and stored.
  - A Name and address of a medical institution where single-use medical devices used for re-manufacturing were used
  - B Date on which a marketing authorization holder of re-manufactured single-use medical devices received recycled parts from a medical institution
  - C Serial numbers, etc. of recycled parts if they have already been re-manufactured
  - D Number of times that recycled parts were re-manufactured
  - E Results of confirmation of compliance with the matters listed in 1 (1) to (12) of Part 4
  - F Matters necessary for ensuring the quality, performance, and safety of recycled parts in addition to those listed in A through E
- (2) For re-manufactured single-use medical devices, the traceability shall be ensured by properly preparing and retaining records of recycled parts, inspections, manufacturing, work environment conditions, and distribution.

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This content is from the eCFR and is authoritative but unofficial.

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**Title 21 –Food and Drugs**

**Chapter I –Food and Drug Administration, Department of Health and Human Services**

**Subchapter H –Medical Devices**

## Part 803 Medical Device Reporting

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## PART 803—MEDICAL DEVICE REPORTING

**Authority:** 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

**Source:** 79 FR 8846, Feb. 14, 2014, unless otherwise noted.

### Subpart A—General Provisions

#### § 803.1 What does this part cover?

- (a) This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified followup. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use. If you are a medical device distributor, you must maintain records (files) of incidents, but you are not required to report these incidents.
- (b) This part supplements and does not supersede other provisions of this chapter, including the provisions of part 820 of this chapter.
- (c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

#### § 803.3 How does FDA define the terms used in this part?

Some of the terms we use in this part are specific to medical device reporting and reflect the language used in the statute (law). Other terms are more general and reflect our interpretation of the law. This section defines the following terms as used in this part:

- (a) **Ambulatory surgical facility (ASF)** means a distinct entity that operates for the primary purpose of furnishing same day outpatient surgical services to patients. An ASF may be either an independent entity (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An ASF is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.

- (b) **Become aware** means that an employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred.
- (1) If you are a device user facility, you are considered to have “become aware” when medical personnel, as defined in this section, who are employed by or otherwise formally affiliated with your facility, obtain information about a reportable event.
  - (2) If you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with § 803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.
  - (3) If you are an importer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported by you within 30 days.
- (c) **Caused or contributed** means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:
- (1) Failure,
  - (2) Malfunction,
  - (3) Improper or inadequate design,
  - (4) Manufacture,
  - (5) Labeling, or
  - (6) User error.
- (d) **Device user facility** means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in this section, which is not a physician's office, as defined in this section. School nurse offices and employee health units are not device user facilities.
- (e) **Distributor** means any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repack or otherwise change the container, wrapper, or labeling of the device or device package. If you repack or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.
- (f) **Expected life of a device** means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified “end of life” (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through activities such as maintenance, repairs, or upgrades, for an estimated period of time.
- (g) **FDA, we, us, or Agency** means the Food and Drug Administration.

- (h) **Five-day report** means a medical device report that must be submitted by a manufacturer to us under § 803.53 within 5 work days.
- (i) **Hospital** means a distinct entity that operates for the primary purpose of providing diagnostic, therapeutic (such as medical, occupational, speech, physical), surgical, and other patient services for specific and general medical conditions. Hospitals include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities. A hospital may be either independent (e.g., not a part of a provider of services or any other facility) or may be operated by another medical entity (e.g., under the common ownership, licensure, or control of another entity). A hospital is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the hospital must report that event regardless of the nature or location of the medical service provided by the hospital.
- (j) **Importer** means any person who imports a device into the United States and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repack or otherwise change the container, wrapper, or labeling of the device or device package. If you repack or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.
- (k) **Malfunction** means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in § 801.4 of this chapter.
- (l) **Manufacturer** means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who either:
- (1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;
  - (2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;
  - (3) Manufactures components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or
  - (4) Is the U.S. agent of a foreign manufacturer.
- (m) **Manufacturer or importer report number.** This number uniquely identifies each individual adverse event report submitted by a manufacturer or importer. This number consists of the following three parts:
- (1) The FDA registration number for the manufacturing site of the reported device, or the registration number for the importer. If the manufacturing site or the importer does not have an establishment registration number, we will assign a temporary MDR reporting number until the site is registered in accordance with part 807 of this chapter. We will inform the manufacturer or importer of the temporary MDR reporting number;
  - (2) The four-digit calendar year in which the report is submitted; and
  - (3) The five-digit sequence number of the reports submitted during the year, starting with 00001. (For example, the complete number will appear as follows: 1234567-2011-00001.)

(n) **MDR** means medical device report.

(o) **MDR reportable event (or reportable event)** means:

- (1) An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury or
- (2) An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:
  - (i) May have caused or contributed to a death or serious injury, or
  - (ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(p) **Medical personnel** means an individual who:

- (1) Is licensed, registered, or certified by a State, territory, or other governing body, to administer health care;
- (2) Has received a diploma or a degree in a professional or scientific discipline;
- (3) Is an employee responsible for receiving medical complaints or adverse event reports; or
- (4) Is a supervisor of these persons.

(q) **Nursing home** means:

- (1) An independent entity (i.e., not a part of a provider of services or any other facility) or one operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing:
  - (i) Skilled nursing care and related services for persons who require medical or nursing care;
  - (ii) Hospice care to the terminally ill; or
  - (iii) Services for the rehabilitation of the injured, disabled, or sick.
- (2) A nursing home is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the nursing home must report that event regardless of the nature or location of the medical service provided by the nursing home.

(r) **Outpatient diagnostic facility** means:

- (1) A distinct entity that:
  - (i) Operates for the primary purpose of conducting medical diagnostic tests on patients,
  - (ii) Does not assume ongoing responsibility for patient care, and
  - (iii) Provides its services for use by other medical personnel.
- (2) Outpatient diagnostic facilities include outpatient facilities providing radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography, and in vitro testing. An outpatient diagnostic facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the

common ownership, licensure, or control of an entity). An outpatient diagnostic facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.

- (s) ***Outpatient treatment facility*** means a distinct entity that operates for the primary purpose of providing nonsurgical therapeutic (medical, occupational, or physical) care on an outpatient basis or in a home health care setting. Outpatient treatment facilities include ambulance providers, rescue services, and home health care groups. Examples of services provided by outpatient treatment facilities include the following: Cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and treatment for substance abuse. An outpatient treatment facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient treatment facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.
- (t) ***Patient of the facility*** means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. This includes employees of the facility or individuals affiliated with the facility who, in the course of their duties, suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.
- (u) ***Physician's office*** means a facility that operates as the office of a physician or other health care professional for the primary purpose of examination, evaluation, and treatment or referral of patients. Examples of physician offices include: Dentist offices, chiropractor offices, optometrist offices, nurse practitioner offices, school nurse offices, school clinics, employee health clinics, or freestanding care units. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.
- (v) ***Remedial action means*** any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.
- (w) ***Serious injury*** means an injury or illness that:
  - (1) Is life-threatening,
  - (2) Results in permanent impairment of a body function or permanent damage to a body structure, or
  - (3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.
- (x) ***User facility report number*** means the number that uniquely identifies each report submitted by a user facility to manufacturers and to us. This number consists of the following three parts:
  - (1) The user facility's 10-digit Centers for Medicare and Medicaid Services (CMS) number (if the CMS number has fewer than 10 digits, fill the remaining spaces with zeros);
  - (2) The four-digit calendar year in which the report is submitted; and

(3) The four-digit sequence number of the reports submitted for the year, starting with 0001. (For example, a complete user facility report number will appear as follows: 1234560000-2011-0001. If a user facility has more than one CMS number, it must select one that will be used for all of its MDR reports. If a user facility has no CMS number, it should use all zeros in the appropriate space in its initial report (e.g., 0000000000-2011-0001). We will assign a number for future use and send that number to the user facility. This number is used in our record of the initial report, in subsequent reports, and in any correspondence with the user facility. If a facility has multiple sites, the primary site may submit reports for all sites and use one reporting number for all sites if the primary site provides the name, address, and CMS number for each respective site.)

(y) **Work day** means Monday through Friday, except Federal holidays.

(z) [Reserved]

(aa) **Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device** means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

(bb) **Unique device identifier (UDI)** means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A *unique device identifier* is composed of:

- (1) A *device identifier*—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and
- (2) A *production identifier*—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
  - (i) The lot or batch within which a device was manufactured;
  - (ii) The serial number of a specific device;
  - (iii) The expiration date of a specific device;
  - (iv) The date a specific device was manufactured.
  - (v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015]

## § 803.9 What information from the reports do we disclose to the public?

- (a) We may disclose to the public any report, including any FDA record of a telephone report, submitted under this part. Our disclosures are governed by part 20 of this chapter.
- (b) Before we disclose a report to the public, we will delete the following:
  - (1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter;
  - (2) Any personal, medical, and similar information, including the serial number of implanted devices, which would constitute an invasion of personal privacy under § 20.63 of this chapter. However, if a patient requests a report, we will disclose to that patient all the information in the report concerning that patient, as provided in § 20.61 of this chapter; and

- (3) Any names and other identifying information of a third party that voluntarily submitted an adverse event report.
- (c) We may not disclose the identity of a device user facility that makes a report under this part except in connection with:
  - (1) An action brought to enforce section 301(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)), including the failure or refusal to furnish material or information required by section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j);
  - (2) A communication to a manufacturer of a device that is the subject of a report required to be submitted by a user facility under § 803.30; or
  - (3) A disclosure to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

## § 803.10 Generally, what are the reporting requirements that apply to me?

- (a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows:
  - (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event:
    - (i) Submit reports of device-related deaths to us and to the manufacturer, if known, or
    - (ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us.
  - (2) Submit annual reports (described in § 803.33) to us.
- (b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:
  - (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:
    - (i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer or
    - (ii) Submit reports of device-related malfunctions to the manufacturer.
  - (2) [Reserved]
- (c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows:
  - (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.
  - (2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:
    - (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health or
    - (ii) A reportable event for which we made a written request.
  - (3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

## § 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

- (a) If you are a manufacturer or importer, you must submit reports of individual adverse events to FDA in an electronic format in accordance with § 803.12(a) and § 803.20, unless granted an exemption under § 803.19.
- (b) Importer reports submitted to device manufacturers may be in paper format or an electronic format that includes all required data fields to ensure that the manufacturer has all required information.
- (c) If you are a user facility, you must submit reports of individual adverse events in accordance with § 803.12(b) and § 803.20.
- (d) Form FDA 3500A is available on the internet at <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>.

[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015; 85 FR 18441, Apr. 2, 2020]

## § 803.12 How do I submit initial and supplemental or followup reports?

- (a) Manufacturers and importers must submit initial and supplemental or followup reports to FDA in an electronic format that FDA can process, review, and archive.
- (b) User facilities that submit their reports and additional information to FDA electronically must use an electronic format that FDA can process, review, and archive. User facilities that submit their reports to FDA on paper must submit any written report or additional information required under this part to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002, using Form FDA 3500A. Each report must be identified (e.g., "User Facility Report" or "Annual Report").
- (c) If you are confronted with a public health emergency, this can be brought to FDA's attention by contacting FDA's Office of Crisis Management, Emergency Operations Center by telephone, 24-hours a day, at 301-796-8240 or toll free at 866-300-4374, followed by the submission of an email to: [emergency.operations@fda.hhs.gov](mailto:emergency.operations@fda.hhs.gov).

Note: This action does not satisfy your obligation to report under part 803.

- (d) You may submit a voluntary telephone report to the MedWatch office at 800-FDA-1088. You may also obtain information regarding voluntary reporting from the MedWatch office at 800-FDA-1088. You may also find the voluntary Form FDA 3500 and instructions to complete it at: <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>.

## § 803.13 Do I need to submit reports in English?

Yes. You must submit all reports required by this part in English.

## § 803.15 How will I know if you require more information about my medical device report?

- (a) We will notify you in writing if we require additional information and will tell you what information we need. We will require additional information if we determine that protection of the public health requires additional or clarifying information for medical device reports submitted to us and in cases when the additional information is beyond the scope of FDA reporting forms or is not readily accessible to us.

- (b) In any request under this section, we will state the reason or purpose for the information request, specify the due date for submitting the information, and clearly identify the reported event(s) related to our request. If we verbally request additional information, we will confirm the request in writing.

### **§ 803.16 When I submit a report, does the information in my report constitute an admission that the device caused or contributed to the reportable event?**

No. A report or other information submitted by you, and our release of that report or information, is not necessarily an admission that the device, or you or your employees, caused or contributed to the reportable event. You do not have to admit and may deny that the report or information submitted under this part constitutes an admission that the device, you, or your employees, caused or contributed to a reportable event.

### **§ 803.17 What are the requirements for developing, maintaining, and implementing written MDR procedures that apply to me?**

If you are a user facility, importer, or manufacturer, you must develop, maintain, and implement written MDR procedures for the following:

- (a) Internal systems that provide for:

- (1) Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements;
- (2) A standardized review process or procedure for determining when an event meets the criteria for reporting under this part; and
- (3) Timely transmission of complete medical device reports to manufacturers or to us, or to both if required.

- (b) Documentation and recordkeeping requirements for:

- (1) Information that was evaluated to determine if an event was reportable;
- (2) All medical device reports and information submitted to manufacturers and/or us;
- (3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and
- (4) Systems that ensure access to information that facilitates timely followup and inspection by us.

### **§ 803.18 What are the requirements for establishing and maintaining MDR files or records that apply to me?**

- (a) If you are a user facility, importer, or manufacturer, you must establish and maintain MDR event files. You must clearly identify all MDR event files and maintain them to facilitate timely access.

- (b)

- (1) For purposes of this part, "MDR event files" are written or electronic files maintained by user facilities, importers, and manufacturers. MDR event files may incorporate references to other information (e.g., medical records, patient files, engineering reports), in lieu of copying and maintaining duplicates in this file. Your MDR event files must contain:

- (i) Information in your possession or references to information related to the adverse event, including all documentation of your deliberations and decision making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this part;
  - (ii) Copies of all reports submitted under this part (whether paper or electronic), and of all other information related to the event that you submitted to us or other entities such as an importer, distributor, or manufacturer; and
  - (iii) Copies of all electronic acknowledgments FDA sends you in response to electronic MDR submissions.
- (2) If you are a user facility, importer, or manufacturer, you must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify the records required by this part.
- (c) If you are a user facility, you must retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event. If you are a manufacturer or importer, you must retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. If the device is no longer distributed, you still must maintain MDR event files for the time periods described in this paragraph (c).
- (d)
- (1) If you are a device distributor, you must establish and maintain device complaint records (files). Your records must contain any incident information, including any written, electronic, or oral communication, either received or generated by you, that alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device. You must also maintain information about your evaluation of the allegations, if any, in the incident record. You must clearly identify the records as device incident records and file these records by device name. You may maintain these records in written or electronic format. You must back up any file maintained in electronic format.
  - (2) You must retain copies of the required device incident records for a period of 2 years from the date of inclusion of the record in the file or for a period of time equivalent to the expected life of the device, whichever is greater. You must maintain copies of these records for this period even if you no longer distribute the device.
  - (3) You must maintain the device complaint files established under this section at your principal business establishment. If you are also a manufacturer, you may maintain the file at the same location as you maintain your complaint file under part 820 of this chapter. You must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify the records required by this part.
- (e) If you are a manufacturer, you may maintain MDR event files as part of your complaint file, under part 820 of this chapter, if you prominently identify these records as MDR reportable events. We will not consider your submitted MDR report to comply with this part unless you evaluate an event in accordance with the quality system requirements described in part 820 of this chapter. You must document and maintain in your MDR event files an explanation of why you did not submit or could not obtain any information required by this part, as well as the results of your evaluation of each event.

## § 803.19 Are there exemptions, variances, or alternative forms of adverse event reporting requirements?

- (a) We exempt the following persons from the adverse event reporting requirements in this part:
- (1) A licensed practitioner who prescribes or administers devices intended for use in humans and manufactures or imports devices solely for use in diagnosing and treating persons with whom the practitioner has a "physician-patient" relationship;
  - (2) An individual who manufactures devices intended for use in humans solely for this person's use in research or teaching and not for sale. This includes any person who is subject to alternative reporting requirements under the investigational device exemption regulations (described in part 812 of this chapter), which require reporting of all adverse device effects; and
  - (3) Dental laboratories or optical laboratories.
- (b) If you are a manufacturer, importer, or user facility, you may request an exemption or variance from any or all of the reporting requirements in this part, including the requirements of § 803.12. You must submit the request to the Center for Devices and Radiological Health (CDRH) in writing at [MDRPolicy@fda.hhs.gov](mailto:MDRPolicy@fda.hhs.gov). Your request must include information necessary to identify you and the device; a complete statement of the request for exemption, variance, or alternative reporting; and an explanation why your request is justified. If you are requesting an exemption from the requirement to submit reports to FDA in electronic format under § 803.12(a), your request should indicate for how long you will require this exemption.
- (c) If you are a manufacturer, importer, or user facility, we may grant in writing an exemption or variance from, or alternative to, any or all of the reporting requirements in this part, and may change the frequency of reporting to quarterly, semiannually, annually or other appropriate time period. We may grant these modifications in response to your request, as described in paragraph (b) of this section, or at our discretion. When we grant modifications to the reporting requirements, we may impose other reporting requirements to ensure the protection of public health.
- (d) We may revoke or modify in writing an exemption, variance, or alternative reporting requirement if we determine that revocation or modification is necessary to protect the public health.
- (e) If we grant your request for a reporting modification, you must submit any reports or information required in our approval of the modification. The conditions of the approval will replace and supersede the regular reporting requirement specified in this part until such time that we revoke or modify the alternative reporting requirements in accordance with paragraph (d) of this section or until the date specified in our response granting your variance, at which time the provisions of this part will again apply.

[79 FR 8846, Feb. 14, 2014, as amended at 85 FR 18441, Apr. 2, 2020; 88 FR 16879, Mar. 21, 2023]

## Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

### § 803.20 How do I complete and submit an individual adverse event report?

- (a) *What form must I complete and submit ?*
- (1) If you are a health professional or consumer or other entity, you may submit voluntary reports to FDA regarding devices or other FDA-regulated products using the Form FDA 3500.
  - (2) To submit a mandatory report in written form, a user facility must use Form FDA 3500A.

(3) An electronic submission of a mandatory report from a user facility, importer, or manufacturer must contain the information from the applicable blocks of Form FDA 3500A. All electronic submissions must include information about the patient, the event, the device, and the "initial reporter." An electronic submission from a user facility or importer must include the information from block F. An electronic submission from a manufacturer must include the information from blocks G and H. If you are a manufacturer and you receive a report from a user facility or importer, you must incorporate that information in your electronic submission and include any corrected or missing information.

(b) *To whom must I submit reports and when?*

(1) If you are a user facility, you must submit MDR reports to:

- (i) The manufacturer and to us no later than 10 work days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or
- (ii) The manufacturer no later than 10 work days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury. If the manufacturer is not known, you must submit this report to us.

(2) If you are an importer, you must submit MDR reports to:

- (i) The manufacturer and to us, no later than 30 calendar days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury or
- (ii) The manufacturer, no later than 30 calendar days after receiving information that a device you market has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(3) If you are a manufacturer, you must submit MDR reports to us:

- (i) No later than 30 calendar days after the day that you become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury or
- (ii) No later than 30 calendar days after the day that you become aware of information that reasonably suggests a device has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur; or
- (iii) Within 5 work days if required by § 803.53.

(c) *What kind of information reasonably suggests that a reportable event has occurred?*

- (1) Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
- (2) If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a

malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers. You must keep in your MDR event files (described in § 803.18) the information that the qualified person used to determine whether or not a device-related event was reportable.

## § 803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?

- (a) The MedWatch Medical Device Reporting Code Instruction Manual contains adverse event codes for use with Form FDA 3500A. You may obtain the coding manual from FDA's website at: <https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/mdr-adverse-event-codes>.
- (b) We may sometimes use additional coding of information on the reporting forms or modify the existing codes. If we do make modifications, we will ensure that we make the new coding information available to all reporters.

[79 FR 8846, Feb. 14, 2014, as amended at 85 FR 18441, Apr. 2, 2020]

## § 803.22 What are the circumstances in which I am not required to file a report?

- (a) If you become aware of information from multiple sources regarding the same patient and same reportable event, you may submit one medical device report.
- (b) You are not required to submit a medical device report if:
  - (1) You are a user facility, importer, or manufacturer, and you determine that the information received is erroneous in that a device-related adverse event did not occur. You must retain documentation of these reports in your MDR files for the time periods specified in § 803.18.
  - (2) You are a manufacturer or importer and you did not manufacture or import the device about which you have adverse event information. When you receive reportable event information in error, you must forward this information to us with a cover letter explaining that you did not manufacture or import the device in question.

## § 803.23 Where can I find information on how to prepare and submit an MDR in electronic format?

- (a) You may obtain information on how to prepare and submit reports in an electronic format that FDA can process, review, and archive at: <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm>.
- (b) We may sometimes update information on how to prepare and submit reports electronically. If we do make modifications, we will ensure that we alert reporters by updating the eMDR Web page.

## Subpart C—User Facility Reporting Requirements

### § 803.30 If I am a user facility, what reporting requirements apply to me?

- (a) You must submit reports to the manufacturer or to us, or both, as specified in paragraphs (a)(1) and (a)(2) of this section as follows:

- (1) **Reports of death.** You must submit a report to us as soon as practicable but no more than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of your facility. You must also submit the report to the device manufacturer, if known. You must submit the information required by § 803.32. Reports sent to the Agency must be submitted in accordance with the requirements of § 803.12(b).
- (2) **Reports of serious injury.** You must submit a report to the manufacturer of the device no later than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of your facility. If the manufacturer is not known, you must submit the report to us. You must report information required by § 803.32. Reports sent to the Agency must be submitted in accordance with the requirements of § 803.12 (b).
- (b) **What information does FDA consider "reasonably known" to me?** You must submit all information required in this subpart C that is reasonably known to you. This information includes information found in documents that you possess and any information that becomes available as a result of reasonable followup within your facility. You are not required to evaluate or investigate the event by obtaining or evaluating information that you do not reasonably know.

## **§ 803.32 If I am a user facility, what information must I submit in my individual adverse event reports?**

You must include the following information in your report, if reasonably known to you, as described in § 803.30(b). These types of information correspond generally to the elements of Form FDA 3500A:

- (a) Patient information (Form FDA 3500A, Block A). You must submit the following:
  - (1) Patient name or other identifier;
  - (2) Patient age at the time of event, or date of birth;
  - (3) Patient gender; and
  - (4) Patient weight.
- (b) Adverse event or product problem (Form FDA 3500A, Block B). You must submit the following:
  - (1) Identification of adverse event or product problem;
  - (2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:
    - (i) A life-threatening injury or illness;
    - (ii) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
    - (iii) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
  - (3) Date of event;
  - (4) Date of this report;

(5) Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests, including dates and laboratory data; and

(7) Description of other relevant history, including preexisting medical conditions.

(c) Device information (Form FDA 3500A, Block D). You must submit the following:

(1) Brand name;

(2) Product Code, if known, and Common Device Name;

(3) Manufacturer name, city, and state;

(4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package;

(5) Operator of the device (health professional, lay user/patient, other);

(6) Date of device implantation (month, day, year), if applicable;

(7) Date of device explantation (month, day, year), if applicable;

(8) Whether the device is a single-use device that was reprocessed and reused on a patient (Yes, No)?

(9) If the device is a single-use device that was reprocessed and reused on a patient (yes to paragraph (c)(8) of this section), the name and address of the reprocessor;

(10) Whether the device was available for evaluation and whether the device was returned to the manufacturer; if so, the date it was returned to the manufacturer; and

(11) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)

(d) Initial reporter information (Form FDA 3500A, Block E). You must submit the following:

(1) Name, address, and telephone number of the reporter who initially provided information to you, or to the manufacturer or distributor;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to us, if known.

(e) User facility information (Form FDA 3500A, Block F). You must submit the following:

(1) An indication that this is a user facility report (by marking the user facility box on the form);

(2) Your user facility number;

(3) Your address;

(4) Your contact person;

(5) Your contact person's telephone number;

(6) Date that you became aware of the event (month, day, year);

- (7) Type of report (initial or followup); if it is a followup, you must include the report number of the initial report;
- (8) Date of your report (month, day, year);
- (9) Approximate age of device;
- (10) Event problem codes—patient code and device code (refer to the “MedWatch Medical Device Reporting Code Instructions”);
- (11) Whether a report was sent to us and the date it was sent (month, day, year);
- (12) Location where the event occurred;
- (13) Whether the report was sent to the manufacturer and the date it was sent (month, day, year); and
- (14) Manufacturer name and address, if available.

[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015]

### § 803.33 If I am a user facility, what must I include when I submit an annual report?

- (a) You must submit to us an annual report on Form FDA 3419. You must submit an annual report by January 1, of each year. You may obtain this form on the internet at: <https://www.fda.gov/media/72292/download>.
- (b) You must clearly identify your annual report as such. You must submit your annual report to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002. Your annual report must include:
  - (1) Your CMS provider number used for medical device reports, or the number assigned by us for reporting purposes in accordance with § 803.3;
  - (2) Reporting year;
  - (3) Your name and complete address;
  - (4) Total number of reports attached or summarized;
  - (5) Date of the annual report and report numbers identifying the range of medical device reports that you submitted during the report period (e.g., 1234567890-2011-0001 through 1000);
  - (6) Name, position title, and complete address of the individual designated as your contact person responsible for reporting to us and whether that person is a new contact for you; and
  - (7) Information for each reportable event that occurred during the annual reporting period including:
    - (i) Report number;
    - (ii) Name and address of the device manufacturer;
    - (iii) Device brand name and common name;
    - (iv) Product model, catalog, serial, and lot number and unique device identifier (UDI) that appears on the device label or on the device package;
    - (v) A brief description of the event reported to the manufacturer and/or us; and
    - (vi) Where the report was submitted, i.e., to the manufacturer, importer, or us.

- (c) In lieu of submitting the information in paragraph (b)(7) of this section, you may submit a copy of each medical device report that you submitted to the manufacturers and/or to us during the reporting period.
- (d) If you did not submit any medical device reports to manufacturers or us during the time period, you do not need to submit an annual report.

[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015; 85 FR 18442, Apr. 2, 2020]

## Subpart D—Importer Reporting Requirements

### § 803.40 If I am an importer, what reporting requirements apply to me?

- (a) **Reports of deaths or serious injuries.** You must submit a report to us, and a copy of this report to the manufacturer, as soon as practicable, but no later than 30 calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of your marketed devices may have caused or contributed to a death or serious injury. You must submit the information required by § 803.42. Reports sent to the Agency must be submitted in accordance with the requirements of § 803.12(a).
- (b) **Reports of malfunctions.** You must submit a report to the manufacturer as soon as practicable but no later than 30 calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or through your own research, testing, evaluation, servicing, or maintenance of one of your devices, that reasonably suggests that one of your devices has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. You must submit the information required by § 803.42. Reports to manufacturers may be made in accordance with § 803.11(b).

### § 803.42 If I am an importer, what information must I submit in my individual adverse event reports?

You must include the following information in your report, if the information is known or should be known to you, as described in § 803.40. These types of information correspond generally to the format of Form FDA 3500A:

- (a) Patient information (Form FDA 3500A, Block A). You must submit the following:
  - (1) Patient name or other identifier;
  - (2) Patient age at the time of event, or date of birth;
  - (3) Patient gender; and
  - (4) Patient weight.
- (b) Adverse event or product problem (Form FDA 3500A, Block B). You must submit the following:
  - (1) Identification of adverse event or product problem;
  - (2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:
    - (i) A life-threatening injury or illness;

- (ii) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
  - (iii) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
- (3) Date of event;
- (4) Date of this report;
- (5) Description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;
- (6) Description of relevant tests, including dates and laboratory data; and
- (7) Description of other relevant patient history, including preexisting medical conditions.

(c) Device information (Form FDA 3500A, Block D). You must submit the following:

- (1) Brand name;
- (2) Product Code, if known, and Common Device Name;
- (3) Manufacturer name, city, and state;
- (4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package;
- (5) Operator of the device (health professional, lay user/patient, other);
- (6) Date of device implantation (month, day, year), if applicable;
- (7) Date of device explantation (month, day, year), if applicable;
- (8) Whether the device is a single-use device that was reprocessed and reused on a patient (Yes, No)?
- (9) If the device is a single-use device that was reprocessed and reused on a patient (yes to paragraph (c)(8) of this section), the name and address of the reprocessor;
- (10) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and
- (11) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)

(d) Initial reporter information (Form FDA 3500A, Block E). You must submit the following:

- (1) Name, address, and telephone number of the reporter who initially provided information to the manufacturer, user facility, or distributor;
- (2) Whether the initial reporter is a health professional;
- (3) Occupation; and
- (4) Whether the initial reporter also sent a copy of the report to us, if known.

(e) Importer information (Form FDA 3500A, Block F). You must submit the following:

- (1) An indication that this is an importer report (by marking the importer box on the form);

- (2) Your importer report number;
- (3) Your address;
- (4) Your contact person;
- (5) Your contact person's telephone number;
- (6) Date that you became aware of the event (month, day, year);
- (7) Type of report (initial or followup). If it is a followup report, you must include the report number of your initial report;
- (8) Date of your report (month, day, year);
- (9) Approximate age of device;
- (10) Event problem codes—patient code and device code (refer to FDA MedWatch Medical Device Reporting Code Instructions);
- (11) Whether a report was sent to us and the date it was sent (month, day, year);
- (12) Location where event occurred;
- (13) Whether a report was sent to the manufacturer and the date it was sent (month, day, year); and
- (14) Manufacturer name and address, if available.

[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015]

## Subpart E—Manufacturer Reporting Requirements

### § 803.50 If I am a manufacturer, what reporting requirements apply to me?

- (a) If you are a manufacturer, you must report to us the information required by § 803.52 in accordance with the requirements of § 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:
  - (1) May have caused or contributed to a death or serious injury or
  - (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.
- (b) What information does FDA consider “reasonably known” to me?
  - (1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:
    - (i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;
    - (ii) Any information in your possession; or
    - (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.
  - (2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.

- (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under § 803.56 in accordance with the requirements of § 803.12(a).

## § 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

You must include the following information in your reports, if known or reasonably known to you, as described in § 803.50(b). These types of information correspond generally to the format of Form FDA 3500A:

- (a) Patient information (Form FDA 3500A, Block A). You must submit the following:

- (1) Patient name or other identifier;
- (2) Patient age at the time of event, or date of birth;
- (3) Patient gender; and
- (4) Patient weight.

- (b) Adverse event or product problem (Form FDA 3500A, Block B). You must submit the following:

- (1) Identification of adverse event or product problem;
- (2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:
  - (i) A life-threatening injury or illness;
  - (ii) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
  - (iii) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
- (3) Date of event;
- (4) Date of this report;
- (5) Description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;
- (6) Description of relevant tests, including dates and laboratory data; and
- (7) Other relevant patient history including preexisting medical conditions.

- (c) Device information (Form FDA 3500A, Block D). You must submit the following:

- (1) Brand name;
- (2) Product Code, if known, and Common Device Name;
- (3) Manufacturer name, city, and state;

- (4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package;
  - (5) Operator of the device (health professional, lay user/patient, other);
  - (6) Date of device implantation (month, day, year), if applicable;
  - (7) Date of device explantation (month, day, year), if applicable;
  - (8) Whether the device is a single-use device that was reprocessed and reused on a patient (Yes, No)?
  - (9) If the device is a single-use device that was reprocessed and reused on a patient (yes to paragraph (c)(8) of this section), the name and address of the reprocessor;
  - (10) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and
  - (11) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)
- (d) Initial reporter information (Form FDA 3500A, Block E). You must submit the following:
- (1) Name, address, and telephone number of the reporter who initially provided information to you, or to the user facility or importer;
  - (2) Whether the initial reporter is a health professional;
  - (3) Occupation; and
  - (4) Whether the initial reporter also sent a copy of the report to us, if known.
- (e) Reporting information for all manufacturers (Form FDA 3500A, Block G). You must submit the following:
- (1) Your reporting office's contact name and address and device manufacturing site;
  - (2) Your contact person's telephone number;
  - (3) Your report sources;
  - (4) Date received by you (month, day, year);
  - (5) PMA/510k Number and whether or not the product is a combination product;
  - (6) Type of report being submitted (e.g., 5-day, initial, followup); and
  - (7) Your report number.
- (f) Device manufacturer information (Form FDA 3500A, Block H). You must submit the following:
- (1) Type of reportable event (death, serious injury, malfunction, etc.);
  - (2) Type of followup report, if applicable (e.g., correction, response to FDA request, etc.);
  - (3) If the device was returned to you and evaluated by you, you must include a summary of the evaluation. If you did not perform an evaluation, you must explain why you did not perform an evaluation;
  - (4) Device manufacture date (month, day, year);
  - (5) Whether the device was labeled for single use;

- (6) Evaluation codes (including event codes, method of evaluation, result, and conclusion codes) (refer to FDA MedWatch Medical Device Reporting Code Instructions);
- (7) Whether remedial action was taken and the type of action;
- (8) Whether the use of the device was initial, reuse, or unknown;
- (9) Whether remedial action was reported as a removal or correction under section 519(f) of the Federal Food, Drug, and Cosmetic Act, and if it was, provide the correction/removal report number; and
- (10) Your additional narrative; and/or
- (11) Corrected data, including:
  - (i) Any information missing on the user facility report or importer report, including any event codes that were not reported, or information corrected on these forms after your verification;
  - (ii) For each event code provided by the user facility under § 803.32(e)(10) or the importer under § 803.42(e)(10), you must include a statement of whether the type of the event represented by the code is addressed in the device labeling; and
  - (iii) If your report omits any required information, you must explain why this information was not provided and the steps taken to obtain this information.

[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015]

### **§ 803.53 If I am a manufacturer, in which circumstances must I submit a 5-day report?**

You must submit a 5-day report to us with the information required by § 803.52 in accordance with the requirements of § 803.12(a) no later than 5 work days after the day that you become aware that:

- (a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis or
- (b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

### **§ 803.56 If I am a manufacturer, in what circumstances must I submit a supplemental or followup report and what are the requirements for such reports?**

If you are a manufacturer, when you obtain information required under this part that you did not provide because it was not known or was not available when you submitted the initial report, you must submit the supplemental information to us within 30 calendar days of the day that you receive this information. You must submit the supplemental or followup report in accordance with the requirements of § 803.12(a). On a supplemental or followup report, you must:

- (a) Indicate that the report being submitted is a supplemental or followup report;

- (b) Submit the appropriate identification numbers of the report that you are updating with the supplemental information (e.g., your original manufacturer report number and the user facility or importer report number of any report on which your report was based), if applicable; and
- (c) Include only the new, changed, or corrected information.

## § 803.58 Foreign manufacturers.

- (a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with § 807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and § 807.40 of this chapter, and shall update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a change in the designated agent information.
- (b) U.S.-designated agents of foreign manufacturers are required to:
  - (1) Report to FDA in accordance with §§ 803.50, 803.52, 803.53, and 803.56;
  - (2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of § 803.50;
  - (3) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;
  - (4) Maintain complaint files in accordance with § 803.18; and
  - (5) Register, list, and submit premarket notifications in accordance with part 807 of this chapter.

**Effective Date Note:** At 79 FR 8846, Feb. 14, 2014, part 803 was revised. At 79 FR 8855, Feb. 14, 2014, § 803.58 was stayed indefinitely.

This content is from the eCFR and is authoritative but unofficial.

## Title 21 –Food and Drugs

### Chapter I –Food and Drug Administration, Department of Health and Human Services

#### Subchapter H –Medical Devices

## Part 806 Medical Devices; Reports of Corrections and Removals

### Subpart A General Provisions

**§ 806.1** Scope.

**§ 806.2** Definitions.

### Subpart B Reports and Records

**§ 806.10** Reports of corrections and removals.

**§ 806.20** Records of corrections and removals not required to be reported.

**§ 806.30** FDA access to records.

**§ 806.40** Public availability of reports.

## PART 806—MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS

**Authority:** 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

**Source:** 62 FR 27191, May 19, 1997, unless otherwise noted.

### Subpart A—General Provisions

#### § 806.1 Scope.

(a) This part implements the provisions of section 519(g) of the Federal Food, Drug, and Cosmetic Act (the act) requiring device manufacturers and importers to report promptly to the Food and Drug Administration (FDA) certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA.

(b) The following actions are exempt from the reporting requirements of this part:

- (1) Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.
- (2) Market withdrawal as defined in § 806.2(i).
- (3) Routine servicing as defined in § 806.2(l).
- (4) Stock recovery as defined in § 806.2(m).

[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 84 FR 12083, Apr. 1, 2019]

## § 806.2 Definitions.

As used in this part:

- (a) **Act** means the Federal Food, Drug, and Cosmetic Act.
- (b) **Agency or FDA** means the Food and Drug Administration.
- (c) **Consignee** means any person or firm that has received, purchased, or used a device subject to correction or removal.
- (d) **Correction** means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location.
- (e) **Correction or removal report number** means the number that uniquely identifies each report submitted.
- (f) **Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device** means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.
- (g) **Importer** means, for the purposes of this part, any person who imports a device into the United States.
- (h) **Manufacturer** means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures. The term includes any person who:
  - (1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user or consumer;
  - (2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or
  - (3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.
- (i) **Market withdrawal** means a correction or removal of a distributed device that involves a minor violation of the act that would not be subject to legal action by FDA or that involves no violation of the act, e.g., normal stock rotation practices.
- (j) **Removal** means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.
- (k) **Risk to health** means
  - (1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or
  - (2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

- (l) **Routine servicing** means any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy, e.g., calibration, replacement of batteries, and responses to normal wear and tear. Repairs of an unexpected nature, replacement of parts earlier than their normal life expectancy, or identical repairs or replacements of multiple units of a device are not routine servicing.
- (m) **Stock recovery** means the correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e., the device is located on the premises owned, or under the control of, the manufacturer, and no portion of the lot, model, code, or other relevant unit involved in the corrective or removal action has been released for sale or use.
- (n) **Unique device identifier (UDI)** means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A UDI is composed of:
  - (1) A *device identifier*—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and
  - (2) A *production identifier*—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
    - (i) The lot or batch within which a device was manufactured;
    - (ii) The serial number of a specific device;
    - (iii) The expiration date of a specific device;
    - (iv) The date a specific device was manufactured.
    - (v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 78 FR 58821, Sept. 24, 2013]

## Subpart B—Reports and Records

### § 806.10 Reports of corrections and removals.

- (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:
  - (1) To reduce a risk to health posed by the device; or
  - (2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under § 806.1(b).
- (b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal.
- (c) The manufacturer or importer shall include the following information in the report:
  - (1) The seven digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R". For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567:

1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows:

1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven digit registration number will be assigned a seven digit central file number by the district office reviewing the reports.

- (2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal.
  - (3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device.
  - (4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA.
  - (5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.
  - (6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report.
  - (7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.
  - (8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers.
  - (9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal.
  - (10) The date of manufacture or distribution and the device's expiration date or expected life.
  - (11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee.
  - (12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section.
  - (13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted.
- (d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10-working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the

information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available.

- (e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury.
- (f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter.

[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 58821, Sept. 24, 2013]

## § 806.20 Records of corrections and removals not required to be reported.

- (a) Each device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.10 shall keep a record of such correction or removal.
- (b) Records of corrections and removals not required to be reported to FDA under § 806.10 shall contain the following information:
  - (1) The brand name, common or usual name, classification, name and product code if known, and the intended use of the device.
  - (2) The unique device identifier (UDI) of the device, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.
  - (3) A description of the event(s) giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken.
  - (4) Justification for not reporting the correction or removal action to FDA, which shall contain conclusions and any followups, and be reviewed and evaluated by a designated person.
  - (5) A copy of all communications regarding the correction or removal.
- (c) The manufacturer or importer shall retain records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device. Records required to be maintained under paragraph (b) of this section must be transferred to the new manufacturer or importer of the device and maintained for the required period of time.

[62 FR 27191, May 19, 1997, as amended at 63 FR 42233, Aug. 7, 1998; 78 FR 58821, Sept. 24, 2013]

## § 806.30 FDA access to records.

Each device manufacturer or importer required under this part to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by FDA and under section 704(e) of the act, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records and reports.

[63 FR 42233, Aug. 7, 1998]

## § 806.40 Public availability of reports.

- (a) Any report submitted under this part is available for public disclosure in accordance with part 20 of this chapter.
- (b) Before public disclosure of a report, FDA will delete from the report:
  - (1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter; and
  - (2) Any personnel, medical, or similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under § 20.63 of this chapter or 5 U.S.C. 552(b)(6); provided, that except for the information under § 20.61 of this chapter or 5 U.S.C. 552(b)(4), FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

This content is from the eCFR and is authoritative but unofficial.

## Title 21 –Food and Drugs

### Chapter I –Food and Drug Administration, Department of Health and Human Services

#### Subchapter H –Medical Devices

##### Part 807 Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices

###### Subpart A General Provisions

###### § 807.3 Definitions.

###### Subpart B Procedures for Device Establishments

###### § 807.20 Who must register and submit a device list?

###### § 807.21 How to register establishments and list devices.

###### § 807.22 Times for establishment registration and device listing.

###### § 807.25 Information required for device establishment registration and device listing.

###### § 807.26 Additional listing information.

###### § 807.28 Updating device listing information.

###### § 807.34 Summary of requirements for owners or operators granted a waiver from submitting required information electronically.

###### § 807.35 Notification of registrant.

###### § 807.37 Public availability of establishment registration and device listing information.

###### § 807.39 Misbranding by reference to establishment registration or to registration number.

###### Subpart C Procedures for Foreign Device Establishments

###### § 807.40 Establishment registration and device listing for foreign establishments importing or offering for import devices into the United States.

###### § 807.41 Identification of importers and persons who import or offer for import.

###### Subpart D Exemptions

###### § 807.65 Exemptions for device establishments.

###### Subpart E Premarket Notification Procedures

###### § 807.81 When a premarket notification submission is required.

###### § 807.85 Exemption from premarket notification.

###### § 807.87 Information required in a premarket notification submission.

###### § 807.90 Format of a premarket notification submission.

###### § 807.92 Content and format of a 510(k) summary.

###### § 807.93 Content and format of a 510(k) statement.

###### § 807.94 Format of a class III certification.

###### § 807.95 Confidentiality of information.

###### § 807.97 Misbranding by reference to premarket notification.

###### § 807.100 FDA action on a premarket notification.

# PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

**Authority:** 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360e-4, 360i, 360j, 360bbb-8b, 371, 374, 379k-1, 381, 393; 42 U.S.C. 264, 271.

**Source:** 42 FR 42526, Aug. 23, 1977, unless otherwise noted.

## Subpart A—General Provisions

### § 807.3 Definitions.

- (a) **Act** means the Federal Food, Drug, and Cosmetic Act.
- (b) **Commercial distribution** means any distribution of a device intended for human use which is held or offered for sale but does not include the following:
  - (1) Internal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company;
  - (2) Any distribution of a device intended for human use which has in effect an approved exemption for investigational use under section 520(g) of the act and part 812 of this chapter;
  - (3) Any distribution of a device, before the effective date of part 812 of this chapter, that was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and that is classified into class III under section 513(f) of the act: *Provided*, That the device is intended solely for investigational use, and under section 501(f)(2)(A) of the act the device is not required to have an approved premarket approval application as provided in section 515 of the act; or
  - (4) For foreign establishments, the distribution of any device that is neither imported nor offered for import into the United States.
- (c) **Establishment** means a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed.
- (d) **Manufacture, preparation, propagation, compounding, assembly, or processing** of a device means the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the act. These terms include the following activities:
  - (1) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer;
  - (2) Initial importation of devices manufactured in foreign establishments; or
  - (3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications.
- (e) **Official correspondent** means the person designated by the owner or operator of an establishment as responsible for the following:
  - (1) The annual registration of the establishment;

- (2) Contact with the Food and Drug Administration for device listing;
  - (3) Maintenance and submission of a current list of officers and directors to the Food and Drug Administration upon the request of the Commissioner; and
  - (4) The receipt of pertinent correspondence from the Food and Drug Administration directed to and involving the owner or operator and/or any of the firm's establishments.
- (f) **Owner or operator** means the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering establishment.
- (g) **Initial importer** means any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.
- (h) Any term defined in section 201 of the act shall have that meaning.
- (i) **Restricted device** means a device for which a requirement restricting sale, distribution, or use has been established by a regulation issued under section 520(e) of the act, by order as a condition of premarket approval under section 515(d)(1)(B)(ii) of the act, or by a performance standard issued in accordance with sections 514(a)(2)(B)(v) and 514(b) of the act.
- (j) **Classification name** means the term used by the Food and Drug Administration and its classification panels to describe a device or class of devices for purposes of classifying devices under section 513 of the act.
- (k) **Product code** means the code used by FDA to identify the generic category of a device.
- (l) **Representative sampling of advertisements** means typical advertising material that gives the promotional claims made for the device.
- (m) **Representative sampling of any other labeling** means typical labeling material (excluding labels and package inserts) that gives the promotional claims made for the device.
- (n) **Material change** includes any change or modification in the labeling or advertisements that affects the identity or safety and effectiveness of the device. These changes may include, but are not limited to, changes in the common or usual or proprietary name, declared ingredients or components, intended use, contraindications, warnings, or instructions for use. Changes that are not material may include graphic layouts, grammar, or correction of typographical errors which do not change the content of the labeling, changes in lot number, and, for devices where the biological activity or known composition differs with each lot produced, the labeling containing the actual values for each lot.
- (o) **510(k) summary** (summary of any information respecting safety and effectiveness) means a summary, submitted under section 513(i) of the act, of the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence can be based. Safety and effectiveness information refers to safety and effectiveness data and information supporting a finding of substantial equivalence, including all adverse safety and effectiveness information.
- (p) **510(k) statement** means a statement, made under section 513(i) of the act, asserting that all information in a premarket notification submission regarding safety and effectiveness will be made available within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information to be made available will be a duplicate of the

premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret or confidential commercial information, as defined in § 20.61 of this chapter.

- (q) ***Class III certification*** means a certification that the submitter of the 510(k) has conducted a reasonable search of all known information about the class III device and other similar, legally marketed devices.
- (r) ***Class III summary*** means a summary of the types of safety and effectiveness problems associated with the type of device being compared and a citation to the information upon which the summary is based. The summary must be comprehensive and describe the problems to which the type of device is susceptible and the causes of such problems.
- (s) ***United States agent*** means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.
- (t) ***Wholesale distributor*** means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.
- (u) ***Fiscal year*** means the FDA fiscal year, which runs from October 1 through September 30.
- (v) ***FURLS*** means the Food and Drug Administration's Unified Registration and Listing System,
- (w) ***FDA premarket submission number*** means the number assigned by FDA to a premarket device submission, such as a Premarket Approval Application (PMA); Humanitarian Device Exemption (HDE); New Drug Application (NDA); Biologics License Application (BLA); de novo classification petition; or Premarket Notification (510(k)).
- (x) ***Importer*** means, for purposes of this part, a company or individual in the United States that is an owner, consignee, or recipient, even if not the initial owner, consignee, or recipient, of the foreign establishment's device that is imported into the United States. An importer does not include the consumer or patient who ultimately purchases, receives, or uses the device, unless the foreign establishment ships the device directly to the consumer or patient.
- (y) ***Person who imports or offers for import*** means, for purposes of this part, an agent, broker, or other entity, other than a carrier, that the foreign establishment uses to facilitate the import of its device into the United States.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37997, Aug. 25, 1978; 57 FR 18066, Apr. 28, 1992; 58 FR 46522, Sept. 1, 1993; 59 FR 64295, Dec. 14, 1994; 60 FR 63606, Dec. 11, 1995; 63 FR 51826, Sept. 29, 1998; 66 FR 59159, Nov. 27, 2001; 77 FR 45940, Aug. 2, 2012]

## Subpart B—Procedures for Device Establishments

### § 807.20 Who must register and submit a device list?

- (a) An owner or operator of an establishment not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use shall register and submit

listing information for those devices in commercial distribution, except that registration and listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. The term "device" includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. An owner or operator of an establishment located in any State as defined in section 201(a)(1) of the Federal Food, Drug, and Cosmetic Act shall register its name, places of business, and all establishments and list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use, including any person who:

- (1) Initiates or develops specifications for a device that is to be manufactured by a second party;
- (2) Sterilizes or otherwise makes a device for or on behalf of a specifications developer or any other person;
- (3) Repackages or relabels a device;
- (4) Reprocesses a single use device that has previously been used on a patient;
- (5) Acts as an initial importer as defined in § 807.3(g), except that initial importers may fulfill their listing obligation for any device for which they did not initiate or develop the specifications for the device or repackage or relabel the device by submitting the name and address of the manufacturer. Initial importers shall also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which they are the initial importer;
- (6) Manufactures components or accessories that are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g. blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks.

- (b) Registration or listing does not constitute an admission or agreement or determination that a product is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act.
- (c) Registration and listing requirements shall not pertain to any person who acts as a wholesale distributor, as defined in § 807.3(t), and who does not manufacture, repackage, process, or relabel a device.
- (d) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter, that are regulated under the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-based products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing contained in this part, except that the additional listing information requirements of § 807.26 remain applicable.
- (e) Owners and operators of establishments that manufacture devices licensed under section 351 of the Public Health Service Act as well as licensed biological products used in the manufacture of a licensed device must register and list following the procedures set out in part 607 of this chapter, instead of the procedures for registration and listing contained in this part.

[77 FR 45941, Aug. 2, 2012]

## § 807.21 How to register establishments and list devices.

- (a) Owners or operators of establishments that are subject to the registration and listing requirements of this part must provide the following information to us using our electronic device registration and listing system, except as provided in paragraphs (b), (c), and (d) of this section:
- (1) Initial establishment registration information as required by §§ 807.22(a) and 807.25;
  - (2) Updates to registration information as required by §§ 807.22(b) and 807.25;
  - (3) Initial device listing information as required by §§ 807.22(a), 807.25, and 807.28;
  - (4) Updates to device listing information as required by §§ 807.22(b), 807.25, and 807.28, including updates to reflect the discontinuance or resumption of the commercial distribution of a previously-listed device as specified at paragraphs (d) and (e) of § 807.28.
- (b) If the information under § 807.21(a) cannot be submitted electronically, a waiver may be requested. Waivers will be granted only if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants must send a letter to the Imports and Registration and Listing Team, Division of Regulatory Programs 2, Office of Regulatory Programs, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1432, Silver Spring, MD 20993-0002, that includes the following information:
- (1) The name and address of the device establishment(s) to be registered, a contact person for the owner or operator of the establishment, and the telephone number at which that person can be reached. If the establishment has already registered in the past, the letter should also include the owner or operator number, registration number, and any listing numbers previously assigned by FDA for devices manufactured at that establishment.
  - (2) Information about whether the company is an initial importer as defined in § 807.3(g) and, if so, whether it also conducts any other activities or operations relating to devices.
  - (3) A statement that use of the Internet is not reasonable for the person requesting the waiver, and an explanation of why such use is not reasonable. The statement must be signed by the owner or operator of the establishment, or by a person employed by the owner or operator who is authorized to make the declaration on behalf of the owner or operator.
- (c) Those owners or operators who have obtained a waiver from filing registration and listing information electronically should refer to § 807.34 for information on how to submit such information by postal mail.
- (d) When additional device listing information (e.g., copies of labeling or advertisements) is requested by FDA as described at § 807.26(e), such information may be submitted by postal mail or electronically by email, but will not be submitted using the FDA electronic device registration and listing system.

[77 FR 45941, Aug. 2, 2012, as amended at 85 FR 18442, Apr. 2, 2020]

## § 807.22 Times for establishment registration and device listing.

- (a) ***Initial registration and listing.*** An owner or operator of an establishment who has not previously entered into an operation described in § 807.20(a) shall register within 30 days after entering into such an operation and submit device listing information at that time.

- (b) **Registration and listing updates.** Owners or operators shall review and update all of their establishment registration and device listing information that is on file at FDA, documenting any changes that were not previously reported as follows:
- (1) Annual registration for each fiscal year is required for all establishments. Annual registration shall take place during the period beginning on October 1 and ending on December 31 of each fiscal year;
  - (2) Updates to the registration information as described in § 807.25(b) shall be made within 30 days of any change to such information;
  - (3) Every fiscal year, during the period beginning on October 1 and ending on December 31, owners or operators shall review and update all of their device listing information that is on file at FDA, reporting any changes or deletions to listings and any new listings that were not previously reported. The accuracy of all information on file must be confirmed each year regardless of whether any changes were made to the owner or operator's list of devices; and
  - (4) Changes to listing information may also be made at other times, such as when a device is introduced into commercial distribution, when a change is made to a previously-listed device, or when a previously-listed device is removed from commercial distribution.
- (c) **Failure to submit required information.** Failure to submit any of the required information on time, as specified in paragraphs (a) and (b) of this section, will put the establishment in a "failed to register" or "failed to list" status as applicable. The establishment will not be considered active and the establishment registration and device listing information may not appear on the FDA Web site until such time as the owner or operator submits and FDA processes the required information.

[77 FR 45942, Aug. 2, 2012]

## § 807.25 Information required for device establishment registration and device listing.

- (a) All owners or operators that are subject to the registration and listing requirements of this part shall provide such information to us by using the FDA electronic device registration and listing system, unless granted a waiver from electronic submission in accordance with § 807.21(b). Electronic submissions of registration and listing information must comply with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e), and the corresponding requirements in § 11.30 of this chapter. Those owners or operators granted a waiver from electronic submission should refer to paragraphs (c) and (g) of this section and § 807.34 for instructions on how to submit device registration and listing information.
- (b) Registration information required to be submitted includes: The name and mailing address of the device establishment; the Web site address of the device establishment, if any; the name, address, phone number, fax number, and email address of the owner or operator; the name, address, phone number, fax number, and email address of the establishment's official correspondent; and all trade names used by the establishment.
- (c) Owners or operators who have been granted a waiver from electronic filing must submit the establishment registration information described in paragraph (b) of this section, except for the Web site and email address information, in paper form using the procedures set forth in § 807.34.
- (d) Each owner or operator is required to maintain a listing of all officers, directors, and partners for each establishment registered by the owner or operator and to furnish this information to FDA upon request.

- (e) For each establishment, an official correspondent must be designated by the owner or operator to serve as a point of contact with FDA on matters relating to the registration of device establishments and the listing of device products. Each owner or operator shall also provide FDA with the name of a contact person at the owner or operator's offices who will be responsible for identifying the official correspondent for each establishment. The owner or operator contact person will be the official correspondent in the event no one else has been properly designated. The official correspondent is responsible for:
- (1) Providing FDA with all required registration and listing information electronically unless a waiver from electronic submission has been granted in accordance with § 807.21(b);
  - (2) Receiving all correspondence from FDA concerning registration and listing;
  - (3) Supplying, when requested by FDA, the names of all officers, directors, and partners; and
  - (4) Receiving communications from FDA by email, or by postal mail if the owner or operator has been granted a waiver from the requirement to file registration and listing information electronically.
- (f) The designation of an official correspondent does not in any manner affect the liability of the owner or operator of the establishment or any other individual under section 301(p) or any other provision of the Federal Food, Drug, and Cosmetic Act.
- (g) Device listing information must be submitted to FDA electronically unless a waiver from electronic submission has been granted in accordance with § 807.21(b). Owners or operators who have been granted a waiver must submit the required device listing information, including information required by this paragraph, § 807.28, and any listing information requested by FDA under § 807.26(e), in paper form using the procedures set forth in § 807.34. The information required for each device listed includes:
- (1) The current registration number and name of each establishment under the ownership and control of the owner or operator where the device is manufactured, repackaged, relabeled, or otherwise processed, or where specifications are developed.
  - (2) The product code for each device that is exempt from premarket notification and approval or which was in commercial distribution prior to May 28, 1976.
  - (3) The proprietary or brand name(s) under which each device is marketed.
  - (4) The FDA-assigned premarket submission number of the approved application, cleared premarket notification, granted de novo classification petition, or approved humanitarian device exemption for each device listed that is subject to sections 505, 510(k), 513(f)(2), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act, which includes devices that are not exempt from premarket notification and approval.
  - (5) Each activity or process that is conducted on or done to the device at each establishment, such as manufacturing, repacking, relabeling, developing specifications, remanufacturing, single-use device reprocessing, contract manufacturing, contract sterilizing, or manufacturing for export only.

[77 FR 45942, Aug. 2, 2012]

## § 807.26 Additional listing information.

- (a) Each owner or operator shall maintain a historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing, as follows:

- (1) For each device subject to section 514 or 515 of the act that is not a restricted device, a copy of all labeling for the device;
  - (2) For each restricted device, a copy of all labeling and advertisements for the device;
  - (3) For each device that is neither restricted nor subject to section 514 or 515 of the act, a copy of all labels, package inserts, and a representative sampling of any other labeling.
- (b) In addition to the requirements set forth in paragraph (a) of this section, each owner or operator shall maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing.
- (c) Each owner or operator may discard labeling and advertisements from the historical file 3 years after the date of the last shipment of a discontinued device by an owner or operator.
- (d) Location of the file:
- (1) Currently existing systems for maintenance of labeling and advertising may be used for the purpose of maintaining the historical file as long as the information included in the systems fulfills the requirements of this section, but only if the labeling and advertisements are retrievable in a timely manner.
  - (2) The contents of the historical file may be physically located in more than one place in the establishment or in more than one establishment provided there exists joint ownership and control among all the establishments maintaining the historical file. If no joint ownership and control exists, the registered establishment must provide the Food and Drug Administration with a letter authorizing the establishment outside its control to maintain the historical file.
  - (3) A copy of the certification and disclosure statements as required by part 54 of this chapter shall be retained and physically located at the establishment maintaining the historical file.
- (e) Each owner or operator shall be prepared to submit to the Food and Drug Administration, only upon specific request, the following information:
- (1) For a device subject to section 514 or 515 of the act that is not a restricted device, a copy of all labeling for the device.
  - (2) For a device that is a restricted device, a copy of all labeling for the device, a representative sampling of advertisements for the device, and for good cause, a copy of all advertisements for a particular device. A request for all advertisements will, where feasible, be accompanied by an explanation of the basis for such request.
  - (3) For a device that is neither a restricted device, nor subject to section 514 or 515 of the act, the label and package insert for the device and a representative sampling of any other labeling for the device.
  - (4) For a particular device, a statement of the basis upon which the registrant has determined that the device is not subject to section 514 or 515 of the act.
  - (5) For a particular device, a statement of the basis upon which the registrant has determined the device is not a restricted device.
  - (6) For a particular device, a statement of the basis for determining that the product is a device rather than a drug.

- (7) For a device that the owner or operator has manufactured for distribution under a label other than its own, the names of all distributors for whom it has been manufactured.

- (f) Labeling, advertisements, and other information to be submitted upon request in accordance with paragraph (e) of this section may be submitted by postal mail or electronically by email, but will not be submitted using the FDA electronic device registration and listing system. Electronic submissions of such information must comply with part 11 of this chapter, except for the requirements in § 11.10 (a), (c) through (h), and (k), and the corresponding requirements in § 11.30 of this chapter. The information provided in electronic format must be in a form that we can process, review, and archive.

[43 FR 37999, Aug. 25, 1978, as amended at 51 FR 33033, Sept. 18, 1986; 63 FR 5253, Feb. 2, 1998. Redesignated and amended at 77 FR 45943, Aug. 2, 2012]

## § 807.28 Updating device listing information.

- (a) Updating of device listing information is required if an additional establishment begins to engage in any of the activities described in § 807.3(d) with respect to a listed device, such as manufacturing, developing specifications, repackaging, relabeling, or otherwise processing the device. Updating of the listing is also required if an establishment begins performing another activity on or to the device, or ceases to perform an activity on or to the device that had previously been identified on the device listing.
- (b) An owner or operator shall create a new device listing using the FDA electronic device registration and listing system:
- (1) If introducing into commercial distribution an exempt device identified with a product code that is not currently listed by the owner or operator; or
- (2) If introducing into commercial distribution a non-exempt device with an FDA premarket submission number that is not currently listed by the owner or operator.
- (c) All device listings for foreign establishments must be submitted before the device may be imported or offered for import into the United States.
- (d) An owner or operator who discontinues commercial distribution of a device shall discontinue the device listing using the FDA electronic device registration and listing system. A device listing is considered discontinued if:
- (1) All devices under an exempt product code have been discontinued or
- (2) All devices associated with an FDA premarket submission number have been discontinued.
- (e) If commercial distribution of a discontinued device is resumed, the owner or operator must reactivate the previously-discontinued listing using the electronic device registration and listing system. Any changes to the listing information for the product that is the subject of the listing such as a new establishment, new activity, or new proprietary name must be made using the electronic device registration and listing system at the time the listing is reactivated.
- (f) FDA will assign one listing number for all devices exempt from premarket notification requirements under a single product code. For products not exempt from premarket notification requirements, a single listing number will be assigned by FDA for each FDA premarket submission number.

[77 FR 45943, Aug. 2, 2012]

## § 807.34 Summary of requirements for owners or operators granted a waiver from submitting required information electronically.

- (a) For initial registration and listing, owners or operators who have been granted a waiver from electronic filing using the procedures set forth in § 807.21(b) must send a letter containing all of the registration and listing information described in §§ 807.22, 807.25 (and § 807.26 when such information is requested by FDA), at the times described in § 807.22, to: The Imports and Registration and Listing Team, Division of Regulatory Programs 2, Office of Regulatory Programs, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1432, Silver Spring, MD 20993-0002.
- (b) As specified in § 807.22(b)(1) and (b)(3), all owners or operators shall update their establishment registration and device listings annually during the period beginning on October 1 and ending on December 31 of each fiscal year.
- (c) Failure to submit any of the required information on time, as specified in § 807.22(a) and (b), will put the establishment in a “failed to register” or “failed to list” status as applicable.

The establishment will not be considered active and the establishment registration and device listing information may not appear on the FDA Web site until the required information is submitted to and processed by FDA.

[77 FR 45943, Aug. 2, 2012, as amended at 85 FR 18442, Apr. 2, 2020]

## § 807.35 Notification of registrant.

- (a) The Food and Drug Administration will assign each device establishment a registration number after verifying the initial establishment registration information that has been submitted. The owner or operator of the establishment will also be assigned an identifying number. Both numbers will be sent to the official correspondent by email, or by postal mail if the owner or operator has been granted a waiver from the requirement to file registration and listing information electronically.
- (b) Owners or operators of device establishments who also manufacture or process biological products (including devices licensed under section 351 of the Public Health Service Act) or drug products at the same establishment must also register and list those products under part 607 or part 207 of this chapter, as appropriate. Registration and listing for human blood and blood products, devices licensed under section 351 of the Public Health Service Act, and licensed biological products used in the manufacture of a device licensed under section 351 of the Public Health Service Act, are subject to part 607 of this chapter; registration and listing for all other drug products (including other biological products that are also regulated as drug products) are subject to part 207 of this chapter.
- (c) Although establishment registration and device listing are required to engage in the device activities described in § 807.20, validation of registration and the assignment of a device listing number in itself does not establish that the holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Food and Drug Administration as to the status of any device.

[69 FR 11312, Mar. 10, 2004, as amended at 77 FR 45943, Aug. 2, 2012]

## § 807.37 Public availability of establishment registration and device listing information.

- (a) Establishment registration and device listing information is available for public inspection in accordance with section 510(f) of the Federal Food, Drug, and Cosmetic Act and will be posted on the FDA website, with the exception of the information identified in paragraph (b) of this section. Requests for information by persons who do not have access to the internet should be directed to the Imports and Registration and Listing Team, Division of Regulatory Programs 2, Office of Regulatory Programs, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.1432, Silver Spring, MD 20993-0002. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district offices. Upon request, verification of a registration number or location of a registered establishment will be provided.
- (b) The following listing information will not be available for public inspection or posted on the FDA Web site:
- (1) For contract manufacturers, contract sterilizers, and private label manufacturers, the proprietary or brand name(s) under which a device is marketed and the FDA-assigned premarket submission number, if this information would reveal a confidential business relationship;
  - (2) FDA-assigned listing numbers.

[77 FR 45943, Aug. 2, 2012, as amended at 85 FR 18442, Apr. 2, 2020]

## § 807.39 Misbranding by reference to establishment registration or to registration number.

Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.

## Subpart C—Procedures for Foreign Device Establishments

### § 807.40 Establishment registration and device listing for foreign establishments importing or offering for import devices into the United States.

- (a) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall register such establishment and list such devices using the FDA electronic device registration and listing system in conformance with the procedures in this section, § 807.41, and subpart B of this part. The official correspondent for the foreign establishment shall facilitate communication between the foreign establishment's management and representatives of FDA for matters relating to the registration of device establishments and the listing of device products.
- (b) Each foreign establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with subpart B of this part. Each foreign establishment shall designate only one United States agent and may designate the United States agent to act as its official correspondent.
- (1) The United States agent shall reside or maintain a place of business in the United States.
  - (2) Upon request from FDA, the United States agent shall assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of

the foreign establishment. If the agency is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

- (3) The foreign establishment or the United States agent shall report changes in the United States agent's name, address, or phone number to FDA within 10-business days of the change.
- (c) No device may be imported or offered for import into the United States unless it is the subject of a device listing as required under subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment; however, this restriction does not apply to devices imported or offered for import under the investigational use provisions of part 812 of this chapter.
- (d) The device establishment registration and device listing information shall be in the English language.

[66 FR 59160, Nov. 27, 2001, as amended at 77 FR 45944, Aug. 2, 2012]

## § 807.41 Identification of importers and persons who import or offer for import.

- (a) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA electronic device registration and listing system, submit the name, address, telephone and fax numbers, email address, and registration number, if any has been assigned, of any importer (defined in § 807.3(x)) of the establishment's devices that is known to the foreign establishment. The foreign establishment must also specify which of the establishment's listed products each importer receives from the foreign establishment.
- (b) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA electronic device registration and listing system, submit the name, address, telephone and fax numbers, email address, and registration number, if any has been assigned, of each person who imports or offers for import the establishment's devices into the United States. The term "person who imports or offers for import," which is defined in § 807.3(y), includes agents, brokers, or other parties used by the foreign establishment to facilitate the import of its device into the United States.
- (c) For each individual or organization identified by the foreign establishment under paragraphs (a) and (b) of this section, the foreign establishment must submit to FDA electronically the current FDA premarket submission number and any other identifying information that is known to the establishment for each device being imported or offered for import by the named individuals or organizations.

[77 FR 45944, Aug. 2, 2012]

## Subpart D—Exemptions

### § 807.65 Exemptions for device establishments.

The following classes of persons are exempt from registration in accordance with § 807.20 under the provisions of section 510(g)(1), (g)(2), and (g)(3) of the act, or because the Commissioner of Food and Drugs has found, under section 510(g)(5) of the act, that such registration is not necessary for the protection of the public health. The exemptions in paragraphs (d), (e), (f), and (i) of this section are limited to those classes of persons located in any State as defined in section 201(a)(1) of the act.

- (a) A manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register under the provisions of this part.
- (b) A manufacturer of devices to be used solely for veterinary purposes.
- (c) A manufacturer of general purpose articles such as chemical reagents or laboratory equipment whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses.
- (d) Licensed practitioners, including physicians, dentists, and optometrists, who manufacture or otherwise alter devices solely for use in their practice.
- (e) Pharmacies, surgical supply outlets, or other similar retail establishments making final delivery or sale to the ultimate user. This exemption also applies to a pharmacy or other similar retail establishment that purchases a device for subsequent distribution under its own name, e.g., a properly labeled health aid such as an elastic bandage or crutch, indicating "distributed by" or "manufactured for" followed by the name of the pharmacy.
- (f) Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution.
- (g) [Reserved]
- (h) Carriers by reason of their receipt, carriage, holding or delivery of devices in the usual course of business as carriers.
- (i) Persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived from the use of a device; for example, a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic x-ray systems, and personnel from a hospital, clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device.

[42 FR 42526, Aug. 23, 1977, as amended at 58 FR 46523, Sept. 1, 1993; 61 FR 44615, Aug. 28, 1996; 65 FR 17136, Mar. 31, 2000; 66 FR 59160, Nov. 27, 2001]

## Subpart E—Premarket Notification Procedures

### § 807.81 When a premarket notification submission is required.

- (a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:
  - (1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to,
    - (i) a device in commercial distribution before May 28, 1976, or
    - (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.

- (2) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device meets the criteria in paragraph (a)(1) of this section.
  - (3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:
    - (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.
    - (ii) A major change or modification in the intended use of the device.
- (b)
- (1) A premarket notification under this subpart is not required for a device for which:
    - (i) A premarket approval application under section 515 of the act, or for which a petition to reclassify under section 513(f)(2) of the act, is pending before the Food and Drug Administration, or
    - (ii) There is a predetermined change control plan (PCCP) cleared under section 515C of the act, provided that the change is consistent with the PCCP.
  - (2) The appropriate FDA Center Director may determine that the submission and grant of a written request for an exception or alternative under § 801.128 or § 809.11 of this chapter satisfies the requirement in paragraph (a)(3) of this section.
- (c) In addition to complying with the requirements of this part, owners or operators of device establishments that manufacture radiation-emitting electronic products, as defined in § 1000.3 of this chapter, shall comply with the reporting requirements of part 1002 of this chapter.

[42 FR 42526, Aug. 23, 1977, as amended at 72 FR 73601, Dec. 28, 2007; 89 FR 18792, Mar. 15, 2024]

## § 807.85 Exemption from premarket notification.

- (a) A custom device is exempt from premarket notification requirements of this subpart if the device is within the meaning of section 520(b) of the Federal Food, Drug, and Cosmetic Act.
  - (1) It is intended for use by a patient named in the order of the physician or dentist (or other specially qualified person); or
  - (2) It is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons).
- (b) A distributor who places a device into commercial distribution for the first time under his own name and a repackager who places his own name on a device and does not change any other labeling or otherwise affect the device shall be exempted from the premarket notification requirements of this subpart if:
  - (1) The device was in commercial distribution before May 28, 1976; or
  - (2) A premarket notification submission was filed by another person.

[42 FR 42526, Aug. 23, 1977, as amended at 81 FR 70340, Oct. 12, 2016]

## § 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

- (a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.
- (b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.
- (c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.
- (d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.
- (e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.
- (f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.
- (g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.
- (h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.
- (i) A financial certification or disclosure statement or both, as required by part 54 of this chapter.
- (j) For a submission supported by clinical data:
  - (1) If the data are from clinical investigations conducted in the United States, a statement that each investigation was conducted in compliance with applicable requirements in the protection of human subjects regulations in part 50 of this chapter, the institutional review boards regulations in part 56 of this chapter, or was not subject to the regulations under § 56.104 or § 56.105, and the investigational device exemptions regulations in part 812 of this chapter, or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.
  - (2) If the data are from clinical investigations conducted outside the United States, the requirements under § 812.28 of this chapter apply. If any such investigation was not conducted in accordance with good clinical practice (GCP) as described in § 812.28(a) of this chapter, include either a waiver request in accordance with § 812.28(c) of the chapter or a brief statement of the reason for not

conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected.

- (k) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:
- (1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and
  - (2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.
- (l) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.
- (m) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

[42 FR 42526, Aug. 23, 1977, as amended at 57 FR 18066, Apr. 28, 1992; 59 FR 64295, Dec. 14, 1994; 63 FR 5253, Feb. 2, 1998; 83 FR 7385, Feb. 21, 2018; 89 FR 18793, Mar. 15, 2024]

## § 807.90 Format of a premarket notification submission.

Each premarket notification submission pursuant to this part shall be submitted in accordance with this section. Each submission shall:

- (a)
  - (1) For devices regulated by the Center for Devices and Radiological Health, be addressed to the current address displayed on the website <https://www.fda.gov/cdrhsubmissionaddress>.
  - (2) For devices regulated by the Center for Biologics Evaluation and Research, be addressed to the current address displayed on the website <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm>; or for devices regulated by the Center

for Drug Evaluation and Research, be addressed to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266. Information about devices regulated by the Center for Biologics Evaluation and Research is available at <https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/default.htm>.

- (3) All inquiries regarding a premarket notification submission should be sent to the address in this section or one of the current addresses displayed on the Food and Drug Administration's website.
- (b) [Reserved]
- (c) Be submitted as a single version in electronic format.
- (d) Be submitted separately for each product the manufacturer intends to market.
- (e) Designated "510(k) Notification" in the cover letter.

[42 FR 42526, Aug. 23, 1977, as amended at 53 FR 11252, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990; 65 FR 17137, Mar. 31, 2000; 70 FR 14986, Mar. 24, 2005; 75 FR 20915, Apr. 22, 2010; 80 FR 18094, Apr. 3, 2015; 84 FR 68339, Dec. 16, 2019]

## § 807.92 Content and format of a 510(k) summary.

- (a) A 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. FDA will accept summaries as well as amendments thereto until such time as FDA issues a determination of substantial equivalence. All 510(k) summaries shall contain the following information:
- (1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;
- (2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;
- (3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process;
- (4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;
- (5) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled; and

- (6) If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.
- (b) 510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information:
  - (1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence;
  - (2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence; and
  - (3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.
- (c) The summary should be in a separate section of the submission, beginning on a new page and ending on a page not shared with any other section of the premarket notification submission, and should be clearly identified as a "510(k) summary."
- (d) Any other information reasonably deemed necessary by the agency.

[57 FR 18066, Apr. 28, 1992, as amended at 59 FR 64295, Dec. 14, 1994]

## § 807.93 Content and format of a 510(k) statement.

(a)

- (1) A 510(k) statement submitted as part of a premarket notification shall state as follows:

I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

- (2) The statement in paragraph (a)(1) of this section should be signed by the certifier, made on a separate page of the premarket notification submission, and clearly identified as "510(k) statement."
- (b) All requests for information included in paragraph (a) of this section shall be made in writing to the certifier, whose name will be published by FDA on the list of premarket notification submissions for which substantial equivalence determinations have been made.

- (c) The information provided to requestors will be a duplicate of the premarket notification submission, including any adverse information, but excluding all patient identifiers, and trade secret and confidential commercial information as defined in § 20.61 of this chapter.

[59 FR 64295, Dec. 14, 1994]

## § 807.94 Format of a class III certification.

- (a) A class III certification submitted as part of a premarket notification shall state as follows:

I certify, in my capacity as (position held in company), of (company name), that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for the (type of device). I further certify that I am aware of the types of problems to which the (type of device) is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about the (type of device) is complete and accurate.

- (b) The statement in paragraph (a) of this section should be signed by the certifier, clearly identified as "class III certification," and included at the beginning of the section of the premarket notification submission that sets forth the class III summary.

[59 FR 64296, Dec. 14, 1994]

## § 807.95 Confidentiality of information.

- (a) The Food and Drug Administration will disclose publicly whether there exists a premarket notification submission under this part:
- (1) Where the device is on the market, i.e., introduced or delivered for introduction into interstate commerce for commercial distribution;
  - (2) Where the person submitting the premarket notification submission has disclosed, through advertising or any other manner, his intent to market the device to scientists, market analysts, exporters, or other individuals who are not employees of, or paid consultants to, the establishment and who are not in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy; or
  - (3) Where the device is not on the market and the intent to market the device has not been so disclosed, except where the submission is subject to an exception under paragraph (b) or (c) of this section.
- (b) The Food and Drug Administration will not disclose publicly the existence of a premarket notification submission for a device that is not on the market and where the intent to market the device has not been disclosed for 90 days from the date of receipt of the submission, if:
- (1) The person submitting the premarket notification submission requests in the submission that the Food and Drug Administration hold as confidential commercial information the intent to market the device and submits a certification to the Commissioner:
    - (i) That the person considers his intent to market the device to be confidential commercial information;

- (ii) That neither the person nor, to the best of his knowledge, anyone else, has disclosed through advertising or any other manner, his intent to market the device to scientists, market analysts, exporters, or other individuals, except employees of, or paid consultants to, the establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy;
  - (iii) That the person will immediately notify the Food and Drug Administration if he discloses the intent to market the device to anyone, except employees of, or paid consultants to, the establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy;
  - (iv) That the person has taken precautions to protect the confidentiality of the intent to market the device; and
  - (v) That the person understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q); and
- (2) The Commissioner agrees that the intent to market the device is confidential commercial information.
- (c) Where the Commissioner determines that the person has complied with the procedures described in paragraph (b) of this section with respect to a device that is not on the market and where the intent to market the device has not been disclosed, and the Commissioner agrees that the intent to market the device is confidential commercial information, the Commissioner will not disclose the existence of the submission for 90 days from the date of its receipt by the agency. In addition, the Commissioner will continue not to disclose the existence of such a submission for the device for an additional time when any of the following occurs:
- (1) The Commissioner requests in writing additional information regarding the device pursuant to § 807.87(h), in which case the Commissioner will not disclose the existence of the submission until 90 days after the Food and Drug Administration's receipt of a complete premarket notification submission;
  - (2) The Commissioner determines that the device intended to be introduced is a class III device and cannot be marketed without premarket approval or reclassification, in which case the Commissioner will not disclose the existence of the submission unless a petition for reclassification is submitted under section 513(f)(2) of the act and its existence can be disclosed under § 860.5(d) of this chapter; or
- (d) FDA will make a 510(k) summary of the safety and effectiveness data available to the public within 30 days of the issuance of a determination that the device is substantially equivalent to another device. Accordingly, even when a 510(k) submitter has complied with the conditions set forth in paragraphs (b) and (c) of this section, confidentiality for a premarket notification submission cannot be granted beyond 30 days after FDA issues a determination of equivalency.
- (e) Data or information submitted with, or incorporated by reference in, a premarket notification submission (other than safety and effectiveness data that have not been disclosed to the public) shall be available for disclosure by the Food and Drug Administration when the intent to market the device is no longer confidential in accordance with this section, unless exempt from public disclosure in accordance with part 20 of this chapter. Upon final classification, data and information relating to safety and effectiveness of a device classified in class I (general controls) or class II (performance standards) shall be available for public disclosure. Data and information relating to safety and effectiveness of a device classified in class

III (premarket approval) that have not been released to the public shall be retained as confidential unless such data and information become available for release to the public under § 860.5(d) or other provisions of this chapter.

[42 FR 42526, Aug. 23, 1977, as amended at 53 FR 11252, Apr. 6, 1988; 57 FR 18067, Apr. 28, 1992; 59 FR 64296, Dec. 14, 1994; 84 FR 68339, Dec. 16, 2019]

## § 807.97 Misbranding by reference to premarket notification.

Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

## § 807.100 FDA action on a premarket notification.

- (a) After review of a premarket notification, FDA will:
  - (1) Issue an order declaring the device to be substantially equivalent to a legally marketed predicate device;
  - (2) Issue an order declaring the device to be not substantially equivalent to any legally marketed predicate device;
  - (3) Request additional information; or
  - (4) Withhold the decision until a certification or disclosure statement is submitted to FDA under part 54 of this chapter.
  - (5) Advise the applicant that the premarket notification is not required. Until the applicant receives an order declaring a device substantially equivalent, the applicant may not proceed to market the device.
- (b) FDA will determine that a device is substantially equivalent to a predicate device using the following criteria:
  - (1) The device has the same intended use as the predicate device; and
  - (2) The device:
    - (i) Has the same technological characteristics as the predicate device; or
    - (ii)
      - (A) Has different technological characteristics, such as a significant change in the materials, design, energy source, or other features of the device from those of the predicate device;
      - (B) The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the Commissioner, that demonstrates that the device is as safe and as effective as a legally marketed device; and
      - (C) Does not raise different questions of safety and effectiveness than the predicate device.

- (3) The predicate device has not been removed from the market at the initiative of the Commissioner of Food and Drugs or has not been determined to be misbranded or adulterated by a judicial order.

*[57 FR 58403, Dec. 10, 1992, as amended at 63 FR 5253, Feb. 2, 1998]*

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This content is from the eCFR and is authoritative but unofficial.

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**Title 21 –Food and Drugs**

**Chapter I –Food and Drug Administration, Department of Health and Human Services**

**Subchapter H –Medical Devices**

## Part 820 Quality System Regulation

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## PART 820—QUALITY SYSTEM REGULATION

Link to an amendment published at 89 FR 7523, Feb. 2, 2024.

**Authority:** 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

**Source:** 61 FR 52654, Oct. 7, 1996, unless otherwise noted.

### Subpart A—General Provisions

#### § 820.1 Scope.

- (a) **Applicability.**
  - (1) Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged. With respect to class I devices, design controls apply only to those devices listed in § 820.30(a)(2). This regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance. Manufacturers of blood and blood components used for transfusion or for further manufacturing are not subject to this part, but are subject to subchapter F of this chapter. Manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in § 1271.3(d) of this chapter, that are medical devices (subject to premarket review or notification, or exempt from notification, under an application submitted under the device provisions of the act or under a biological product license application under section 351 of the Public Health Service Act) are subject to this part and are also subject to the donor-eligibility procedures set forth in part 1271 subpart C of this chapter and applicable

current good tissue practice procedures in part 1271 subpart D of this chapter. In the event of a conflict between applicable regulations in part 1271 and in other parts of this chapter, the regulation specifically applicable to the device in question shall supersede the more general.

- (2) The provisions of this part shall be applicable to any finished device as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.
  - (3) In this regulation the term "where appropriate" is used several times. When a requirement is qualified by "where appropriate," it is deemed to be "appropriate" unless the manufacturer can document justification otherwise. A requirement is "appropriate" if nonimplementation could reasonably be expected to result in the product not meeting its specified requirements or the manufacturer not being able to carry out any necessary corrective action.
- (b) The quality system regulation in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event of a conflict between applicable regulations in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other generally applicable requirements.
- (c) **Authority.** Part 820 is established and issued under authority of sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383). The failure to comply with any applicable provision in this part renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.
- (d) **Foreign manufacturers.** If a manufacturer who offers devices for import into the United States refuses to permit or allow the completion of a Food and Drug Administration (FDA) inspection of the foreign facility for the purpose of determining compliance with this part, it shall appear for purposes of section 801(a) of the act, that the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, or servicing of any devices produced at such facility that are offered for import into the United States do not conform to the requirements of section 520(f) of the act and this part and that the devices manufactured at that facility are adulterated under section 501(h) of the act.

(e) **Exemptions or variances.**

- (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the Federal Food, Drug, and Cosmetic Act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the FDA's administrative procedures. For guidance on how to proceed for a request for a variance, contact Division of Regulatory Programs 2, Office of Regulatory Programs, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1438, Silver Spring, MD 20993-0002.
- (2) FDA may initiate and grant a variance from any device quality system requirement when the agency determines that such variance is in the best interest of the public health. Such variance will remain in effect only so long as there remains a public health need for the device and the device would not likely be made sufficiently available without the variance.

[61 FR 52654, Oct. 7, 1996, as amended at 65 FR 17136, Mar. 31, 2000; 65 FR 66636, Nov. 7, 2000; 69 FR 29829, May 25, 2005; 72 FR 17399, Apr. 9, 2007; 75 FR 20915, Apr. 22, 2010; 80 FR 29906, May 22, 2015; 85 FR 18442, Apr. 2, 2020]

## § 820.3 Definitions.

Link to an amendment published at 89 FR 82945, Oct. 15, 2024.

- (a) **Act** means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-903, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-394)). All definitions in section 201 of the act shall apply to the regulations in this part.
- (b) **Complaint** means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.
- (c) **Component** means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.
- (d) **Control number** means any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished devices can be determined.
- (e) **Design history file (DHF)** means a compilation of records which describes the design history of a finished device.
- (f) **Design input** means the physical and performance requirements of a device that are used as a basis for device design.
- (g) **Design output** means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.
- (h) **Design review** means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.
- (i) **Device history record (DHR)** means a compilation of records containing the production history of a finished device.
- (j) **Device master record (DMR)** means a compilation of records containing the procedures and specifications for a finished device.
- (k) **Establish** means define, document (in writing or electronically), and implement.
- (l) **Finished device** means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.
- (m) **Lot or batch** means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.
- (n) **Management with executive responsibility** means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.

- (o) **Manufacturer** means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.
- (p) **Manufacturing material** means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.
- (q) **Nonconformity** means the nonfulfillment of a specified requirement.
- (r) **Product** means components, manufacturing materials, in-process devices, finished devices, and returned devices.
- (s) **Quality** means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.
- (t) **Quality audit** means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.
- (u) **Quality policy** means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.
- (v) **Quality system** means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.
- (w) **Remanufacturer** means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.
- (x) **Rework** means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.
- (y) **Specification** means any requirement with which a product, process, service, or other activity must conform.
- (z) **Validation** means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.
  - (1) **Process validation** means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.
  - (2) **Design validation** means establishing by objective evidence that device specifications conform with user needs and intended use(s).
- (aa) **Verification** means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
- (bb) **Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device** means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

- (cc) **Unique device identifier (UDI)** means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is composed of:
- (1) A **device identifier**—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and
  - (2) A **production identifier**—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
    - (i) The lot or batch within which a device was manufactured;
    - (ii) The serial number of a specific device;
    - (iii) The expiration date of a specific device;
    - (iv) The date a specific device was manufactured.
    - (v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.
- (dd) **Universal product code (UPC)** means the product identifier used to identify an item sold at retail in the United States.

[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 58822, Sept. 24, 2013]

## § 820.5 Quality system.

Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.

## Subpart B—Quality System Requirements

### § 820.20 Management responsibility.

- (a) **Quality policy.** Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.
- (b) **Organization.** Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part.
  - (1) **Responsibility and authority.** Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.
  - (2) **Resources.** Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.
  - (3) **Management representative.** Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:

- (i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and
  - (ii) Reporting on the performance of the quality system to management with executive responsibility for review.
- (c) **Management review.** Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented.
- (d) **Quality planning.** Each manufacturer shall establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured. The manufacturer shall establish how the requirements for quality will be met.
- (e) **Quality system procedures.** Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.

## § 820.22 Quality audit.

Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented.

## § 820.25 Personnel.

- (a) **General.** Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.
- (b) **Training.** Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.
  - (1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.
  - (2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

## Subpart C—Design Controls

### § 820.30 Design controls.

- (a) **General.**
  - (1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

- (2) The following class I devices are subject to design controls:
- (i) Devices automated with computer software; and
  - (ii) The devices listed in the following chart.

Section	Device
868.6810	Catheter, Tracheobronchial Suction.
878.4460	Glove, Surgeon's.
880.6760	Restraint, Protective.
892.5650	System, Applicator, Radionuclide, Manual.
892.5740	Source, Radionuclide Teletherapy.

- (b) **Design and development planning.** Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.
- (c) **Design input.** Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.
- (d) **Design output.** Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.
- (e) **Design review.** Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF).
- (f) **Design verification.** Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

- (g) ***Design validation.*** Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.
- (h) ***Design transfer.*** Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.
- (i) ***Design changes.*** Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.
- (j) ***Design history file.*** Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

## Subpart D—Document Controls

### § 820.40 Document controls.

Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:

- (a) ***Document approval and distribution.*** Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part. The approval, including the date and signature of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.
- (b) ***Document changes.*** Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be communicated to the appropriate personnel in a timely manner. Each manufacturer shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.

## Subpart E—Purchasing Controls

### § 820.50 Purchasing controls.

Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

- (a) ***Evaluation of suppliers, contractors, and consultants.*** Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall:

- (1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.
  - (2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
  - (3) Establish and maintain records of acceptable suppliers, contractors, and consultants.
- (b) **Purchasing data.** Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with § 820.40.

## Subpart F—Identification and Traceability

### § 820.60 Identification.

Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mixups.

### § 820.65 Traceability.

Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

## Subpart G—Production and Process Controls

### § 820.70 Production and process controls.

- (a) **General.** Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:
- (1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;
  - (2) Monitoring and control of process parameters and component and device characteristics during production;
  - (3) Compliance with specified reference standards or codes;
  - (4) The approval of processes and process equipment; and
  - (5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

- (b) **Production and process changes.** Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to § 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with § 820.40.
- (c) **Environmental control.** Where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. Environmental control system(s) shall be periodically inspected to verify that the system, including necessary equipment, is adequate and functioning properly. These activities shall be documented and reviewed.
- (d) **Personnel.** Each manufacturer shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on product quality. The manufacturer shall ensure that maintenance and other personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained individual.
- (e) **Contamination control.** Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.
- (f) **Buildings.** Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mixups, and assure orderly handling.
- (g) **Equipment.** Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.
  - (1) **Maintenance schedule.** Each manufacturer shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented.
  - (2) **Inspection.** Each manufacturer shall conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules. The inspections, including the date and individual(s) conducting the inspections, shall be documented.
  - (3) **Adjustment.** Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.
- (h) **Manufacturing material.** Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.
- (i) **Automated processes.** When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

## § 820.72 Inspection, measuring, and test equipment.

- (a) ***Control of inspection, measuring, and test equipment.*** Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.
- (b) ***Calibration.*** Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented.
  - (1) ***Calibration standards.*** Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.
  - (2) ***Calibration records.*** The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.

## § 820.75 Process validation.

- (a) Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.
- (b) Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.
  - (1) Each manufacturer shall ensure that validated processes are performed by qualified individual(s).
  - (2) For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented.
- (c) When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.

## Subpart H—Acceptance Activities

### § 820.80 Receiving, in-process, and finished device acceptance.

- (a) ***General.*** Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.

- (b) **Receiving acceptance activities.** Each manufacturer shall establish and maintain procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.
- (c) **In-process acceptance activities.** Each manufacturer shall establish and maintain acceptance procedures, where appropriate, to ensure that specified requirements for in-process product are met. Such procedures shall ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented.
- (d) **Final acceptance activities.** Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until:
  - (1) The activities required in the DMR are completed;
  - (2) the associated data and documentation is reviewed;
  - (3) the release is authorized by the signature of a designated individual(s); and
  - (4) the authorization is dated.
- (e) **Acceptance records.** Each manufacturer shall document acceptance activities required by this part. These records shall include:
  - (1) The acceptance activities performed;
  - (2) the dates acceptance activities are performed;
  - (3) the results;
  - (4) the signature of the individual(s) conducting the acceptance activities; and
  - (5) where appropriate the equipment used. These records shall be part of the DHR.

## § 820.86 Acceptance status.

Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

## Subpart I—Nonconforming Product

### § 820.90 Nonconforming product.

- (a) **Control of nonconforming product.** Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.
- (b) **Nonconformity review and disposition.**

- (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.
- (2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

## Subpart J—Corrective and Preventive Action

### § 820.100 Corrective and preventive action.

- (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:
  - (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;
  - (2) Investigating the cause of nonconformities relating to product, processes, and the quality system;
  - (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
  - (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;
  - (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
  - (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
  - (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.
- (b) All activities required under this section, and their results, shall be documented.

## Subpart K—Labeling and Packaging Control

### § 820.120 Device labeling.

Each manufacturer shall establish and maintain procedures to control labeling activities.

- (a) **Label integrity.** Labels shall be printed and applied so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and where appropriate use.

- (b) **Labeling inspection.** Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct unique device identifier (UDI) or universal product code (UPC), expiration date, control number, storage instructions, handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination, shall be documented in the DHR.
- (c) **Labeling storage.** Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mixups.
- (d) **Labeling operations.** Each manufacturer shall control labeling and packaging operations to prevent labeling mixups. The label and labeling used for each production unit, lot, or batch shall be documented in the DHR.
- (e) **Control number.** Where a control number is required by § 820.65, that control number shall be on or shall accompany the device through distribution.

[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 58822, Sept. 24, 2013]

## § 820.130 Device packaging.

Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

## Subpart L—Handling, Storage, Distribution, and Installation

### § 820.140 Handling.

Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.

### § 820.150 Storage.

- (a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.
- (b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

### § 820.160 Distribution.

- (a) Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. Where a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed.
- (b) Each manufacturer shall maintain distribution records which include or refer to the location of:
  - (1) The name and address of the initial consignee;

- (2) The identification and quantity of devices shipped;
- (3) The date shipped; and
- (4) Any control number(s) used.

## § 820.170 Installation.

- (a) Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.
- (b) The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the manufacturer's instructions and procedures and shall document the inspection and any test results to demonstrate proper installation.

## Subpart M—Records

### § 820.180 General requirements.

All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

- (a) **Confidentiality.** Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.
- (b) **Record retention period.** All records required by this part shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer.
- (c) **Exceptions.** This section does not apply to the reports required by § 820.20(c) Management review, § 820.22 Quality audits, and supplier audit reports used to meet the requirements of § 820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.

### § 820.181 Device master record.

Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with § 820.40. The DMR for each type of device shall include, or refer to the location of, the following information:

- (a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;

- (b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;
- (c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;
- (d) Packaging and labeling specifications, including methods and processes used; and
- (e) Installation, maintenance, and servicing procedures and methods.

#### **§ 820.184 Device history record.**

Each manufacturer shall maintain device history records (DHR's). Each manufacturer shall establish and maintain procedures to ensure that DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this part. The DHR shall include, or refer to the location of, the following information:

- (a) The dates of manufacture;
- (b) The quantity manufactured;
- (c) The quantity released for distribution;
- (d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR;
- (e) The primary identification label and labeling used for each production unit; and
- (f) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.

[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 58822, Sept. 24, 2013]

#### **§ 820.186 Quality system record.**

Each manufacturer shall maintain a quality system record (QSR). The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this part that are not specific to a particular type of device(s), including, but not limited to, the records required by § 820.20. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with § 820.40.

#### **§ 820.198 Complaint files.**

- (a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:
  - (1) All complaints are processed in a uniform and timely manner;
  - (2) Oral complaints are documented upon receipt; and
  - (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting.

- (b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.
- (c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.
- (d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by § 820.198(e), records of investigation under this paragraph shall include a determination of:
  - (1) Whether the device failed to meet specifications;
  - (2) Whether the device was being used for treatment or diagnosis; and
  - (3) The relationship, if any, of the device to the reported incident or adverse event.
- (e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:
  - (1) The name of the device;
  - (2) The date the complaint was received;
  - (3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;
  - (4) The name, address, and phone number of the complainant;
  - (5) The nature and details of the complaint;
  - (6) The dates and results of the investigation;
  - (7) Any corrective action taken; and
  - (8) Any reply to the complainant.
- (f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.
- (g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:
  - (1) A location in the United States where the manufacturer's records are regularly kept; or
  - (2) The location of the initial distributor.

[61 FR 52654, Oct. 7, 1996, as amended at 69 FR 11313, Mar. 10, 2004; 71 FR 16228, Mar. 31, 2006; 78 FR 58822, Sept. 24, 2013]

## Subpart N—Servicing

## § 820.200 Servicing.

- (a) Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.
- (b) Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with § 820.100.
- (c) Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of § 820.198.
- (d) Service reports shall be documented and shall include:
  - (1) The name of the device serviced;
  - (2) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;
  - (3) The date of service;
  - (4) The individual(s) servicing the device;
  - (5) The service performed; and
  - (6) The test and inspection data.

[61 FR 52654, Oct. 7, 1996, as amended at 69 FR 11313, Mar. 10, 2004; 78 FR 58822, Sept. 24, 2013]

## Subpart O—Statistical Techniques

### § 820.250 Statistical techniques.

- (a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.
- (b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.

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This content is from the eCFR and is authoritative but unofficial.

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## Title 21 –Food and Drugs

### Chapter I –Food and Drug Administration, Department of Health and Human Services

#### Subchapter H –Medical Devices

## Part 821 Medical Device Tracking Requirements

### Subpart A General Provisions

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### Subpart D Records and Inspections

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**§ 821.55** Confidentiality.

**§ 821.60** Retention of records.

## PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

**Authority:** 21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, 374.

**Source:** 58 FR 43447, Aug. 16, 1993, unless otherwise noted.

### Subpart A—General Provisions

#### § 821.1 Scope.

- (a) The regulations in this part implement section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act), which provides that the Food and Drug Administration may require a manufacturer to adopt a method of tracking a class II or class III device, if the device meets one of the following three criteria and FDA issues an order to the manufacturer: the failure of the device would be reasonably likely to have serious adverse health consequences; or the device is intended to be implanted in the human body for more than 1 year; or the device is a life-sustaining or life-supporting device used outside a device user facility. A device that meets one of these criteria and is the subject of an FDA order must comply with this part and is referred to, in this part, as a “tracked device.”

- (b) These regulations are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. Effective tracking of devices from the manufacturing facility, through the distributor network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities, and licensed practitioners) and, ultimately, to the patient is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device recall (section 518(e) of the act). Although these regulations do not preclude a manufacturer from involving outside organizations in that manufacturer's device tracking effort, the legal responsibility for complying with this part rests with manufacturers who are subject to tracking orders, and that responsibility cannot be altered, modified, or in any way abrogated by contracts or other agreements.
- (c) The primary burden for ensuring that the tracking system works rests upon the manufacturer. A manufacturer or any other person, including a distributor, final distributor, or multiple distributor, who distributes a device subject to tracking, who fails to comply with any applicable requirement of section 519(e) of the act or of this part, or any person who causes such failure, misbrands the device within the meaning of section 502(t)(2) of the act and commits a prohibited act within the meaning of sections 301(e) and 301(q)(1)(B) of the act.
- (d) Any person subject to this part who permanently discontinues doing business is required to notify FDA at the time the person notifies any government agency, court, or supplier, and provide FDA with a complete set of its tracking records and information. However, if a person ceases distribution of a tracked device but continues to do other business, that person continues to be responsible for compliance with this part unless another person, affirmatively and in writing, assumes responsibility for continuing the tracking of devices previously distributed under this part. Further, if a person subject to this part goes out of business completely, but other persons acquire the right to manufacture or distribute tracked devices, those other persons are deemed to be responsible for continuing the tracking responsibility of the previous person under this part.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002; 73 FR 34860, June 19, 2008]

## § 821.2 Exemptions and variances.

- (a) A manufacturer, importer, or distributor may seek an exemption or variance from one or more requirements of this part.
- (b) A request for an exemption or variance shall be submitted in the form of a petition under § 10.30 of this chapter and shall comply with the requirements set out therein, except that a response shall be issued in 90 days. The Director or Deputy Directors, CDRH, or the Director or Principal Deputy Director of the Office of Product Evaluation and Quality, CDRH, shall issue responses to requests under this section. The petition shall also contain the following:
  - (1) The name of the device and device class and representative labeling showing the intended use(s) of the device;
  - (2) The reasons that compliance with the tracking requirements of this part is unnecessary;
  - (3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that an effective tracking system is in place; and
  - (4) Other information justifying the exemption or variance.

- (c) An exemption or variance is not effective until the Director or Deputy Directors, CDRH, or the Director or Principal Deputy Director of the Office of Product Evaluation and Quality, CDRH, approves the request under § 10.30(e)(2)(i) of this chapter.

[58 FR 43447, Aug. 16, 1993, as amended at 59 FR 31138, June 17, 1994; 67 FR 5951, Feb. 8, 2002; 72 FR 17399, Apr. 9, 2007; 85 FR 18443, Apr. 2, 2020; 86 FR 17065, Apr. 1, 2021]

## § 821.3 Definitions.

The following definitions and terms apply to this part:

- (a) **Act** means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., as amended.
- (b) **Importer** means the initial distributor of an imported device who is subject to a tracking order. "Importer" does not include anyone who only furthers the marketing, e.g., brokers, jobbers, or warehousers.
- (c) **Manufacturer** means any person, including any importer, repacker and/or relabeler, who manufactures, prepares, propagates, compounds, assembles, or processes a device or engages in any of the activities described in § 807.3(d) of this chapter.
- (d) **Device failure** means the failure of a device to perform or function as intended, including any deviations from the device's performance specifications or intended use.
- (e) **Serious adverse health consequences** means any significant adverse experience related to a device, including device-related events which are life-threatening or which involve permanent or long-term injuries or illnesses.
- (f) **Device intended to be implanted in the human body for more than 1 year** means a device that is intended to be placed into a surgically or naturally formed cavity of the human body for more than 1 year to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include a device that is intended and used only for temporary purposes or that is intended for explantation in 1 year or less.
- (g) **Life-supporting or life-sustaining device used outside a device user facility** means a device which is essential, or yields information that is essential, to the restoration or continuation of a bodily function important to the continuation of human life that is intended for use outside a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. Physicians' offices are not device user facilities and, therefore, devices used therein are subject to tracking if they otherwise satisfy the statutory and regulatory criteria.
- (h) **Distributor** means any person who furthers the distribution of a device from the original place of manufacture to the person who makes delivery or sale to the ultimate user, i.e., the final or multiple distributor, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.
- (i) **Final distributor** means any person who distributes a tracked device intended for use by a single patient over the useful life of the device to the patient. This term includes, but is not limited to, licensed practitioners, retail pharmacies, hospitals, and other types of device user facilities.

- (j) **Distributes** means any distribution of a tracked device, including the charitable distribution of a tracked device. This term does not include the distribution of a device under an effective investigational device exemption in accordance with section 520(g) of the act and part 812 of this chapter or the distribution of a device for teaching, law enforcement, research, or analysis as specified in § 801.125 of this chapter.
- (k) **Multiple distributor** means any device user facility, rental company, or any other entity that distributes a life-sustaining or life-supporting device intended for use by more than one patient over the useful life of the device.
- (l) **Licensed practitioner** means a physician, dentist, or other health care practitioner licensed by the law of the State in which he or she practices to use or order the use of the tracked device.
- (m) Any term defined in section 201 of the act shall have the same definition in this part.
- (n) **Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device** means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.
- (o) **Unique device identifier (UDI)** means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is composed of:
  - (1) A **device identifier**—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and
  - (2) A **production identifier**—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
    - (i) The lot or batch within which a device was manufactured;
    - (ii) The serial number of a specific device;
    - (iii) The expiration date of a specific device;
    - (iv) The date a specific device was manufactured.
    - (v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002; 78 FR 58822, Sept. 24, 2013]

## § 821.4 Imported devices.

For purposes of this part, the importer of a tracked device shall be considered the manufacturer and shall be required to comply with all requirements of this part applicable to manufacturers. Importers must keep all information required under this part in the United States.

## Subpart B—Tracking Requirements

### § 821.20 Devices subject to tracking.

- (a) A manufacturer of any class II or class III device that fits within one of the three criteria within § 821.1(a) must track that device in accordance with this part, if FDA issues a tracking order to that manufacturer.

- (b) When responding to premarket notification submissions and premarket approval applications, FDA will notify the sponsor by issuing an order that states that FDA believes the device meets the criteria of section 519(e)(1) of the act and, by virtue of the order, the sponsor must track the device.

[67 FR 5951, Feb. 8, 2002]

## § 821.25 Device tracking system and content requirements: manufacturer requirements.

- (a) A manufacturer of a tracked device shall adopt a method of tracking for each such type of device that it distributes that enables a manufacturer to provide FDA with the following information in writing for each tracked device distributed:

(1) Except as required by order under section 518(e) of the act, within 3 working days of a request from FDA, prior to the distribution of a tracked device to a patient, the name, address, and telephone number of the distributor, multiple distributor, or final distributor holding the device for distribution and the location of the device;

(2) Within 10 working days of a request from FDA for tracked devices that are intended for use by a single patient over the life of the device, after distribution to or implantation in a patient:

(i) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, telephone number, and social security number (if available) of the patient receiving the device, unless not released by the patient under § 821.55(a);

(iv) The date the device was provided to the patient;

(v) The name, mailing address, and telephone number of the prescribing physician;

(vi) The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

(vii) If applicable, the date the device was explanted and the name, mailing address, and telephone number of the explanting physician; the date of the patient's death; or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(3) Except as required by order under section 518(e) of the act, within 10 working days of a request from FDA for tracked devices that are intended for use by more than one patient, after the distribution of the device to the multiple distributor:

(i) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, and telephone number of the multiple distributor;

(iv) The name, address, telephone number, and social security number (if available) of the patient using the device, unless not released by the patient under § 821.55(a);

(v) The location of the device;

- (vi) The date the device was provided for use by the patient;
  - (vii) The name, address, and telephone number of the prescribing physician; and
  - (viii) If and when applicable, the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.
- (b) A manufacturer of a tracked device shall keep current records in accordance with its standard operating procedure of the information identified in paragraphs (a)(1), (a)(2) and (a)(3)(i) through (a)(3)(iii) of this section on each tracked device released for distribution for as long as such device is in use or in distribution for use.
- (c) A manufacturer of a tracked device shall establish a written standard operating procedure for the collection, maintenance, and auditing of the data specified in paragraphs (a) and (b) of this section. A manufacturer shall make this standard operating procedure available to FDA upon request. A manufacturer shall incorporate the following into the standard operating procedure:
- (1) Data collection and recording procedures, which shall include a procedure for recording when data which is required under this part is missing and could not be collected and the reason why such required data is missing and could not be collected;
  - (2) A method for recording all modifications or changes to the tracking system or to the data collected and maintained under the tracking system, reasons for any modification or change, and dates of any modification or change. Modification and changes included under this requirement include modifications to the data (including termination of tracking), the data format, the recording system, and the file maintenance procedures system; and
  - (3) A quality assurance program that includes an audit procedure to be run for each device product subject to tracking, at not less than 6-month intervals for the first 3 years of distribution and at least once a year thereafter. This audit procedure shall provide for statistically relevant sampling of the data collected to ensure the accuracy of data and performance testing of the functioning of the tracking system.
- (d) When a manufacturer becomes aware that a distributor, final distributor, or multiple distributor has not collected, maintained, or furnished any record or information required by this part, the manufacturer shall notify the FDA district office responsible for the area in which the distributor, final distributor, or multiple distributor is located of the failure of such persons to comply with the requirements of this part. Manufacturers shall have taken reasonable steps to obtain compliance by the distributor, multiple distributor, or final distributor in question before notifying FDA.
- (e) A manufacturer may petition for an exemption or variance from one or more requirements of this part according to the procedures in § 821.2 of this chapter.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002; 78 FR 58822, Sept. 24, 2013]

## Subpart C—Additional Requirements and Responsibilities

## § 821.30 Tracking obligations of persons other than device manufacturers: distributor requirements.

- (a) A distributor, final distributor, or multiple distributor of any tracked device shall, upon purchasing or otherwise acquiring any interest in such a device, promptly provide the manufacturer tracking the device with the following information:
- (1) The name and address of the distributor, final distributor or multiple distributor;
  - (2) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device;
  - (3) The date the device was received;
  - (4) The person from whom the device was received;
  - (5) If and when applicable, the date the device was explanted, the date of the patient's death, or the date the device was returned to the distributor, permanently retired from use, or otherwise permanently disposed of.
- (b) A final distributor, upon sale or other distribution of a tracked device for use in or by the patient, shall promptly provide the manufacturer tracking the device with the following information:
- (1) The name and address of the final distributor;
  - (2) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device;
  - (3) The name, address, telephone number, and social security number (if available) of the patient receiving the device, unless not released by the patient under § 821.55(a);
  - (4) The date the device was provided to the patient or for use in the patient;
  - (5) The name, mailing address, and telephone number of the prescribing physician;
  - (6) The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and
  - (7) When applicable, the date the device was explanted and the name, mailing address, and telephone number of the explanting physician, the date of the patient's death, or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.
- (c)
- (1) A multiple distributor shall keep written records of the following each time such device is distributed for use by a patient:
    - (i) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device;
    - (ii) The name, address, telephone number, and social security number (if available) of the patient using the device;
    - (iii) The location of the device, unless not released by the patient under § 821.55(a);
    - (iv) The date the device was provided for use by the patient;

- (v) The name, address, and telephone number of the prescribing physician;
  - (vi) The name, address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and
  - (vii) When applicable, the date the device was permanently retired from use or otherwise permanently disposed of.
- (2) Except as required by order under section 518(e) of the act, any person who is a multiple distributor subject to the recordkeeping requirement of paragraph (c)(1) of this section shall, within 5 working days of a request from the manufacturer or within 10 working days of a request from FDA for the information identified in paragraph (c)(1) of this section, provide such information to the manufacturer or FDA.
- (d) A distributor, final distributor, or multiple distributor shall make any records required to be kept under this part available to the manufacturer of the tracked device for audit upon written request by an authorized representative of the manufacturer.
- (e) A distributor, final distributor, or multiple distributor may petition for an exemption or variance from one or more requirements of this part according to the procedures in § 821.2.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002; 78 FR 58822, Sept. 24, 2013]

## Subpart D—Records and Inspections

### § 821.50 Availability.

- (a) Manufacturers, distributors, multiple distributors, and final distributors shall, upon the presentation by an FDA representative of official credentials and the issuance of Form FDA 482 at the initiation of an inspection of an establishment or person under section 704 of the act, make each record and all information required to be collected and maintained under this part and all records and information related to the events and persons identified in such records available to FDA personnel.
- (b) Records and information referenced in paragraph (a) of this section shall be available to FDA personnel for purposes of reviewing, copying, or any other use related to the enforcement of the act and this part. Records required to be kept by this part shall be kept in a centralized point for each manufacturer or distributor within the United States.

[58 FR 43447, Aug. 16, 1993, as amended at 65 FR 43690, July 14, 2000]

### § 821.55 Confidentiality.

- (a) Any patient receiving a device subject to tracking requirements under this part may refuse to release, or refuse permission to release, the patient's name, address, telephone number, and social security number, or other identifying information for the purpose of tracking.
- (b) Records and other information submitted to FDA under this part shall be protected from public disclosure to the extent permitted under part 20 of this chapter, and in accordance with § 20.63 of this chapter, information contained in such records that would identify patient or research subjects shall not be available for public disclosure except as provided in those parts.

- (c) Patient names or other identifiers may be disclosed to a manufacturer or other person subject to this part or to a physician when the health or safety of the patient requires that such persons have access to the information. Such notification will be pursuant to agreement that the record or information will not be further disclosed except as the health aspects of the patient requires. Such notification does not constitute public disclosure and will not trigger the availability of the same information to the public generally.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002]

### § 821.60 Retention of records.

Persons required to maintain records under this part shall maintain such records for the useful life of each tracked device they manufacture or distribute. The useful life of a device is the time a device is in use or in distribution for use. For example, a record may be retired if the person maintaining the record becomes aware of the fact that the device is no longer in use, has been explanted, returned to the manufacturer, or the patient has died.



## **FINAL DOCUMENT**

### **Global Harmonization Task Force**

**Title:** Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange

**Authoring Group:** Study Group 3 of the Global Harmonization Task Force

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This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

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## Preface

This document was produced by the Global Harmonization Task Force (GHTF), a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development. It is expected that the reader is proficient with the requirements of ISO 13485:2003.

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## Introduction

This document is intended for regulatory authorities and auditing organizations. It introduces a standardized nonconformity grading system for regulatory purposes with a Regulatory Audit Information Exchange Form providing consistent audit information in order to enable exchange among regulatory authorities.

Currently, the significance of a nonconformity related to a medical device manufacturer's Quality Management System (QMS) may vary between regulatory authorities and auditing organizations. All parties will benefit from the use of a standardized and transparent grading system of QMS nonconformities. This will build the confidence necessary for the potential mutual acceptance of the results of a regulatory audit.

The major and minor classification of nonconformities commonly used does not provide enough detail for global information exchange. Therefore the terms major and minor nonconformity will not be defined nor utilized in this document. The intent of this new grading system for regulatory purposes is to support the exchange of audit results that go beyond the binary concept of major and minor to a 5 level grading system of nonconformities.

The regulatory authorities can determine how the audit information provided in the Regulatory Audit Information Exchange Form will be utilized within their jurisdiction. Regulatory authorities may also consider other data sources in addition to the outcome of the regulatory audits such as product evaluations, recalls, vigilance reports, etc. for regulatory oversight.

## 1.0 Scope

This document provides a method to present outcomes of regulatory audits that can be used by regulatory authorities for information exchange. It introduces a nonconformity grading system for regulatory purposes with a Regulatory Audit Information Exchange Form providing standardized results.

The following are not included in the scope of this document:

- How to perform audits and prepare associated reports (see GHTF SG4 documents)
- How the Regulatory Audit Information Exchange Form will be utilized by regulatory authorities

## **2.0 Definitions**

### **2.1 Manufacturer**

Any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). (GHTF SG1/N55:2009)

### **2.2 Nonconformity**

Non fulfillment of a requirement. (ISO 9000:2005, 3.6.2)

### **2.3 Quality management system (QMS)**

Management system to direct and control an organization with regard to quality. (ISO 9000:2005, 3.2.3)

## **3.0 References**

GHTF SG4/N28R4:2008 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 1: General Requirements

GHTF SG4/N30:2010 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy

GHTF SG4/N33R16:2007 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports

GHTF SG4/N83:2010 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 4: Multiple Site Auditing

GHTF SG4/N84:2010 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 5: Audits of Manufacturer Control of Suppliers

ISO 13485:2003 – Medical Devices –Quality Management Systems - Requirements for Regulatory Purposes

ISO 9000:2005 - Quality Management Systems – Fundamentals and Vocabulary

ISO 17021:2011 – Conformity Assessment – Requirements for bodies providing audit and certification of management systems

ISO 19011:2011 – Guidelines for Auditing Management Systems

## 4.0 General

The following sections introduce a standardized nonconformity grading system for regulatory purposes. To enable consistent grading, guidance has been provided on how to write a nonconformity. The Regulatory Audit Information Exchange Form at the end of this document is a tool used to capture the grading so that it can be utilized in an exchange of information between interested regulatory bodies.

### 4.1 Writing Nonconformities

Regulatory audits should be performed in accordance with GHTF SG4 documents and other applicable regulatory references. The output of those audits may include nonconformities.

In order for the significance of nonconformities to be characterized utilizing the nonconformity grading system described in this document, it is essential that nonconformities are clearly worded with factual and precise language that enables the reader to comprehend the actual non-fulfillment that was detected during the audit. The information presented should be an accurate representation of the reviewed records, samples and procedures, as well as interviews conducted.

The nonconformity should<sup>1</sup>:

- a) be a statement of nonconformity written in a clear, concise manner:
  - be self-explanatory and related to the issue, not just be a restatement of the audit evidence, or be used in lieu of audit evidence
- b) be supported by objective evidence:
  - justify the extent of evidence (e.g. number of records) - what exactly was found or not found, with an example(s)
  - identify the location or basis (source document) for the evidence (e.g. in a record, procedure, interview, or visual observation)
- c) identify the specific requirements which have not been met:
  - use the words of ISO 13485:2003
  - document the source of the requirement (e.g. medical device regulations, other applicable standards, procedures or requirements established by the organization, etc.)

Multiple instances of non-fulfillment of a requirement should be combined into a single nonconformity unless the instances originate or relate to different aspects of a clause (see Appendix A – “NC #2”). Examples of poorly and better worded nonconformities are provided in Appendix A.

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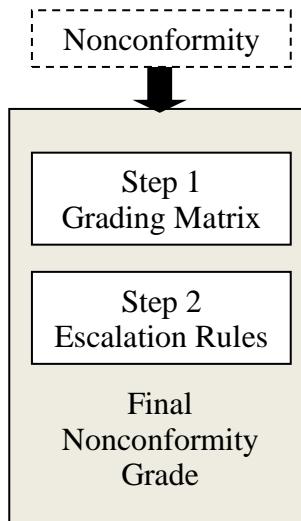
<sup>1</sup> ISO & IAF 9001 Auditing Practices Group Guidance on: Documenting a Nonconformity (5 June 2009)  
[www.iso.org/tc176/ISO9001AuditingPracticesGroup](http://www.iso.org/tc176/ISO9001AuditingPracticesGroup)

## 4.2 Grading of Nonconformities

The nonconformity grading for regulatory purposes consists of a two-step approach that leads to calculation of a final grade for each nonconformity (Figure 1 – shaded area):

**Step 1** - A Nonconformity Grading Matrix, which provides an initial grade

**Step 2** - Additional escalation rules are applied, to determine a final grade



**Figure 1: Grading Overview**

#### 4.2.1 Step 1 Grading Matrix

As illustrated in Figure 1 above, the Grading Matrix is the first step in grading a nonconformity.

Direct	3	4
QMS Impact		
Indirect	1	2
	First	Repeat
	Occurrence	

**Figure 2: Grading Matrix**

The Y-axis of the Grading Matrix (Figure 2) is **QMS Impact**. It is related to the influence of the QMS clause on medical device safety and performance. It is vitally important to highlight that all the clauses of the standard are equally required if applicable,<sup>2</sup> to effectively establish and maintain a quality management system that will meet regulatory purposes.

For the purpose of improved stratification in the grading system<sup>3</sup>, the clauses of the standard are divided into two categories:

- **Indirect QMS Impact:** ISO 13485:2003 clauses 4.1 through 6.3, are seen as “enablers” (making it possible or feasible) for the QMS processes to operate. These clauses are therefore considered to have indirect influence on medical device safety and performance.
- **Direct QMS impact:** ISO 13485:2003 clauses 6.4 through 8.5, are seen as having direct influence on design, and manufacturing controls. These clauses are therefore considered to have direct influence on medical device safety and performance.

There are two basic principles that the auditors should follow when writing the nonconformity and assigning a clause number for purposes of utilizing this grading system.

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<sup>2</sup> See ISO 13485:2003 clause 1.2

<sup>3</sup> Justification for approach: In order to assist the evaluation of QMS impact for this grading system, it was designed to categorize the QMS requirements contained within ISO 13485:2003 standard at a specific sub-clause level (e.g., 6 vs. 6.2 vs. 6.2.2).

- When the nonconformity has the potential to affect safety or performance, it should be written against the specific requirement in ISO 13485:2003 found in clauses 6.4 through 8.5, because it has direct QMS impact.
- When the nonconformity is against the manufacturer's quality manual, procedures or requirements, is not specifically required in ISO 13485:2003 or does not impact safety or performance, then the nonconformity should be assigned to clauses 4.1 through 6.3, because it has indirect QMS impact.

The X-axis of the Grading Matrix in Figure 2 is **Occurrence** and is divided into two categories:

- **First:** The first category addresses a nonconformity in a particular sub-clause (X.X.X)<sup>4</sup> of ISO 13485:2003 identified for the first time. The first time is defined as not observed in the two previous QMS audits which evaluated the same sub-clause.
- **Repeat:** The second category is a nonconformity that has been identified within either of two previous QMS audits which evaluated the same sub-clause (X.X.X). Such a nonconformity poses an increased risk because it is an indicator that a corrective action has not been adequately taken or implemented.

The "two previous QMS audits which evaluated the same sub-clause" was selected because:

- in order to assess the risk of repeat occurrence accurately, it is important to assess comparable nonconformities;
- historical data beyond the two previous QMS audits may not represent the current state; and
- review of more audit reports may be counterproductive for an efficient grading system.

However, it is important to ensure that the audits reviewed for the **Occurrence** assessment, have at a minimum evaluated the same sub-clause.

Occurrence in this document is directed at the frequency of a nonconformity cited from one audit to the next performed by the same auditing organization. It is not the occurrences of examples within a given sample size that the auditor may take to determine if a nonconformity exists during an audit.

Nonconformities can often be written up against more than one clause. Therefore, it is the auditor's obligation to determine the impact of the non-conformity on the QMS and assign the appropriate clause. The QMS impact of the nonconformity will determine whether the resulting clause will be **Direct** or **Indirect**. Some examples to help illustrate the grading process in Step 1 are provided below.

- **Nonconformity where safety issues raise the grading to Direct Impact:** A manufacturer distributes a product in the European Union, Canada and the US. The manufacturer has a documented procedure for notification of adverse events that meets the criteria of the European regulations, but has no references or requirements for adverse event reporting in the other jurisdictions. The medical device caused an adverse event and the manufacturer

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<sup>4</sup> The system was assessed at several different tier levels and it was determined that the QMS impact should be started at the second sub-clause (X.X) level of standard, while the Occurrence should be started at the third sub-clause (X.X.X) level and to allow the subsequent rules to be added for further refinement of the grading system.

followed their procedures related to adverse event reporting. The manufacturer reported the event to the appropriate European Competent Authority and did not consider reporting it to the other jurisdictions. This nonconformity should therefore be assigned to clause 8.5 – Improvement and not to 4.2 Documentation Requirements.

- ***Nonconformity where safety is not an issue that is against a self imposed requirement in a procedure leads to a starting grade with an Indirect Impact:*** A manufacturer's procedure for a process revalidation of an injection molding process requires annual revalidation regardless of changes or process deviations. The annual revalidation was not performed, however there were no changes or process deviations noted. In this example, ISO 13485:2003 clause 7.5 does not require annual revalidation. There were no process changes or deviations and there does not appear to be a safety issue. This nonconformity should be assigned to clause 4.2 - Documentation Requirements for the manufacturer not following their own procedure and not against clause 7.5 – Production and Service provision.
- ***Nonconformity where safety is an issue, that is against a self imposed requirement based on a standard leads to a starting grade of a Direct Impact:*** A manufacturer is utilizing standard ISO 11137-1 for validating their radiation sterilization process and the standard requires quarterly dose audits. This was not performed as required by the standard. In this example, there is a safety issue since the standard requires quarterly dose audits to assure product sterility. Therefore this nonconformity should be assigned to clause 7.5 – Production and Service Provision.
- ***Nonconformity to illustrate a Repeat Occurrence:*** An initial nonconformity was found in 7.5.2.2 relating to a nonconformity in a sterilization process validation. A subsequent audit found a nonconformity in 7.5.2.1 in an injection molding process validation. Both nonconformities fall within 7.5.2 - Validation of Processes for Product and Service Provision. Therefore, the subsequent occurrence should be categorized as a Repeat Occurrence to the X.X.X level of the appropriate clause.

NOTE: If the scenarios are altered within the examples it must be recognized that the conclusions may change.

#### **4.2.2 Step 2 Grading – Escalation Rules**

The resultant grading from Step 1 is carried forward to Step 2, which is a rules-based escalation process to address areas of higher risk that have a potential to affect product safety and performance. Under this grading system the Step 1 grade is increased by 1 for each rule:

##### **1. Absence of a documented process or procedure**

The absence of a documented process or procedure will fundamentally affect consistency and effective implementation of any process.

The word “absent” (or “absence”) should be used in the nonconformity statement when there is no documented process or procedure for the requirement. It is critical that this word be obvious within the nonconformity statement in order to consistently grade the nonconformity.

## 2. Release of a Nonconforming Medical Device

A nonconformity which resulted in the release of a nonconforming medical device to the market is direct evidence of a QMS failure. This rule in the grading system is assessing the QMS nonconformity at a higher risk, because nonconforming product is on the market and outside the control of the manufacturer’s QMS. If a nonconforming medical device is released under concession with adequate technical and scientific justification, then the nonconformity has been resolved. It is no longer considered a nonconforming product and the escalation rule will not be applied.

### 4.3 Applying the Nonconformity Grading System

#### *Step 1 – Using the Nonconformity Grading Matrix*

**A. Direct or Indirect Impact:** When a nonconformity is written and the clause assigned, identify whether it is “direct impact” (score of 3) or “indirect impact” (score of 1), as defined above.

**B. Repeat nonconformities against the same QMS sub-clause (X.X.X):** The auditor should check the previous two audit reports which evaluated the same sub-clause to see if a nonconformity that is identified in the current audit was previously raised. The nonconformity does not have to be identical to the nonconformity in the previous audit, just cited to the same QMS sub-clause (X.X.X). If the nonconformity is a repeat, the grade increases by 1.

#### *Step 2 – Application of Escalation Rules*

In this step of grading, the Nonconformity Grading Matrix is no longer used. Each rule below is applied to determine the final grade of the nonconformity.

**Rule 1 - Absence:** Absence of a documented process or procedure of any requirement, the grade increases by 1.

**Rule 2 - Medical Device:** Release of a Nonconforming Medical Device outside of the controls of the manufacturer’s QMS, the grade increases by 1.

The final grade for a nonconformity under this grading scheme will be a number between 1 and 6. However, the grade of “5” was determined to be the maximum, because this represents a significantly high enough risk that some intervention is required. The differentiation between 5 and 6 was not felt to be of benefit in the grading system. Therefore, if a grade of 6 is achieved, the final grade is documented as “5.” Refer to Appendix B, example #8.

### 4.4 Regulatory Audit Information Exchange Form

To enable information exchange between regulators, the following Regulatory Audit Information Exchange Form (Form) is introduced.

List of Nonconformities		Nonconformity Grading				Medical Device Country Specific Regulatory Requirements						
NC#	Nonconformity	ISO 13485:2003 Clause	Step 1 Grade	Absence	Medical Device	Grade	EU	CAN	USA	AUS	JPN	OTHER
1												
2												

**Table 1 - Regulatory Audit Information Exchange Form**

This Form consists of three sections (see Table 1):

- List of Nonconformities** - It is important to provide sufficient insight into the context and relevance of each nonconformity listed on the Form. The list of nonconformities provided in the Form should be identical to that provided in the audit report.
- Nonconformity Grading** - The details of how the final nonconformity grade was obtained for nonconformities specifically against ISO 13485:2003. The use of this section of the Form provides transparency in the calculation process.
- Medical Device Country Specific Regulatory Requirements** - Nonconformities that are within the manufacturer's QMS but are outside the specific requirements within the clauses of ISO 13485:2003 should be identified in the Medical Device Country Specific Regulatory Requirements section of the Form. This area is not graded, but the auditor should reference the specific section of the applicable Regulation or Legislation against which the nonconformity is cited.

#### **4.5 Use of the Regulatory Audit Information Exchange Form**

When the Form is exchanged between regulatory authorities, specific information about the audit should be included with the Form. Examples include: date of the audit, scope of the audit, sites audited, auditors' name(s), etc.

The Nonconformity Grading section of the Form is intended to capture the grade of nonconformities against ISO 13485:2003. If a nonconformity is against a ISO 13485:2003 clause, it should at minimum be captured under the Nonconformity Grading section of the Form and graded.

The intent of the Medical Device Country Specific Regulatory Requirements section is to capture additional issues outside the specific requirements of ISO 13485:2003. This section is not graded but the nonconformities are listed by regulatory jurisdictions (covered by the audit) and general regulatory requirements for that jurisdiction. Certain regulatory jurisdictions (such as Canada) may require that nonconformities against country specific regulatory requirements are written against a specific clause in the standard in the Nonconformity Grading section.

Below is a completed Form with some specific examples:

List of Nonconformities		Nonconformity Grading					Medical Device Country Specific Regulatory Requirements					
NC#	Nonconformity	ISO 13485 :2003 Clause	Step 1 Grade	Absence	Medical Device	Grade	EU	CAN	USA	AUS	JPN	OTHER
1	There is an absence of a Quality Policy in the organization.	5.3	1	+1		2						
2	Documented procedures for identifying training needs are not established.								21 CFR 820.25		Ord 169 (Article 23 subpart 2)	
3	The injection molding process has not been validated, as per procedure DOC12345 but has not resulted in non-conforming product being released to the market.	7.5.2	3			3	MDD (93/42/ EEC) (Annex II)					
4	The WIDGET™ device was sold in Canada without a medical device license. Procedure DOC12345 requires that all medical devices class II, III & IV are licensed prior to sale in Canada, according to section 26 of the CMDR. This type of NC was also cited in last year's audit.	4.1	2			2			CMDR section 26			

- Nonconformity #1 – An example of a nonconformity of the QMS from the requirements of ISO 13485:2003.
- Nonconformity #2 – An example of a country specific regulatory requirement that is a nonconformity within the manufacturer's QMS but more specific than the requirements of the clauses of ISO 13485:2003.
- Nonconformity #3 – An example of a nonconformity within the QMS that is also against a country specific regulatory requirement. In this case, the nonconformity could also be written against the EU Medical Device Directive.
- Nonconformity #4 – An example of a nonconformity to a country specific regulatory requirement that is also cited under section 4.1 of ISO 13485:2003. In this case, Canada requires all nonconformities be written against ISO 13485:2003.

The Form provides a transparent and standardized way of exchanging information between regulatory authorities on the outcome of medical device regulatory audits. The intent is that this Form will be provided to the medical device manufacturer after following standard auditing procedures where potential nonconformities are routinely discussed throughout the audit

and at the closing meeting of the audit (ISO 19011:2011, clause 6.4.9). It is recommended that a draft of the Form be provided at the closing meeting of the audit for sake of transparency.

The grade assigned to each nonconformity should not be changed as a result of any correction(s) or corrective action(s) taken by the manufacturer, but may be amended as a result of the auditing organization's documented appeals process (ISO 17021:2011, clause 9.7). After the auditing organization has completed the audit process, the final Form should be provided to the manufacturer. The intent is also that the grading and the Form be a method to accurately capture the assessment of the audit and to provide uniformity and consistency within the process of grading nonconformities.

The Form purposely does not provide a cumulative grade for the overall audit. How the Form is utilized is the decision of each regulatory authority for their appropriate assessment based on their own needs or requirements.

## 5.0 Appendix A: Examples of statements of nonconformities

NC #	Nonconformity Statements		ISO 13485:2003 Clause
	Poorly worded	Improved wording	
1	There was no evidence of training to the medical devices directive	The manufacturer did not follow their own training procedure (#14) requiring training on the medical devices directive (93/42/EEC) for internal auditors.	4.2.1
2	Document control was inadequate because of multiple occurrences of obsolete documents being utilized	<p>The following obsolete documents were found to be in use:</p> <p>Obsolete version of procedure XYZ found to be in use in the calibration department</p> <p>Obsolete version of ABC in receiving area was found to be in use</p> <p>Obsolete version of design review procedure PQR was found to be in use in design department</p>	4.2.3
3	The scheduled internal audit must be conducted and the report provided for review.	There was an absence of a documented procedure for conducting internal audits	8.2.2

## 6.0 Appendix B: Examples Illustrating Nonconformity Grading

Example of Nonconformity	STEP 1				STEP 2			
	ISO 13485 Clause	Occurrence	STEP 1 Grade	Explanation of STEP 1 Grade	Absence	Medical Device	Final Grade	Explanation of Final Grade
1. There is no objective evidence of the establishment of quality objectives for 2011, as required in the auditee's Quality Manual. The same non conformity was cited during the audit of 2010.	5.4.1 (indirect)	Repeat (2010, 2011)	2	This is a repeat NC. Therefore, it leads to a NC grade of 2.	NO	NO	2	This is not an absence of a QMS requirement. There is a documented procedure however the manufacturer could not provide objective evidence that it was being followed. As a result of this NC it is unlikely that a nonconforming product was placed on the market. Therefore the initial grade does not change.
2. Management reviews are held quarterly per procedure number DOC12345. However, there is no documentation of the third quarter management review meeting for 2010.	5.6.1 (indirect)	First NC	1	This is a first NC, leading to a NC grade of 1.	NO	NO	1	This is not an absence of a QMS requirement. As a result of this NC it is unlikely that a nonconforming product was placed on the market. Therefore the initial grade does not change
3. Competence, Awareness and Training processes are <u>absent</u> from the QMS. Documented evidence for training could not be provided. This NC was also raised in a previous QMS audit (2009, 2011).	6.2.2 (indirect)	Repeat NC	2	This is a repeat NC. Therefore, it leads to a NC grade of 2.	YES	NO	3	The absence of a QMS requirement increases the initial grade by 1, making the final grade as 3.
4. Suppliers are not adequately controlled as per procedure DOC1234. Supplier X of was replaced with Supplier Y on 1 <sup>st</sup> May 2011 without approval. This is the second NC issued against the same sub-clause in a previous QMS audit (2010).	7.4.1 (direct)	Repeat NC	4	This is a repeat NC. Therefore, it leads to a NC grade of 4.	NO	NO	4	This is not an absence of a QMS requirement. There is no evidence of nonconforming product being placed on the market. Therefore the initial grade does not change.
5. Suppliers are not adequately controlled as per procedure DOC1234. Product XX was shipped on 2 <sup>nd</sup> of September 2011 and was nonconforming due to an uncontrolled specification change made by the supplier. This is the second NC issued against the same sub-clause in a previous QMS audit (2010).	7.4.1 (direct)	Repeat NC	4	This is a repeat NC. Therefore, it leads to a NC grade of 4.	NO	YES	5	Non conforming product was placed on the market as a result of this QMS nonconformity. This increases the initial grading by 1, to a final grade of 5.

Example of Nonconformity	STEP 1				STEP 2			
	ISO 13485 Clause	Occurrence	STEP 1 Grade	Explanation of STEP 1 Grade	Absence	Medical Device	Final Grade	Explanation of Final Grade
6. There was no evidence of a record for control of storage conditions for a medical device with a 24 month shelf life that requires storage at 2-8°C per procedure (#12345).	7.5.5 (direct)	First NC	3	This is a first NC, leading to a NC grade of 3.	NO	NO	3	The initial grade does not change.
7. There is an <u>absence</u> of a Quality Policy.	5.3 (indirect)	First NC	1	This is a first NC, leading to a grade of 1.	YES	NO	2	There is an absence of a QMS requirement. Therefore, the initial grade increases by 1 to a final grade of 2.
8. There was an <u>absence</u> of the requirement for Design verification in the manufacturer's QMS. As a result design changes to device model XXX were not verified prior to the product release to the market. This is the second NC issued against the same sub-clause in a previous QMS audit (2010).	7.3.5 (direct)	Repeat NC	4	This is a repeat NC. Therefore, it leads to a NC grade of 4.	YES	YES	5	This is an absence of a requirement and non conforming product was placed on the market. Therefore the grade would be 4+2=6. However, since the maximum grade can only be 5, it will be recorded as 5.
9. There was no evidence of design validation as per procedure DOC12 for device model XXX. The product was shipped to five customers.	7.3.6 (direct)	First NC	3	This is a first NC, leading to a grade of 3.	NO	YES	4	Non conforming product was placed on the market as a result of this QMS nonconformity. This increases the initial grade by 1, to a final grade of 4.

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	<b>Version Date:</b> 2021/09/01	<b>Effective Date:</b> 2021/09/08
<b>Title:</b> Guidelines on the use of Quality management system - Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange (GHTF/SG3/N19:2012) for MDSAP purposes	<b>Project Manager:</b> Kimberly Lewandowski-Walker, US FDA	

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## 1. Purpose

This document is intended for regulatory authorities and auditing organizations participating in or utilizing the results of the Medical Device Single Audit Program (MDSAP). It provides guidelines for the use of the document GHTF/SG3/N19:2012: *Quality management system - Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange* for grading nonconformities resulting from MDSAP audits.

## 2. Scope

The “major” and “minor” classification of nonconformities commonly used in medical device audit and certification schemes does not provide enough detail for global information exchange. However, the terms “major” and “minor” nonconformity are defined in ISO 17021-1:2015 clauses 3.12 and 3.13 and are often utilized in medical device certification programs, including those for regulatory purposes, to assign a priority to the implementation of corrective actions. While the terms “major” and “minor” are not the subject of this document, general correlation between “major” and “minor” nonconformities as defined in ISO 17021-1:2015 and the grading system defined in this document is discussed in section 5.2. The intent of this grading system for regulatory purposes is to support the exchange of information about nonconformities from audit findings that go beyond the binary concept of “major” and “minor” to a 5 level grading system of nonconformities.

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The regulatory authorities can determine how the audit information provided in the Regulatory Audit Information Exchange Form will be utilized within their jurisdiction. Regulatory authorities may also choose to consider other data sources in addition to the outcome of the regulatory audits such as product evaluations, recalls, vigilance reports, etc. for regulatory oversight.

### 3. Definitions/Acronyms

AO: Auditing Organization

RA: Regulatory Authority

### 4. Authorities/Responsibilities

Auditing Organizations: responsible for oversight of audits that are conducted in accordance with MDSAP, including ensuring adherence to this procedure and all other relevant MDSAP policies and procedures.

Regulatory Authorities: responsible for evaluation of the graded nonconformities and MDSAP audit reports per their legislation.

## 5. Policy

### 5.0 General

The following sections introduce a standardized nonconformity grading system for regulatory purposes. To enable consistent grading, guidance has been provided on how to write a nonconformity.

Nonconformities identified during an MDSAP audit must be recorded on the Nonconformity Grading and Exchange (NGE) form (MDSAP AU F0019.2)

### 5.1 Writing Nonconformities

Regulatory audits conducted under the MDSAP should be performed in accordance with MDSAP AU documents and other applicable regulatory references. The output of those audits may include nonconformities.

In order for the significance of nonconformities to be characterized utilizing the nonconformity grading system described in this document, it is essential that the most specific requirement is correctly identified and used. Nonconformities are to be clearly worded with factual and precise language that enables the reader to comprehend the actual nonfulfillment that was detected during the audit. A nonconformity must assist the manufacturer to identify its cause. The

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information presented should be an accurate representation of the reviewed records, samples and procedures, as well as interviews conducted.

The nonconformity should:

- a) identify the specific requirements which have not been met:
  - use the words of ISO 13485:2016 or of the applicable regulatory requirement
  - document the source of the requirement (e.g. medical device regulations, other applicable standards, procedures or requirements established by the organization, etc.)

If several requirements may apply:

- choose the one which will result in the highest grade of nonconformity; and
- give preference to a requirement to implement over a requirement to just document.
- b) be a statement of how a requirement is not being fulfilled and written using complete sentences in a clear, concise manner:
  - be related to a requirement, not just be a restatement of the audit evidence, or be used in lieu of audit evidence
  - be significant and relate to an observed or potential problem with the facility, equipment, processes, controls, products, employee practices, or records. "Potential problems" should have a reasonable likelihood of occurring based upon observed conditions or events.
  - contain a statement regarding the product(s) related to the nonconformity using trade name(s) and generic name(s)
  - be factual and avoid opinionated or subjective terms
- c) be supported by objective evidence:
  - the evidence must be directly related to the requirement
  - be traceable so it should identify what (source procedure, record, interview, or visual observation), who (using job titles), when and where (location).
  - justify the extent of evidence (e.g. number of records) - what exactly was found or not found, with an example(s)

Multiple instances (examples) of non-fulfillment of a requirement should be combined into a single nonconformity unless the instances originate or relate to different aspects of a clause.

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## 5.2 Grading of Nonconformities

### 5.2.1 Step 1 Grading – Indirect or Direct QMS Impact

For the purpose of stratification in the grading system, the clauses of the standard are divided into two categories:

- ***Indirect QMS Impact:*** ISO 13485:2016 clauses 4.1 through 6.3 (with the exception of 4.2.3 – Medical device file, which is considered to have Direct QMS impact) are seen as “enablers” (making it possible or feasible) for the QMS processes to operate. These clauses are therefore considered to have indirect influence on medical device safety and performance and are generally analogous to “minor” nonconformities as defined in ISO 17021-1:2015 clause 3.13.
- ***Direct QMS impact:*** ISO 13485:2016 clauses 6.4 through 8.5 (with the exception of 8.2.4 – Internal audits, which is considered to have indirect QMS impact) are seen as having direct influence on design, and manufacturing controls. These clauses are therefore considered to have direct influence on medical device safety and performance and are more likely to be analogous to “major” nonconformities as defined in ISO 17021-1:2015 clause 3.12 when there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements.

Clauses with Indirect QMS impact are graded at this step with a “1”.

Clauses with Direct QMS impact are graded at this step with a “3”.

There are two basic principles that the auditors should follow when writing the statement of nonconformity and assigning a clause number for purposes of utilizing this grading system.

- When an audit observation or audit evidence indicates that more than one applicable requirement has not been fulfilled, the nonconformity must be written against the specific requirement in ISO 13485:2016 found in clauses 4.2.3, 6.4 through 8.5, (if applicable), when the nonconformity does, or has the potential to, affect safety or performance; because it has direct QMS impact.

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In general, nonconformities that have the potential to affect safety or performance are comparable to a “major” nonconformity per ISO 17021-1:2015 clause 3.12. These types of nonconformities would require the Auditing Organization to review, accept and verify the correction and corrective actions prior to granting a certification decision in accordance with ISO 17021-1:2015 clause 9.5.2(b).

- When an audit observation or audit evidence indicates that a requirement of the manufacturer’s quality manual, procedures or requirements, or is not specifically required in ISO 13485:2016, or does not impact safety or performance, then the nonconformity should be assigned to clauses 4.1 through 6.3 (except 4.2.3, which is considered to have direct QMS impact), and 8.2.4; because it has indirect QMS impact.

Nonconformities can often be written up against more than one clause. Therefore, it is the auditor’s obligation to determine the impact of the nonconformity on the QMS and assign the appropriate clause. The QMS impact of the nonconformity will determine whether the resulting clause will be Direct or Indirect. Some examples to help illustrate the grading process for direct versus indirect impact are provided below.

**Example 1: Nonconformity where safety issues raise the grading to Direct Impact:** A manufacturer distributes a product in Australia, Canada and the US. The manufacturer has a documented procedure for notification of adverse events that meets the criteria of Canada and the US, but has no references or requirements for adverse event reporting in Australia. The medical device caused an adverse event within Canada and the manufacturer followed their procedures related to adverse event reporting. The manufacturer reported the event to Health Canada and the US FDA, but did not consider reporting it to Australia. This nonconformity should therefore be assigned to clause 8.2.3 – Reporting to regulatory authorities and not to 4.2.5 Documentation Requirements.

**Example 2: Nonconformity where safety is not an issue that is against a self-imposed requirement in a procedure leads to a starting grade with an Indirect Impact:** A manufacturer’s procedure for a process revalidation of an injection molding process requires annual revalidation regardless of changes or process deviations. The annual revalidation was not performed; however, there were no changes or process deviations noted. In this example, ISO 13485:2016 clause 7.5.6 does not require annual revalidation. There were no process changes or deviations and there does not appear to be a safety issue. This nonconformity should be assigned to clause 4.2.5 - Documentation

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Requirements for the manufacturer not following their own procedure and not against clause 7.5.6 – Validation of processes for production and service provision.

***Nonconformity where safety is an issue, that is against a self-imposed requirement based on a standard leads to a starting grade of a Direct Impact:***

A manufacturer is utilizing standard ISO 11137-1 for validating their radiation sterilization process and the standard requires quarterly dose audits. This was not performed as required by the standard. In this example, there is a safety issue since the standard requires quarterly dose audits to assure product sterility. Therefore, this nonconformity should be assigned to clause 7.5.7 – Particular requirements for validation of processes for sterilization and sterile barrier systems

***Nonconformity to illustrate a Repeat Occurrence:*** An initial nonconformity was found in 7.5.6 relating to a nonconformity in a coating process validation. A subsequent audit found a nonconformity in 7.5.6 in an injection molding process validation. Both nonconformities fall within 7.5.6 - Validation of Processes for Product and Service Provision. Therefore, the subsequent occurrence should be categorized as a Repeat Occurrence to the X.X.X level of the appropriate clause.

NOTE: If the scenarios are altered within the examples it must be recognized that the conclusions may change.

### 5.2.2 Step 2 Grading – Escalation Rules

The resultant grading from Step 1 is carried forward to Step 2, which is a rules-based escalation process to address areas of higher risk that have a potential to affect product safety and performance. Under this grading system the Step 1 grade is increased by 1 for each rule:

The MDSAP form developed to record nonconformities (MDSAP AU F0019.2 – Nonconformity Grading and Exchange (NGE) form) presents the grading as the result of 4 independent criteria:

- Impact on the QMS (direct: 3 or indirect: 1)
- Repeat nonconformity (yes: 1 or no: 0)
- Combination of the absence of a documented process or procedure and failure to implement (yes: 1 or no: 0)
- Release of nonconforming devices (yes: 1 or no: 0)

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### *1. Impact on the QMS*

See section 4.2.1 - Step 1 Grading – Indirect or Direct QMS Impact of this document.

### *2. Repeat nonconformity*

This category is for a nonconformity that has been identified during any audits within the previous 3 years. Such a nonconformity poses an increased risk because it is an indicator that a corrective action has not been adequately taken or implemented.

The “two previous QMS audits which evaluated the same sub-clause” was selected because:

- in order to assess the risk of repeat occurrence accurately, it is important to assess comparable nonconformities;
- historical data beyond the two previous QMS audits may not represent the current state; and
- review of more audit reports may be counterproductive for an efficient grading system. However, it is important to ensure that the audits reviewed for the Occurrence assessment, have at a minimum evaluated the same sub-clause.

Occurrence in this document is directed at the frequency of a nonconformity cited from one audit to the next performed by the same auditing organization. It is not the occurrences of examples within a given sample size that the auditor may take to determine if a nonconformity exists during an audit.

Auditors should refrain from issuing a new (repeat) nonconformity for a similar finding that was observed at a previous audit if the device organization is implementing the timetabled actions that had been proposed by the device organization, and accepted by the AO. If an auditor can demonstrate that previously proposed actions are not effective, considering new occurrences of the nonconformities, then a nonconformity may be issued for an ineffective corrective action system.

Note: see also MDSAP AU P0019 on how to handle nonconformities previously recognized by the device organization and under process of remediation.

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*3. Combination of the absence of a documented process or procedure and the failure to implement a requirement*

The absence of a documented process or procedure will fundamentally affect consistency and effective implementation of any process. The use of this escalation criteria should be limited to situations where there is a combined failure to document and implement a requirement.

Documenting a process or procedure aims at ensuring the consistent and effective implementation of the corresponding activities. However, failing to document a procedure or process does not systematically lead to noncompliant implementations of that activity, and conversely, documenting a procedure or process does not always ensure it will be implemented accordingly. However, where an organization fails to 1) document a procedure or process that ISO 13485:2016 or an applicable regulatory requirement require to be documented and 2) implement the corresponding activities in ways that comply with these same requirements, then the grading of the nonconformity shall be escalated.

This escalation rule applies even in case where the process is generally documented but entirely fails to address the requirements from a jurisdiction entirely and there is evidence that the implementation of the process failed to meet the requirements of that jurisdiction.

This escalation rule may be invoked in cases where the documented procedure entirely fails to address the topic, or only addresses an applicable regulatory requirement by referencing the regulation. However, it would not be invoked when a procedure addresses the topic but incompletely or lacking details.

*4. Release of a Nonconforming Medical Device*

A nonconformity which resulted in the release of a nonconforming medical device to the market is direct evidence of a QMS failure. This escalation criteria is grading the QMS nonconformity at a higher risk, because nonconforming product is on the market and outside the control of the manufacturer's QMS.

This type of direct evidence of QMS failure and release of nonconforming products to the market is analogous to a "major" nonconformity per ISO 17021-1:2015 clause 3.12 and would require that the Auditing Organization review, accept and verify the correction and corrective actions prior to granting a

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certification decision in accordance with ISO 17021-1:2015 clause 9.5.2(b)..

If a nonconforming medical device is released under concession with adequate technical and scientific justification, then the nonconformity has been resolved. It is no longer considered a nonconforming product and the escalation rule will not be applied.

### **5.3 Applying the Nonconformity Grading System**

While it is possible to have the sum of the steps in grading equal a “6” if the nonconformity is a direct QMS impact and all the escalation rules apply, the final grade for a nonconformity under this grading scheme will be a number between 1 and 5. A “5” will be the highest grade.

The grade assigned to each nonconformity should not be changed as a result of any correction(s) or corrective action(s) taken by the manufacturer, but may be amended as a result of the auditing organization’s documented appeals process (ISO 17021-1:2015, clause 9.7). After the auditing organization has completed the audit process, the final MDSAP AU F0019.2 – Nonconformity Grading and Exchange (NGE) form should be provided to the manufacturer. The intent is also that the grading and the NGE form be a method to accurately capture the assessment of the audit and to provide uniformity and consistency within the process of grading nonconformities.

### **5.4 MDSAP AU F0019.2 – Nonconformity Grading and Exchange (NGE) form**

The MDSAP AU F0019.2 – Nonconformity Grading and Exchange (NGE) form is used for information exchange between auditing organizations and regulatory authorities, as well as between regulatory authorities.

Form MDSAP AU F0019.2 can strictly be used as a tool to exchange information with the Regulatory Authorities about the nonconformities issued and their status at the time of the submission. In such case the response of the Audited Facility’s organization to the nonconformity is not recorded in the form. The Auditing Organization using this option needs to record the back and forth with the Audited Facility’s organization using their own tools. Otherwise, the form can also be used to also record the Audited Facility’s response to the nonconformity.

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Nonconformity Reports and NGE forms should be actively updated until the effectiveness of the corrections and corrective actions proposed by the audited facility or organization has been verified.

Upon request from an MDSAP Regulatory Authority, the Auditing Organization is expected to provide updated nonconformity reports within 10 calendar days. It is not necessary for Nonconformity reports to be closed at the time they are shared with the Regulatory Authorities.

Form MDSAP AU F0019.2 purposely does not provide a cumulative grade for the overall audit. How the Form is utilized is the decision of each regulatory authority for their appropriate assessment based on their own needs or requirements.

MDSAP AU G0019.4 - Guidelines NC Grading Exchange Form explains the features of Form MDSAP AU F0019.2 - MDSAP Nonconformity Grading and Exchange Form and clarifies how the form is used.

## 6. Forms

MDSAP AU F0019.2 – Nonconformity Grading and Exchange (NGE) form

## 7. Reference Documents

GHTF/SG3/N19:2012: Quality management system - Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange

MDSAP AU P0019 - Medical Device Regulatory Audit Reports Policy

MDSAP AU G0019.4 - Guidelines NC Grading Exchange Form

MDSAP AU P0027 - Post Audit Activities and Timeline Policy

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## 8. Document History

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## AUDIT APPROACH

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## **Foreword**

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### **Foreword**

The intention of the Medical Device Single Audit Program (MDSAP) is to allow competent auditors from MDSAP recognized Auditing Organizations (AOs) to conduct a single audit of a medical device organization's quality management system that will satisfy the requirements of the medical device Regulatory Authorities (RAs) participating in the MDSAP program.

Audits performed under the MDSAP program will be process-based, focusing on several defined processes, a defined method for linking those processes, and built on a foundation of requirements for risk management.

### **Use of this document**

This document contains specific instructions for performing audits under the MDSAP program. It incorporates an audit sequence, instructions for auditing each specific process and identifies links that highlight the interactions between the processes.

A red box emphasizes the interrelationships of specific processes and the relevant risk management activities; if viewing a color version of the document or are in gray boxes if viewing the black and white version. *"Blue"* font emphasizes the integration of risk management.

This revision of the document combines the formerly separate MDSAP Audit Model and Process Companion documents into a single document containing additional detail regarding each audited process; as well as guidance for assessing the conformity of each process. In electronic form, the navigation bar facilitates quick access to relevant Tasks. The user may create their own bookmarks to quickly navigate to various sections.

## **Overview**

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### **Overview**

The design of the Medical Device Single Audit Program (MDSAP) audit process is to ensure a single audit will provide efficient yet thorough coverage of regulatory requirements. These requirements include; Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016), the Quality Management System requirements of the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch3), the Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022), the Canadian Medical Devices Regulations, the Japanese Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169), the Quality System Regulation (21 CFR Part 820), and specific requirements of the medical device regulatory authorities participating in the MDSAP program.

### **Audit Sequence**

The design and development of the MDSAP audit sequence allows a logical, focused and efficient conduct of an audit. The MDSAP audit sequence follows a process approach and has four primary processes - Management process, Measurement, Analysis and Improvement process, Design and Development process and a Production and Service Controls process with links to the supporting process for Purchasing.

The definition of each process includes a purpose and an outcome that are indicators of process performance. Each participating Regulatory Authority expects that risk management to be the foundation for the five processes that are the requirements of a quality management system for medical device organizations.

The MDSAP audit process has two additional supporting processes: Device Marketing Authorization and Facility Registration and Medical Device Adverse Events and Advisory Notices Reporting. These processes are necessary to fulfill specific requirements of the participating MDSAP regulatory authorities.

The flowchart shown in Figure 1 illustrates the MDSAP audit sequence and interrelationships. The design of the MDSAP audit approach requires the audit of the primary MDSAP processes in the following sequence: (1) Management (2) Measurement, Analysis and Improvement (3) Design and Development, and (4) Production and Service Controls processes. The audit of the Purchasing process is in conjunction with the Measurement, Analysis and Improvement process, the Design and Development process, and the Production and Service Controls process.

The design and implementation of a medical device organization's quality management system is a strategic decision of the medical device organization. Through this system, it can meet the requirements of the participating regulatory jurisdictions in a way that is appropriate for the size of the

## **Overview**

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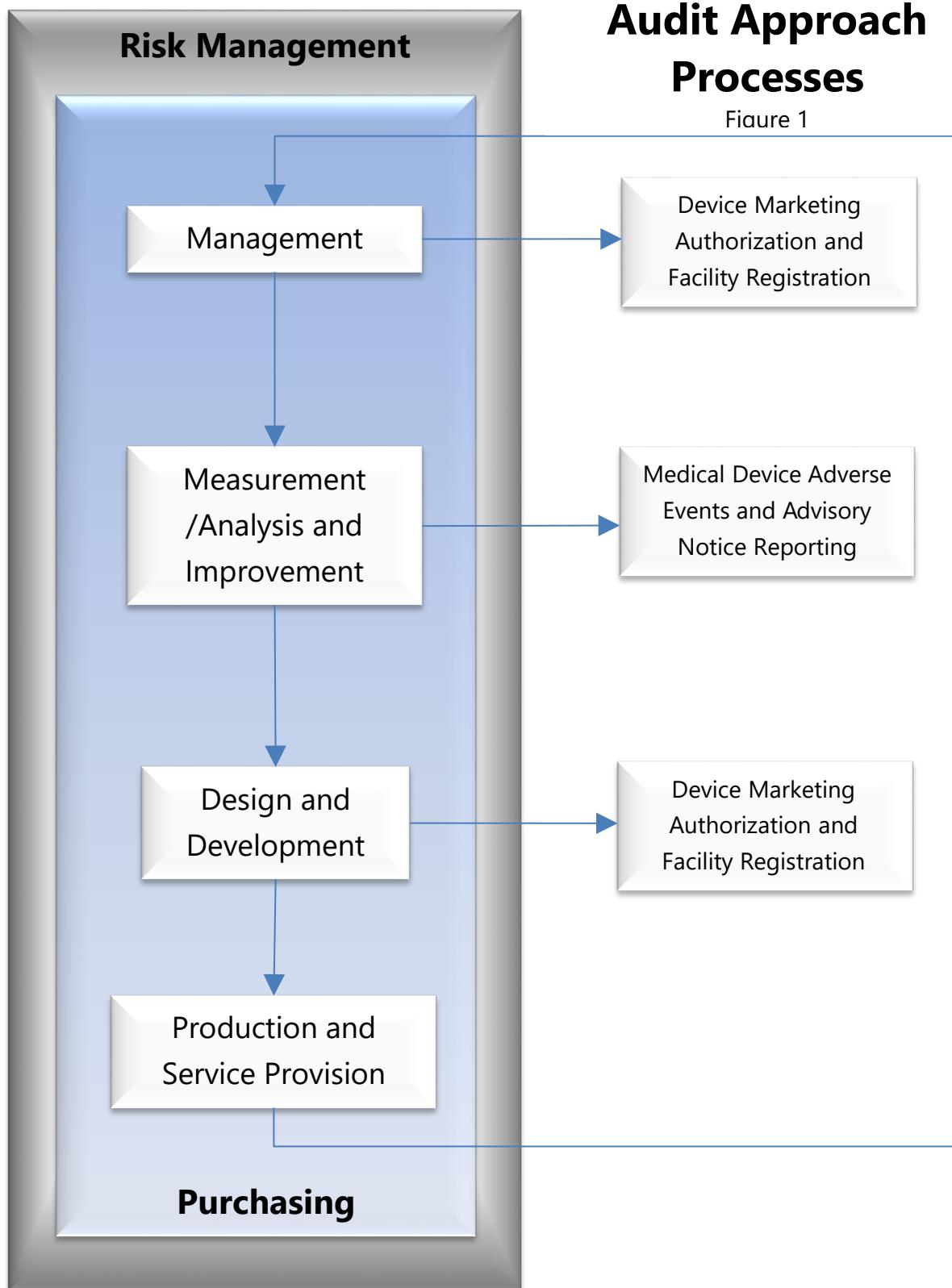
medical device organization, the processes employed and the products supplied. The medical device organization's quality management system does not need to implement certain processes (e.g. Design and Development) if regulation permits the exclusion or non-application of the process. Auditing Organizations are not required to audit such processes. However, if the medical device organization chooses to outsource any processes related to the design and/or manufacture of medical devices for which the medical device organization has responsibility, these processes remain the responsibility of the medical device organization. The medical device organization's quality management system must implement controls for monitoring and maintaining the quality of product from suppliers and outsourced processes.

The participating MDSAP jurisdictions intended to promote a single program of audits that takes into account all of their requirements for quality management systems. Hence, including the regulatory requirements of all MDSAP participating jurisdictions is a default requirement for a medical device organization's participation in the program. Marketing Authorization holders may have previously used an alternative source of evidence to demonstrate compliance with the regulatory requirements of a jurisdiction. The supply of a product into the jurisdiction of a participating MDSAP Regulatory Authority requires the auditor to include the relevant regulatory requirements in the scope of an audit.

However, in addition to the exclusions and non-applications permitted by ISO13485, the medical device organization may exclude the requirements of markets where the medical device organization does not intend to supply product. The audit scope and audit criteria must take into account any justified exclusions or non- applications. When a medical device organization claims an exclusion from the requirements of a target market, the auditor should use caution when applying the guidance provided in the MDSAP processes. Some requirements may not be applicable.

Medical devices regulated for use in pre-market clinical studies under special access programs, humanitarian use exemptions, and investigational device programs are outside of the scope of a typical MDSAP audit. The manufacture and distribution of a device supplied under a special access-type program may be subject to parts of the regulatory requirements included in the MDSAP. Auditing organizations are encouraged to contact the pertinent MDSAP-participating Regulatory Authority for any questions or clarifications.

## Overview



**Note:** Whist there is a prescribed audit sequence for the MDSAP *processes*, auditors may audit *tasks*

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within a given process in any sequence to allow for an efficient and effective audit.

The audit sequence should be followed as designed, however under certain circumstances, including the number and qualification of the auditors assigned to an audit, the unequal amount of information associated with specific client processes and the type of activity being conducted, the rigorous application of the audit sequence might prevent the efficient use of audit time and create problems with audit planning. In these cases, judicious exceptions to the audit sequence are allowed as long as there is sufficient justification and the core elements of the MDSAP Audit Approach, including linkages between processes are defined and risk-based sample selections, are respected.

Examples of reasonable exceptions:

- Auditing Measurement, Analysis and Improvement and Management at the same time to better allocate audit time for a multi-auditor activity.
- Starting the audit of a follow-on MDSAP process, such as Production or Design, when enough information had been gathered by the review of core elements in Measurement, Analysis and Improvement and Management and supporting processes, Device Marketing Authorization and Facility Registration and Medical Device Adverse Events and Advisory Notices Reporting, but prior to the full completion of these processes.
- Allowing an expert, such an expert in specific sterilization techniques, to commence the review of these specific client processes and areas.

In all cases of these adjustments, proper attention should be paid to intra-audit communication so that these decisions are re-evaluated as necessary as additional information is gathered throughout the audit, and appropriate actions taken if this information alters the viability of these changes.

Audit specific adjustments to the MDSAP audit sequence should be documented in the audit report along with appropriate justification.

## **Conducting the Audit**

During the audit of the medical device organization's quality management system, as identified in the MDSAP processes, the audit team will be asked to be mindful of "linkages". In order for a medical device organization's quality management system to function effectively, it needs to identify and manage numerous interrelated (linked) processes in accordance with clause 4.1.2 (c) of ISO 13485:2016. The output of one process often directly forms the input of other processes, or the activities of a supporting process are relevant to other processes. The MDSAP audit sequence and audit tasks include linkages to remind the audit team of the interactions between the processes. For example, linkages assist auditors in making appropriate selections when moving to the next process (e.g. using information from the Measurement, Analysis and Improvement process to select a design project to review where appropriate).

## **Overview**

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An audit of the medical device organization's quality management system processes is to assess the extent to which the medical device organization is applying risk management principles when defining its activities. Implementing the risk-based approach to controls is an integral aspect of a medical device organization's quality management system and it is the responsibility of top management to provide the necessary commitment and resources for this effort. Effective implementation of the risk-based approach usually starts in conjunction with the design and development process, proceeds through product realization, including the selection of suppliers, considers feedback from post-market monitoring and continues until the time the product is decommissioned. Risk-based decisions occur throughout the various quality management system processes, and each medical device organization must implement the risk-based approach as well as risk management in product realization with a determination of how much residual risk is acceptable to ensure medical devices meet requirements for safety and performance and regulatory requirements.

## **Navigating the Audit Sequence**

Each MDSAP audit process will require the audit team to accomplish audit tasks to determine if the process outcomes and the process purposes are achieved. Each audit process task includes *Clause and Regulation* references including; the applicable ISO 13485:2016 clause(s), the corresponding section(s) of the Quality Management System requirements of the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch3), Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022), Canadian Medical Devices Regulations, Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169), the Quality System Regulation (21 CFR 820), and any unique requirements that pertain to a participating MDSAP regulatory authority. These references have been provided to assist the auditors in assuring that the requirements of all MDSAP participating regulatory authorities are addressed during the audit.

Many audit tasks require verification of the availability and control of MDSAP regulator specific documentation and records. These tasks have a *Clause and Regulation* reference to ISO 13485:2016 clause 4.2.1, as the quality management system documentation is to include documentation specified by applicable regulatory requirements (regulations, administrative practices and policies) [4.2.1(e)]. Where a regulatory requirement relates to the documentation required by other, more specific, clauses of ISO 13485:2016 the auditing organization is to reference the more specific clause when recording findings of nonconformity (refer to MDSAP AU P0037 - [Guidelines on the use of GHTF/SG3/N19:2012 for MDSAP purposes](#)). To be consistent with ISO 13485:2016 the audit team is

## **Overview**

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also reminded to apply the concept that “when a requirement is required to be documented, it is also required to be established, implemented and maintained.”<sup>1</sup>

The medical device organization needs to demonstrate its ability to provide medical devices that consistently meet customer and regulatory requirements. During the audit, it is important that the auditors are mindful of any instances where the medical device organization demonstrates failure to fulfill any of the requirements in ISO 13485:2016, or portion of the requirements listed in the audit activities and tasks, and that these nonconformities are recorded in appropriate detail. Particular attention should be paid to the potential interrelationship of the nonconformities observed. For example, audit findings in both purchasing controls and acceptance activities may indicate a significant nonconformity because control over suppliers, and the products they supply, depends on an effective mix of both these activities, and deficiencies in one or the other may affect the quality of the finished device.

Whenever a MDSAP Audit Task requires an auditor to verify the identification and documentation of a requirement in QMS documentation, this verification should be performed as part of the pre-audit preparation and documentation review, as practical, to minimize on-site audit time and to increase the auditor’s familiarity with the medical device organization’s QMS.

## **Terminology**

The term “device” is used throughout the MDSAP processes. For the purpose of applying the MDSAP processes, and to accommodate nuances in the regulatory systems of the participating Regulatory Authorities, the use of the term “device” is to refer to any product that is capable of functioning as a medical device, whether or not it is packaged, labeled, or sterilized. In some jurisdictions, such a product is defined as a “finished device”. In other jurisdictions, a finished device is one that is intended to be used as a medical device and is at a stage where the product is ready to be placed on the market, or put into service, by the medical device organization whose name appears on the labelling.

The term medical device organization in this document is intended to be a reference to the definition in ISO 9000:2016- CI 3.2.1 and as used in ISO 13485:2016. A “manufacturer” is a specific kind of a medical device organization that is variously defined in the regulations of the participating regulatory authorities.

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<sup>1</sup> ISO 13485:2016 – Clause 0.2

## **Overview**

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A purchased or otherwise obtained “product” or “service”<sup>2</sup> is an outsourced product or service. In addition, a “supplier” is anyone that is independent from the medical device organization’s quality management system. This includes a supplier that may be part of the same corporation as the medical device organization but operates under a separate quality management system from the audited medical device organization. For further clarification, if a supplier is not a part of the medical device organization’s internal audit scope, then the supplier is under a separate quality management system. Corporations or companies that have corporate quality policies and procedures do not necessarily place all divisions or groups under the same quality management system. Therefore, one division or group can be a supplier to another division or group within the same corporation/company when not within the scope of the same quality management system. The control of suppliers that are part of the same corporation and not part of the QMS of the audited medical device organization is similar to the way external suppliers are controlled. Therefore, for the purposes of MDSAP and as necessary, an Auditing Organization has the discretion to audit external suppliers of a medical device organization, including corporate suppliers. The medical device organization must have proper controls over outsourced processes that provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

### **Critical Suppliers:**

For the purposes of MDSAP, “critical suppliers” include, but are not limited to;

- those entities that supply the organization with finished devices, i.e. a device, or accessory to any device, that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized;
- suppliers of products, including services, that impact design outputs that are essential for the proper functioning of the device; and
- suppliers of products and services that require process validation.

## **Annexes**

[Annex 1](#) contains country specific information as to the expectations for the audit of product / process related technologies (other than sterilization – See Annex 2) and the audit of technical documentation as part of the execution of the Audit Tasks.

[Annex 2](#) contains information as to the expectation for the audit of requirements for sterile medical devices.

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<sup>2</sup> GHTF/SG3/N17:2008 - Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers

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[Annex 3](#) contains a table showing a summary of timeframes for reporting advisory notices and individual adverse event reports in the participating MDSAP jurisdictions.

[Annex4](#) contains country specific guidance on expectations for various types of written agreements for regulatory purposes.

[Annex 5](#) contains tables showing comparisons between Japan's new and old QMS ordinance. See [footnote 3](#) in Management.

[Annex 6](#) contains a table for acceptable exclusions from a manufacturer's scope of certification.

## MDSAP Audit Cycle

The Medical Device Single Audit Program is based on a three (3) year audit cycle. The Initial Audit, also referred to as the "Initial Certification Audit" is a complete audit of a medical device organization's quality management system (QMS) consisting of a Stage 1 Audit (17021-1:2015 – CI 9.3.1.2) and a Stage 2 Audit (17021-1:2015 – CI 9.3.1.3). The initial Audit is followed by a partial Surveillance Audit (17021-1:2015 – CI 9.6.2.2) in each of the following two (2) years and a complete Re-audit, also referred to as a "Recertification Audit" (17021-1:2015 – CI 9.6.3.2) in the third (3rd) year. A recertification audit may also include a Stage 1 audit if there have been significant changes to the QMS that have not been otherwise adequately assessed.

Special Audits (17021-1:2015 – CI 9.6.4.2), Audits Conducted by Regulatory Authorities, and Unannounced Audits are potential extraordinary audits that may occur at any time within the audit cycle.

**Note:** Not all MDSAP participating regulatory authorities require, or make use of, certification documents that relate to a medical device organization's QMS. The terms "certification" and "recertification" appear within this document to maintain consistency with the terminology used within ISO/IEC 17021-1:2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems.

The audit cycle of a quality management system for sterile medical device should include a comprehensive assessment of the control of the device sterility, generally during the initial/recertification audit. The surveillance audit, in the absence of changes significantly affecting the control of sterility, may be limited to the verification of the appropriate implementation of the validated process parameters; control and monitoring activities; and final product release. While some auditing activities can be conducted remotely (e.g. review of the sterilization process validation report), remote activities alone cannot effectively ensure the comprehensive control of the device sterilization processes. The outcome of such remote review activities must serve as input to the on-site audit and be incorporated or attached to the MDSAP audit report. The off-site assessment of the controls of the

## **Overview**

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product sterility should not prevent the on-site audit team from following audit trails, including audit trails necessitating the review of documents that had previously been assessed remotely.

During the course of the audit cycle, all product families and significant processes should be assessed when possible.

The selection of samples during audits in order to obtain evidence of conformity or nonconformity with MDSAP audit criteria can be either statistically based or judgement based. Judgement based sampling using audit trails from one task or process to inform the selection of samples in other tasks or processes is preferred. Where possible, auditors should select samples of records representing all participating MDSAP jurisdictions applicable to the audit.

## **Initial Audit (Initial Certification Audit)**

The "Initial" also known as "Initial Certification" audit consists of a Stage 1 and a Stage 2 audit.

**Stage 1** – Documentation review, evaluation of preparedness for Stage 2 audit, etc.

A Stage 1 audit shall be conducted in accordance with Clause 9.3.1.2 of ISO/IEC 17021-1:2015 and all applicable MDSAP Audit Process tasks and regulatory requirements.

From an MDSAP perspective, the primary purposes of a Stage 1 audit are (1) to determine if QMS documentation required by ISO 13485:2016 - Clauses 4.2.1 and other applicable MDSAP documentation requirements have been adequately defined, and documented; (2) to assess the medical device organization's preparedness for a Stage 2 audit; (3) to provide a focus for planning a Stage 2 audit; and, (4) to collect information regarding the scope of the quality management system and other aspects of the medical device organization.

Portions of a Stage 1 audit (e.g. documentation review) may be performed at a site other than the site(s) of the medical device organization seeking initial certification.

The outcome of the Stage 1 audit will assist the MDSAP recognized Auditing Organization in its determination of the readiness of the medical device organization to undergo a Stage 2 audit. The Auditing Organization shall determine how best to accomplish tasks of Stage 1 and Stage 2 with regards to off-site documentation and record review and on-site verifications. Hence portions of a Stage 1 audit (e.g. documentation review) may be performed at a site other than the site(s) of the medical device organization seeking initial certification. In practice it is intended that the Auditing Organization may combine elements of Stage 1 and Stage 2 to allow for a single on-site visit for the initial audit or re-audit of the medical device organization.

**Stage 2** – Evaluation of QMS Implementation and Effectiveness

## **Overview**

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A Stage 2 audit shall be conducted in accordance with Clause 9.3.1.3 of ISO/IEC 17021-1:2015 and using all applicable MDSAP Audit Process tasks.

The purpose of a Stage 2 audit is to determine if all applicable requirements of ISO 13485:2016 and the relevant regulatory requirements from participating regulatory authorities have been implemented. Stage 2 audit objectives shall specifically include an evaluation of:

- the effectiveness of the medical device organization's QMS incorporating the applicable regulatory requirements;
- product/process related technologies (e.g. injection molding, sterilization);
- adequate product technical documentation in relation to relevant regulatory requirements; and,
- the medical device organization's ability to comply with these requirements.

As part of achieving these objectives, the auditor is to verify that the medical device organization maintains sufficient and reliable objective evidence to demonstrate its devices meet essential principles of safety, performance, and effectiveness and any other regulatory requirement identified in the audit tasks. This verification is to ensure that documentation and records required by the national regulations of the participating Regulatory Authorities are present, current, and complete. The auditor should expect that the documentation and records are maintained to demonstrate continued compliance with regulatory requirements during the post-market phase of the device life-cycle.

A Stage 2 audit shall be performed at all sites that will be recorded on the certificate. (Hence, any sites which are relevant to the medical device organization's quality management system but audited off-site, should not be recorded on the certificate.)

## **Surveillance Audits**

(1st and 2nd Surveillance Audits):

A Surveillance Audit shall be conducted in accordance with Clause 9.6.2.2 of ISO/IEC 17021-1:2015 and clause 9.6.2 of IMDRF/MDSAP WG/N3:2016 and using applicable MDSAP Audit Process tasks.

The purpose of a series of surveillance audits is to assure that all applicable requirements of ISO 13485:2016 and the relevant regulatory requirements from participating regulatory authorities are audited during the cycle of a three year audit program for the medical device organization.

Surveillance audit objectives during the audit cycle shall specifically include evaluation of:

- the effectiveness of the medical device organization's QMS incorporating the applicable regulatory requirements.
- the medical device organization's ability to comply with these requirements; and,
- new or changed product/process related technologies; and,

## Overview

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- new or amended product technical documentation in relation to relevant regulatory requirements.

In addition, surveillance audits shall include a review of issues related to medical device safety and effectiveness since the last audit such as complaints, problem reports, vigilance reports, and recalls/field corrections/advisory notices.

These objectives allow the MDSAP recognized Auditing Organization to maintain confidence that the QMS continues to meet requirements between re-audits (re-certification audits). The auditor should again expect that the documentation and records are maintained to demonstrate continued compliance with regulatory requirements during the post-market phase of the device life-cycle.

Surveillance audits do not require a Stage 1 audit unless significant changes have occurred since the last audit. For example, where there are QMS changes associated with new legislation, or legislative changes, or if otherwise deemed necessary by the Auditing Organization.

Each *individual* surveillance audit in the cycle need not cover all MDSAP requirements. However, as a minimum, each surveillance audit must address the following (as applicable):

- a) A review of changes to the medical device organization, their QMS, or their products, since the previous audit

**Note:** changes may necessitate regulatory submissions

- b) The MDSAP Audit Process tasks as listed in the table in Appendix 1 of MDSAP AU P0008 – Audit Time Determination Procedure.

**Note:** Where there are indicators of existing or potential nonconformities in the data, or other information observed during a surveillance audit that suggest that such nonconformities have not been adequately addressed by the medical device organization's QMS, an audit of the Design and Development Process and/or the Production and Service Controls Process should focus on those indicators of existing or potential nonconformities.

**Note:** If the first surveillance audit includes the Design and Development Process, the second surveillance should include the Production and Service Controls Process (or vice-versa) unless further indicators of existing or potential nonconformities dictate otherwise.

- c) Confirmation that the medical device organization has arrangements in place to maintain the currency of the technical documentation for all devices (see [Annex 1](#)).
- d) The use of marks and references to certification.

## **Overview**

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Guidance on the selection of samples of data for the audit of the processes in a) and b) above is provided within the relevant tasks of those MDSAP Audit Processes. The selection should be limited to the data that is relevant to the processes in a) and b) above.

## **Re-audit (Recertification Audits)**

A Re-audit (Recertification Audit) shall be conducted in accordance with Clause 9.6.3 of ISO/IEC 17021-1:2015 and using all applicable MDSAP Audit Process tasks.

The purpose of a re-audit is to confirm the continued relevance, applicability and suitability of the medical device organization's QMS (as a whole), to satisfy all applicable requirements of ISO 13485:2016 and the relevant regulatory requirements from participating regulatory authorities, with respect to the scope of certification. Recertification audit objectives shall specifically include evaluation of:

- the effectiveness of the medical device organization's QMS incorporating the applicable regulatory requirements
- product/process related technologies (e.g. injection molding, sterilization)
- adequate product technical documentation in relation to relevant regulatory requirements
- the medical device organization's continued fulfillment of these requirements.

Re-audits do not require a Stage 1 audit unless significant changes have occurred since the last audit. For example, where there are QMS changes associated with new legislation or legislative changes, or if otherwise deemed necessary by the Auditing Organization. If there have been significant changes to the QMS, Auditing Organizations shall review the documentation that implements those changes in accordance with Clause 9.6.3.1.3 of 17021-1:2015. Re-audits may be shorter than initial audits through selective and focused sampling.

As part of achieving the objectives for a Re-Audit, an auditor shall verify the requirements of ISO/IEC 17021-1:2015 Clause 9.6.3.2.1, and the following, where applicable:

- A review of the MDSAP audit reports for the current audit cycle. That is, those prepared since the initial audit or previous re-audit
- A review of changes to the medical device organization, QMS, or products since the previous surveillance audit
- A follow-up of corrections and/or corrective actions stemming from the findings of the previous MDSAP audit, of any kind
- A review of the effectiveness and suitability of the medical device organization's QMS over the current audit cycle
- All applicable MDSAP Audit Process tasks.

## **Overview**

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The audit of the processes and the sampling should focus on the following (based on risk):

- new or modified designs and new products
- previously identified potential and existing nonconformities
- new or modified processes
- areas not sufficiently covered during the surveillance period.

During a recertification audit, the Auditing Organization shall audit all sites that are recorded on the certificate. (Hence any sites which are relevant to the medical device organization's quality management system but audited off-site, should not be recorded on the certificate)

## **Special Audits**

Special audits are extraordinary audits in that they are not part of the planned audit cycle. These audits should only be used when necessary and should focus on specific elements of the medical device organization's QMS.

Special audits may include audits conducted in response to an application for the extension to the scope of an existing certification, to determine whether or not the extension can be granted or as short-notice audits conducted to investigate potentially significant complaints, or if specific information provides reasons to suspect serious non-conformities of the devices, or for other reasons.

Short-notice audits may be conducted at the request, and under the direction, of the MDSAP participating regulatory authorities or at the discretion of the Auditing Organization.

Special audits should be conducted in accordance with the applicable requirements of ISO/IEC 17021-1:2015 Clause 9.6.4 as well as any additional requirements of the MDSAP recognized Auditing Organization and/or the MDSAP participating regulatory authorities (where applicable).

Special audits should be used to address, as applicable:

- The need to extend the scope of the audit or certification of the medical device organization to include new or modified products between regularly programmed audits
- A shortfall in oversight by the MDSAP recognized Auditing Organization. For example, due to insufficient audit time, inappropriate audit team constitution, etc.
- To follow up on specific post-market issues. For example, for potentially significant complaint.
- To follow up on significant findings from a previous MDSAP audit
- At the request of an MDSAP participating regulatory authority (based on a specific assignment)
- To conduct supplier audits as dictated by regulatory authority or Auditing Organization policy.

## **Overview**

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An Auditing Organization that performs a special audit at the request of the recognizing Regulatory Authority(s) shall submit the audit report to the recognizing Regulatory Authority(s) within 15 days from the last day of the audit.

### **Unannounced Audits**

Another type of Special Audit is the unannounced audit. The MDSAP participating regulatory authorities require Auditing Organizations to conduct unannounced audits in circumstances where high grade non-conformities have been detected. See IMDRF/MDSAP WG/N3 Final: 2016 (2nd Ed) for criteria.

### **Audits Conducted by Regulatory Authorities**

Audits may also be conducted by MDSAP participating regulatory authorities at any time and for a range of reasons *including* (1) "For Cause" due to information obtained by the regulatory authority, (2) as follow up to the findings of a previous audit, and (3) to confirm the effective implementation of MDSAP requirements by MDSAP recognized auditing organizations.

The purpose of audits conducted by regulatory authorities is to ensure appropriate oversight of a recognized MDSAP Auditing Organization's audit activities, as an alternative means of assessing medical device organizations that have been identified as undertaking high risk manufacturing processes and have not been adequately audited, where sufficient detail regarding audited processes has not been included in an audit report, or where there is a history of low compliance with QMS or regulatory requirements.

## **Chapter 1 - Management**

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### **Chapter 1 - Management**

The intent of the Management Process is to provide adequate resources for device design, manufacturing, quality assurance, distribution, installation, and servicing activities; to assure the quality management system is functioning properly and effectively; and to monitor the quality management system and make necessary adjustments. A quality management system that has been implemented effectively and is monitored to identify and address existing and potential problems is more likely to produce medical devices that function as intended.

The management representative is responsible for ensuring that the requirements of the quality management system have been effectively defined, documented, implemented, and maintained. Prior to the audit of a process, it may be helpful to interview the management representative (or designee) to obtain an overview of the process and a feel for management's knowledge and understanding of the process.

The Management process is the first process to be audited per the MDSAP audit sequence.

### **Auditing the Management Process**

**Purpose:** The purpose of auditing the Management process is to verify top management ensures an adequate and effective quality management system has been established and maintained. The management processes should be re-evaluated at the end of the audit to determine whether top management has demonstrated the necessary commitment for an effective quality management system that has been communicated to personnel.

**Outcomes:** As a result of the audit of the Management process, objective evidence will show whether the medical device organization has:

- A) Identified processes needed for the quality management system, their application throughout the medical device organization, and their sequence and interaction
- B) Defined, documented, and implemented procedures and instructions to ensure the development and maintenance of an effective quality management system
- C) Established quality objectives at relevant functions and levels within the medical device organization consistent with the quality policy and ensured that these are periodically reviewed for continued suitability
- D) Determined the criteria and methods needed to ensure the operation and control of quality management system processes, including the identification and management of interrelated processes
- E) Committed the appropriate personnel and resources for infrastructure to the quality management system
- F) Assigned responsibility and authority to personnel and established the organizational structure to ensure processes assuring quality are not compromised

# **Chapter 1 - Management**

## Task 1 – QMS Planning, Implementation, Changes and Quality Manual

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- G) Performed risk management planning and ongoing review of the effectiveness of risk management activities to ensure that policies, procedures and practices are established for analyzing, evaluating and controlling risk
  - H) Ensured the continued effectiveness of the quality management system and its processes
  - I) Established a quality management system which is capable of producing devices that are safe, effective and suitable for their intended use.

Links to Other Processes:

**Measurement, Analysis and Improvement; Design and Development; Purchasing; Production and Service Controls; Device Marketing Authorization and Facility Registration**

## **Task 1 – QMS Planning, Implementation, Changes and Quality Manual**

**Confirm that quality management system planning is performed to ensure that all required processes are identified, documented, implemented, monitored and maintained in order to conform to the applicable requirements and meet quality objectives.**

**Verify that changes to the quality management system are managed to maintain the conformity of the quality management system and of the devices produced.**

**Verify that a quality manual has been documented.**

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.1.1, 4.1.2, 4.1.3, 4.2.2, 4.1.4, 5.4.2;

**TGA:** TG(MD)R Sch3 P1 1.4(4);

**ANVISA:** RDC ANVISA 665/2022: Art. 4º, Art. 106

**MHLW/PMDA:** MHLW MO169: 5-1, 5-2, 5-3, 5-4, 7-1, 14; [Old<sup>3</sup>: 5, 7, 14]

**FDA:** 21 CFR 820.20

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<sup>3</sup> The MHLW MO169 was initially established in order to harmonize the Japanese medical device QMS to ISO13485:2003. The ordinance was revised to be aligned to ISO13485:2016 in 2021 and the transition period is set as 3 years. "Old" in this context means the clause numbers of the old ordinance which is aligned to ISO13485:2003. The MDSAP auditors are required to audit against the old ordinance, when the organization selects it as audit criteria during the transition period.

# **Chapter 1 - Management**

Task 1 – QMS Planning, Implementation, Changes and Quality Manual

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## ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Quality management system**

Medical device organizations are required to establish a quality management system (including quality system procedures and instructions) that is tailored to the regulatory roles assumed by the medical device organization and the medical devices they are manufacturing or designing. The medical device organization's quality management system must properly implement all applicable requirements of Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016), the Quality Management System requirements of the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch3), Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022), Japanese QMS Ordinance (MHLW MO 169), the Quality System Regulation (21 CFR Part 820) and specific requirements of medical device regulatory authorities participating in the MDSAP program, as well as other necessary controls to assure its finished devices, the design and manufacturing processes, and all related activities conform to approved specifications.

### **Quality system procedures and instructions**

The medical device organization may refer to these as Level 1 documents. They are typically high-level, non-product and non-process specific documents and can usually be found in the Quality Manual. These procedures and instructions may contain information on the sequence and interaction of various quality management system processes. It is expected that when the standard specifies that a certain process is required to be documented, it is also required to be established, implemented and maintained.<sup>4</sup> The Quality Manual is to outline the structure of the documentation and to describe the interaction of processes (e.g. the processes for identifying nonconformities and corrections, and the processes for investigating nonconformities to determine root cause and corrective actions).

### **Quality Management System Planning**

Quality planning is concerned with the design and implementation of the quality management system. Such planning typically occurs during the initial development and implementation of a quality system, but also occurs when there are changes in quality policy, quality objectives, QMS and regulatory requirements, or when changes are necessary to for the QMS to continue to be effective. Quality

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<sup>4</sup> ISO13485:2016 – Clause 0.2

## **Chapter 1 - Management**

### Task 2 – Management Representative

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planning at this level shouldn't be confounded with quality planning as described in clause 7.1 of ISO 13485:2016.

Evidence of quality system planning should at least include documents that identify and record the inputs and outputs of quality system planning. A procedure for quality system planning may also be available.

The inputs to quality planning can include:

- quality policy
- quality objectives
- quality management system standards (e.g. ISO 13485:2016)
- regulatory requirements
- product-specific requirements (e.g. servicing, installation, etc.)
- risk mitigation strategies (e.g. user training)
- required changes (e.g. identified during audits or management review)

The outputs of quality planning can include, amongst others:

- a description of the QMS processes and their inputs, outputs, sequence, and interactions
- the quality manual and associated procedures
- a gap analysis
- identification or resources needed to implement the QMS
- identification of competences and training needed to implement the QMS
- implementation and action plans.

Quality management system planning should also be used when changes to the quality management system are contemplated or required in order to ensure the continuing conformity of the QMS.

#### ***Links***

[Measurement, Analysis and Improvement; Design and Development; Purchasing; Production and Service Controls; Device Marketing Authorization and Facility Registration](#)

During the audit, whenever a change is identified, verify that the medical device organization has implemented appropriate change controls.

### **Task 2 – Management Representative**

**Confirm top management has documented the appointment of a management representative.**

## **Chapter 1 - Management**

### Task 2 – Management Representative

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**Verify the responsibilities of the management representative include ensuring that quality management system requirements are effectively established and maintained, reporting to top management on the performance of the quality management system, and ensuring the promotion of awareness of regulatory requirements throughout the medical device organization.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 5.5.2

**TGA:** TG(MD)R Sch3 P1 1.4(5)(b)(ii)

**ANVISA:** RDC ANVISA 665/2022: Art. 9º

**MHLW/PMDA:** MHLW MO169: 16

**FDA:** 21 CFR 820.20(b)]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Management representative**

It is important to confirm that top management has appointed a management representative and that the responsibilities and authorities of the management representative have been defined, documented, and implemented. The appointment of the management representative must be documented.

### **Confirm appointment**

The medical device organization may document the appointment of a management representative in an organizational chart, Quality Manual, memorandum to file, position description, or other appropriate manner. The appointment of the management representative may be made by name or title.

### **Evaluate responsibility and authority**

Confirm that management has established the management representative's responsibility and authority for ensuring that the quality management system is effectively defined, documented, implemented, and maintained. The management representative must also have responsibility and authority for reporting to top management on the performance of the quality management system.

# **Chapter 1 - Management**

## Task 3 – Quality Policy and Quality Objectives

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Confirmation can be accomplished by interviewing the management representative and top management and reviewing the Quality Manual, the management representative's position description, or similar documents.

### **Other examples**

Additional examples of evidence of the management representative's responsibilities and authorities may include:

- Sign-off authority for changes to procedures, processes, designs, etc.
- Authority to act on behalf of top management during the audit
- Authority to place products or processes on hold
- Responsibility for managing quality audit functions
- Responsibility for contributing to corrective and preventive action activities, complaint handling and the handling of nonconforming product, etc.

### **Training**

Where the activities performed personally by the management representative result in a determination of whether product meets requirements, including regulatory requirements, the management representative must be competent to perform such activities. In such cases, verify that training and experience includes the relevant regulatory requirements.

### **Links**

None

## **Task 3 – Quality Policy and Quality Objectives**

**Verify that a quality policy and objectives have been set at relevant functions and levels within the medical device organization.**

**Ensure the quality objectives are measurable and consistent with the quality policy.**

**Confirm appropriate measures are taken to achieve the quality objectives.**

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 5.3, 5.4.1

**TGA:** TG(MD)R Sch3 P1 1.4(5)(a)

**ANVISA:** RDC ANVISA 665/2022: Art. 5º, Art. 6º, Art. 7º

**MHLW/PMDA:** MHLW MO169: 12, 13

# **Chapter 1 - Management**

Task 4 – Organizational Structure, Responsibility, Authority, Resources

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**FDA:** 21CFR 820.20(a)]

## ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Quality policy**

A quality policy is comprised of one or more statements of the medical device organization's intentions and direction with respect to meeting agreed requirements. Top management must establish the quality policy and ensure quality objectives are established that are consistent with the quality policy. Top management must ensure that the quality policy is understood and communicated at all levels of the medical device organization. An assessment of whether the medical device organization's quality system is satisfying the established quality policy and objectives should be a topic addressed during management reviews.

### **Quality objectives**

An effective way of determining whether quality objectives have been implemented is to ask for examples of quality objectives and the status of these objectives. Typically, a quality objective is expressed as a measurable target or goal. An example of a medical device organization's quality objective could be "to have all essential components meet specifications at a defined reliability rate or better."

To accomplish this objective, the medical device organization will have to identify, evaluate, and approve reliable suppliers or bring the manufacturing of that component in-house.

### **Links**

None

## **Task 4 – Organizational Structure, Responsibility, Authority, Resources**

**Review the medical device organization's organizational structure and related documents to verify that they include provisions for responsibilities, authorities (e.g., management representative), personnel, resources for infrastructure, competencies, and training to ensure that personnel have the necessary competence to design and manufacture devices in accordance with the planned arrangements and applicable regulatory requirements.**

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 5.1, 5.5.1, 5.5.2, 6.1, 6.2

## **Chapter 1 - Management**

### Task 5 - Extent of Outsourcing

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**TGA:** TG(MD)R Sch3 P1 1.4(5)(b)

**ANVISA:** RDC ANVISA 665/2022: Art. 8º, Art. 13, Art. 14, Art. 15; Art. 16, Art. 17

**MHLW/PMDA:** MHLW MO169: 10, 15, 16, 21, 22, 23

**FDA:** 21 CFR 820.20(b), 820.25]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Responsibility and authority**

Methods for completing this audit task include reviewing the organizational chart(s) and asking authority and responsibility questions. The responsibilities and authorities of various individuals within the medical device organization are also typically described within the Quality Manual, position descriptions, and job postings.

### **Resources**

Top management is responsible for ensuring that resources necessary to maintain an effective quality management system are provided. Resources include money, equipment, supplies, and personnel. One method for confirming that adequate resources are made available is to ask the management representative to provide several examples of recent requests for different types of resources and describe the outcomes of these requests.

### **Links**

None

## **Task 5 - Extent of Outsourcing**

**Determine the extent of outsourcing of processes that may affect the conformity of product with specified requirements and verify the proper documentation of controls in the quality management system.**

**Verify the list of critical suppliers is current and accurate.**

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.1.5, 4.2.1

**TGA:** TG (MD)R Sch3 P1 1.4(5) (b)(iii), (d)(ii)

# **Chapter 1 - Management**

## Task 5 - Extent of Outsourcing

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**ANVISA:** RDC ANVISA 665/2022: Art. 21, Art. 22, Art. 23, Art. 24

**MHLW/PMDA:** MHLW MO169: 5-5, 6; [Old: 5, 6]

**FDA:** 21 CFR 820.50

### ***Additional country-specific requirements***

#### **Australia (TGA):**

The conditions of marketing authorization (ARTG inclusion) require that Australian Sponsors undertake some regulatory activities including; customer complaint handling (Act s 41FN, Reg 5.8), the management and communication of technical files /technical documentation (Act s 41FN(3)), adverse event reporting (Act s 41FN, Reg 5.7), conducting recalls (Part 4-9), ensuring that the name and address of the Sponsor is provided with the device (Reg 10.2), the storage of devices (Act s 41FN,Reg 5.9), the keeping of complaint and distribution records (Act s 41FN,Reg 5.10), annual reporting for an initial period of three years, of specified information to the TGA (ACT s41FN, Reg 5.11) for Class AIMD, Class III and Class IIb devices that are implantable, information about supply of specified IVDs (Act s41FN, Reg 5.12), ensuring that some devices that would contravene Part 2 of the Poisons standards are not supplied.

Some Sponsors also provide services for the installation and servicing of a device on behalf of the Manufacturer and consequently are to be treated as a supplier to the Manufacturer.

Where a regulatory requirement for a Sponsor intersects with a regulatory requirement or a requirement of ISO13485 for the Manufacturer, the activity is to be treated as an outsourced activity and documented in the Manufacturer's QMS. See also Task 5 Purchasing.

The requirement of Regulation 10.2 for "ensuring that the name and address of the Sponsor is provided with the device in such a way that the user of the device can readily identify the Sponsor" is only an obligation on the Sponsor. This activity does not need to be included in the Manufacturer's QMS documentation however the arrangements for the provision of this information should be disclosed in the written agreement between the Manufacturer and the Sponsor. In cases where an activity performed by the Sponsor also includes the provision of information required by Essential Principle 13 (Labels and IFU), or 13A (patient implant cards and leaflets), the Manufacturer must treat the Sponsor as supplier for that activity.

The Sponsor does not need to be treated as a supplier if the scope of the Manufacturer's quality management system includes the site and activities of the Sponsor. The oversight of activities that are required by legislation to be conducted by the Sponsors are to be clearly documented in the QMS and included in plans for internal audit.

# **Chapter 1 - Management**

## Task 6 – Personnel Competency and Training

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### **Canada (HC):**

Verify that the roles and responsibilities of any regulatory correspondents, importers, distributors, or providers of a service are clearly documented in the medical device organization's quality management system and are qualified as suppliers and controlled, as appropriate.

## **Assessing conformity**

### **Outsourcing**

Most organizations outsource at least some products (including services) that affect the ability of the medical device to conform to specified requirements. Some organizations outsource the majority of products. During interview of the management representative, ascertain the extent to which the medical device organization outsources processes essential for the proper functioning of the finished medical device. Process performance and product conformity, including the performance of supplied product, must be included in management review. The medical device organization must ensure control over outsourced products and processes that affect product conformance with specified requirements.

### **Links**

#### **Purchasing**

During audit of the medical device organization's purchasing process, ensure that management has assured the appropriate level of control over suppliers, including an assessment of the relationship between supplied products and product risk.

## **Task 6 – Personnel Competency and Training**

**Confirm the medical device organization has determined the necessary competencies for personnel performing work affecting product quality, provided appropriate training, and made personnel aware of the relevance and importance of their activities on product quality and achievement of the quality objectives.**

**Ensure records of training and competencies are maintained.**

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 6.2

**ANVISA:** RDC ANVISA 665/2022: Art. 8°, Art. 13, Art. 14, Art. 15

**MHLW/PMDA:** MO169: 6, 22, 23

# **Chapter 1 - Management**

## Task 7 – Risk Management Planning and Review

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**FDA:** 21 CFR 820.20(b)(2), 820.25

### ***Additional country-specific requirements***

#### ***Brazil (ANVISA):***

Confirm that the manufacturer ensures that any consultant who gives advice regarding design, purchasing, manufacturing, packaging, labeling, storage, installation, or servicing of medical devices has proper qualification to perform such tasks. Those consultants shall be contracted as a formal service supplier, according to purchasing controls defined by the manufacturer [RDC ANVISA 665/2022: Art. 16, Art. 17].

## **Assessing conformity**

### **Training**

A review of employee training records can be performed to ensure that employees have been trained regarding the medical device organization's quality policy and objectives. In particular, this should be done for employees involved in key operations that affect product realization and product quality.

During the audit of the Production and Service Controls process, ensure that employees who are involved in key operations that affect product realization and product quality have been trained in their specific job tasks, as well as the quality policy and objectives.

When appropriate, review the training records for those employees whose activities have contributed to process nonconformities.

### **Links**

[\*\*Production and Service Controls\*\*](#)

## **Task 7 – Risk Management Planning and Review**

***Verify that management has committed to and has responsibility for overall risk management planning, including ongoing review of the effectiveness of risk management activities ensuring that policies, procedures and practices are established and documented for analyzing, evaluating and controlling product risk throughout product realization.***

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.1.2 (b), 7.1

# **Chapter 1 - Management**

## Task 7 – Risk Management Planning and Review

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**TGA:** TG(MD)R Sch1 P1 2

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20

**MHLW/PMDA:** MO169: 5-2.1.2, 26; [Old: 26]

**FDA:** 21 CFR 820.30(g)

### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Commitment to risk management**

Confirm that top management has shown commitment to the risk management process by ensuring the provision of adequate resources and the assignment of qualified personnel for risk management activities. Risk-based decisions occur throughout the various quality management system processes. Top management is responsible for defining and documenting the policy for determining criteria for risk acceptability. Additionally, ensure top management reviews the suitability of the risk management process. This review may be part of the management review. Previously unidentified risks discovered during production and post-production of the medical device may indicate a need to improve the risk management process. Each medical device organization must decide how much risk is acceptable.

When appropriate, assess the role of top management when risk-based decisions are made that appear to justify levels of risk that do not meet the medical device organization's previously established risk- acceptance criteria.

Risk management usually starts in conjunction with the design and development planning process, at a point in the development when the results of risk analysis can affect the design process. During audit of the Design and Development process, evaluate top management's commitment to risk management activities. Evidence of commitment to risk management may include the implementation of new or more stringent controls in response to changes in the likelihood or severity of a hazard occurring, external controls (e.g. additional supplier-related controls), or design changes to maintain an acceptable level of product risk.

### ***Links***

[\*\*Design and Development\*\*](#)

## **Chapter 1 - Management**

### Task 8 – Document and Record Controls

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#### **Task 8 – Document and Record Controls**

**Verify that procedures have been defined, documented, and implemented for the control of documents and records of both internal and external origin required by the quality management system.**

**Confirm the medical device organization retains records and at least one obsolete copy of controlled documents for a period of time at least equivalent to the lifetime of the device, but not less than two years from the date of product release.**

#### *Clause and Regulation*

**ISO:** ISO 13485:2016: 4.1.4, 4.2.1, 4.2.4, 4.2.5

**TGA:** TG(MD)R Sch3 P1 1.4(4)

**ANVISA:** RDC ANVISA 665/2022: Art. 28, Art. 29, Art. 30, Art. 31, Art. 34, Art. 36, Art. 37

**MHLW/PMDA:** MO169: 5-4, 6, 8, 9; [Old: 5, 6, 8, 9]

**FDA:** 21 CFR 820.40, 820.180]

#### *Additional country-specific requirements*

##### **Australia (TGA):**

Confirm that Quality Management System documentation and records in relation to a device described in TG(MD)R Sch3 P1 1.9 are retained by the Manufacturer for at least 5 years.

Note that the conditions of marketing authorization (ARTG inclusion) require Australian sponsors of Class III/AIMD, implantable Class IIb or Class 4 IVDs to keep records of distribution, and records of information relating to; any malfunction or deterioration in the characteristics or performance of a device, or any inadequacy in the design, manufacture, labelling, instructions for use or advertising materials of a device, or any use in accordance with, or contrary to, the use intended by the manufacturer of a device, that has led to any complaint or problem in relation to the device, for a period of up to 10 years. (Reg 5.10)

These requirements should be reflected in the written agreement between the Australian Sponsor and Manufacturer and may also be identified in the Manufacturer's procedures.

##### **Brazil (ANVISA):**

Verify that change records include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective [RDC ANVISA 665/2022: Art. 32].

## **Chapter 1 - Management**

### Task 8 – Document and Record Controls

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Confirm that the manufacturer maintains a master list of the approved and effective documents [RDC ANVISA 665/2022: Art. 33].

Verify that electronic records and documents have backups [RDC ANVISA 665/2022: Art. 35].

#### ***Japan (MHLW):***

Confirm that Quality Management System documentation and records in relation to a device are retained for the following periods (5 years for training records and documentation). [MHLW MO169: 8, 9, 67, 68]. (1) 15 years for 'specially designated maintenance control required medical devices' [or one year plus the shelf life for products when the shelf life or the expiry date (hereinafter simply referred to as the "shelf life") plus one year exceeds 15 years]. (2) 5 years for the products other than the 'specially designated maintenance control required medical devices' (or one year plus the shelf life for the products of which the shelf life plus one year exceeds 5 years).

**Note:** The 'specially designated maintenance control required medical device' is defined as below in PMD Act 2.8:

A medical device designated by the Minister of Health, Labour and Welfare after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council as those whose potential risk to the diagnosis, treatment or prevention of disease is significant without proper control since this kind of equipment requires expert knowledge and skill in examination for maintenance and inspection, repair and other management.

#### ***United States (FDA):***

Verify that electronic records and documents have backups [21 CFR 820.180].

## **Assessing conformity**

### **Implementation of document and record control procedures**

Confirm that the medical device organization has defined, documented, and implemented procedures for control of quality management system documents and records. Evidence that these controls are effective can be ascertained through the audit of the other quality management system processes. For example, evidence that the document controls process is ineffective might be the observation of obsolete procedures being used or required records being unavailable.

Ensure at least one copy of obsolete controlled documents is maintained.

### ***Links***

None

# **Chapter 1 - Management**

## Task 9 – Management Reviews

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### **Task 9 – Management Reviews**

**Verify that procedures for management review have been documented, management reviews are being conducted at planned intervals and that they include a review of the suitability and effectiveness of the quality policy, quality objectives, and quality management system to assure that the quality management system meets all applicable regulatory requirements.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 5.6

**TGA:** TG(MD)R Sch3 P1 1.4(5)(b)(iii)(f)

**ANVISA:** RDC ANVISA 665/2022: Art. 10, Art. 11, Art. 12

**MHLW/PMDA:** MO169: 18, 19, 20

21 CFR820.20(c)]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Verify implementation of management review procedures**

It is important to verify that the medical device organization has documented and implemented effective management review procedures. Top management must review the suitability, adequacy and effectiveness of the medical device organization's quality management system at defined intervals and with sufficient frequency to ensure that the quality management system satisfies applicable requirements of Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016), Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022), Japanese QMS Ordinance (MHLW MO 169), the Quality System Regulation (21 CFR Part 820) and specific requirements of medical device regulatory authorities participating in the MDSAP program, in addition to the medical device organization's own established quality policy and objectives. The dates and results of the management reviews must be documented. These documentation requirements must be included in the management review procedure.

Other requirements commonly seen in management review procedures include a fixed agenda of topics to be discussed (with flexibility for unique agenda items to be added), the necessary attendees who are to participate in the management review, and how action items resulting from the management review are to be addressed and input into the Measurement, Analysis and Improvement process when necessary. Ensure that the quality policy and objectives have been reviewed for MDSAP AU P0002.007

## **Chapter 1 - Management**

### Task 10 – Distribution of Devices with Appropriate Marketing Authorization

continued suitability and that any changes to regulatory requirements have been identified. Other inputs to management review include results of internal and external audits, customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up actions from previous management reviews, changes that could affect the quality management system, and recommendations for improvement.

During audit of the Measurement, Analysis and Improvement process, confirm when necessary that action items resulting from Management review are considered for corrective or preventive action.

#### **Links**

[\*\*Measurement, Analysis and Improvement\*\*](#)

## **Task 10 – Distribution of Devices with Appropriate Marketing Authorization**

**Confirm that the medical device organization has defined and implemented controls to ensure that only devices that have received the appropriate marketing authorization are distributed or otherwise offered for commercial distribution into the applicable markets.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Responsibilities and authorities of personnel**

During the audit of the Management process, verify that the medical device organization has identified and documented the responsibilities of employees and personnel for ensuring proper registration, listing, licensing, notification and approval information is accurately submitted to regulatory authorities or authorized representatives (e.g. Australian Sponsor) participating in the MDSAP.

Verify that the medical device organization has identified and documented the responsibilities and authorities of personnel who are responsible for implementing controls to ensure that devices are only distributed in participating MDSAP jurisdictions where market authorizations have been obtained.

Verify that these obligations are being carried out by competent personnel.

# **Chapter 1 - Management**

## Task 10 – Distribution of Devices with Appropriate Marketing Authorization

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### **Controls to ensure appropriate market authorization**

Verify that the medical device organization has identified, documented, and implemented controls to ensure that only devices that have received market authorization are released for distribution, or otherwise offered for commercial distribution, into participating MDSAP jurisdictions where the medical device organization intends to supply the product.

Controls can include, but are not limited to:

- Change control processes that ensure that changes are assessed for their impact on existing marketing authorizations
- Procedures and/or work instructions that clearly identify the jurisdictions in which products can be sold
- Separate part numbers for devices, by jurisdictions
- Review of purchase orders to assure the customer requests and receives only product with the appropriate market clearance
- Review of sales and marketing practices and materials (including internet pages) to assure product is promoted only for markets where the product maintains appropriate market clearance
- Segregation of finished devices in warehousing and shipping areas, by jurisdictions
- Business rules in software to prevent the acceptance of purchase orders where marketing authorization is absent
- Specific language in distribution agreements limiting devices that can be distributed in certain jurisdictions
- Jurisdiction-specific marketing materials (catalogues, websites, etc.)
- The availability of accurate information on marketing authorizations obtained by jurisdiction.

The effectiveness of these controls can be verified by, for example:

- Interviewing sales and customer-support personnel
- Interviewing personnel in shipping and distribution
- Challenging sales / ERP software
- Reviewing distribution agreements
- Reviewing marketing material
- Reviewing distribution records and/or DHR records against lists of valid market authorizations.

The verification of the effectiveness of these controls should be specific to the device identifier(s) (e.g. model number) as listed in the marketing authorization(s). A broad sample covering many products and jurisdictions should be selected, particularly when reviewing distribution records.

## **Chapter 1 - Management**

### Task 11 – Top Management Commitment to Quality

In order to prepare for this audit task, audit teams should ensure that they have current lists of market authorizations held by the medical device organization as well as the names of all authorized representatives in the MDSAP jurisdictions prior to coming on site.

The appropriate application of registration, listing, licensing, notification and approval processes, and the accuracy of information for Device Marketing Authorization for submission to Regulatory Authorities or authorized representatives (e.g. Australian Sponsor) participating in the MDSAP will be verified under the Device Marketing Authorization and Facility Registration process. A preliminary review of device marketing authorization and facility registration may be made during the audit of the Management process, followed by comprehensive coverage for specific medical devices selected for review under the Design and Development process.

#### ***Links***

[\*\*Device Marketing Authorization and Facility Registration\*\*](#)

### **Task 11 – Top Management Commitment to Quality**

**At the conclusion of the audit, a decision should be made as to whether top management has demonstrated the necessary commitment to ensure a suitable and effective quality management system is in place and being maintained and whether the effectiveness of the system has been communicated to personnel.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016:4.1.1, 4.1.4, 5.1, 5.5.3

**ANVISA:** RDC ANVISA 665/2022: Art. 4°, Art. 5°, Art. 6°, Art. 7°

**MHLW/PMDA:** MO169: 5-1, 5-4, 10, 17; [Old: 5, 10, 17]

**FDA:** 21 CFR 820.20(a), 820.5]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Audit the other processes**

During the audit of the other MDSAP processes, the audit team will have the opportunity to assess whether management is appropriately carrying out its responsibilities; whether the quality policy is understood, implemented, and maintained at all levels of the medical device organization; if the

## **Chapter 1 - Management**

### Task 11 – Top Management Commitment to Quality

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necessary resources are being provided to maintain an effective quality management system; if the management representative has the necessary responsibilities and authorities; the adequacy of the organizational structure; and whether management reviews and quality audits are effective, etc.

Remember that a quality management system that has been implemented effectively, monitored to identify and address existing and potential problems, and has an integrated risk management process utilizing risk-based decision-making is more likely to produce medical devices that function as intended.

#### ***Links***

None

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

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### **Chapter 2 - Device Marketing Authorization and Facility Registration**

The Device Marketing Authorization and Facility Registration process may be audited as a linkage from the Management process and/or the Design and Development process.

#### **Auditing the Device Marketing Authorization and Facility Registration Process**

**Purpose:** The purpose of auditing the Device Marketing Authorization and Facility Registration process is to verify that the medical device organization has performed the appropriate activities regarding device marketing authorization and facility registration with regulatory authorities participating in the MDSAP.

**Outcomes:** As a result of the audit of the Device Marketing Authorization and Facility Registration process, objective evidence will show whether the medical device organization has:

- A) Complied with requirements to register and/or license device facilities
- B) Submitted device listing information to regulatory authorities when applicable
- C) Obtained device marketing authorization in the appropriate jurisdictions
- D) Arranged for assessment of changes (where applicable) and obtained marketing authorization for changes to devices or the quality management system which require amendment to existing marketing authorization

Links to Other Processes:

[\*\*Management\*\*](#); [\*\*Design and Development\*\*](#)

#### **Task 1 – Submission for Device Marketing Authorization and Facility Registration**

**Verify the medical device organization has complied with regulatory requirements to register and/or license device facilities and submit device listing information in the appropriate jurisdictions where the medical device organization markets or distributes their devices.**

#### **Assessing conformity**

In some jurisdictions, Device Market Authorization is the responsibility of the importer / Marketing Authorization Holder / Sponsor. Market Authorization however may only be appropriate if the medical

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 1 – Submission for Device Marketing Authorization and Facility Registration

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device organization and importer fulfil obligations that have been placed upon them by the relevant legislation, including obligations to each other (e.g. communications concerning feedback, adverse event reporting and the management of advisory notices and recalls).

Prior to an audit, an Auditing Organization shall independently investigate the identity and range of products, facilities and importers (e.g. Importer, MAH, Sponsor, etc.) that are known to the Regulatory Authority of each jurisdiction where the medical device organization intends to supply product.

Verify at audit, or prior to audit, that the regulatory requirements to register and/or license device facilities and submit device listing information have been appropriately applied by the Medical Device Organization for **each** Medical Device Organization / Importer arrangement. Note that some importers / MAHs / Sponsors may have provided information to Regulatory Authorities indicating that a medical device organization is the “legal manufacturer” even though the medical device organization inappropriately considers themselves to be an Original Equipment Manufacturer or an Original Device Manufacturer. A review of labelling for product being supplied to a particular jurisdiction may assist with determining if appropriate market authorization processes have been applied.

Special attention should be paid to instances where products are being marketed to MDSAP jurisdictions that marketing authorization has not been granted. This may be evident through audit of other processes, such as Design and Development.

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3

#### ***Country specific requirements***

##### ***Australia (TGA):***

Manufacturer of a medical device is the person who is responsible for the design, production, packaging and labeling of the device before it is supplied under the person’s name, whether or not it is the person, or another person acting on the person’s behalf, who carries out those operations. A manufacturer of a medical device is also the person who, with a view to supplying the device under a person’s name, does one or more of the following using ready made products: assembles, packages, processes, refurbishes, labels the device, or assigns a different intended purpose through the use of labels, instructions for use, advertising, or technical documentation (TG Act s41BG).

Australian importers (Sponsors) are required to include (register) medical devices from non-Australian Manufacturers in the Australian Register of Therapeutic Goods (ARTG). Sponsors are required to register the Manufacturers that they represent and to obtain a Client ID and Location ID for the manufacturer from the TGA.

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 1 – Submission for Device Marketing Authorization and Facility Registration

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To assist the Australian Sponsor, Manufacturers, who are supplying product to the Australian market and choose to participate in the MDSAP, must undertake the following to demonstrate that they have met the obligations on Manufacturers [TG Act s41DA(1)] who wish to supply to Australia;

- Classify the device using the Australian classification rules
- Identify from the Therapeutic Goods (Medical Devices) Regulation 2002, an Australian conformity assessment procedure that is to be applied in accordance with the classification of the device
- Select a relevant GMDN term and advise the Sponsor.
- Obtain an MDSAP audit of their QMS and their device technical documentation in accordance with this Audit Approach, for demonstrating that the QMS requirements of the selected conformity assessment procedure have been applied.
- Prepare an Australian Declaration of Conformity in accordance with the requirements of the Conformity Assessment Procedure that has been applied [TG(MD)R Sch 3 P1 Cl1.8].
- Enter into a written agreement with the Sponsor. See [Annex 4](#) for guidance on the roles and responsibilities of the Australian Sponsor and an Overseas Manufacturer

**Note:** If the manufacturer chooses to participate in the MDSAP for any reason, and product is supplied to the Australian market, the requirements for QMS in a relevant conformity assessment procedure must be included with the scope of the audit performed by a recognized MDSAP auditing organization.

**Note:** Sponsors are required to provide the Manufacturer with information in relation to the Manufacturer's obligations under a conformity assessment procedure and information in relation to whether the devices comply with the Essential Principles [TG Act 41FN(3)(e)].

Refer to following:

#### *Therapeutic Goods Act 1989*

- Part 4-2 – Essential Principles and medical device standards
- Part 4-3 – Conformity Assessment Procedures
- Part 4-5 – Including medical devices in the Register
- Part 4-9 – Public Notification and recall of medical devices
- Chapter 5 - Advertising

#### *Therapeutic Goods (Medical Devices) Regulations 2002*

- Part 5 – Division 5.2 - Conditions
- Schedule 1 – Essential Principles
- Schedule 2 – Classification Rules
- Schedule 3 – Conformity Assessment Procedures

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 1 – Submission for Device Marketing Authorization and Facility Registration

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#### **Brazil (ANVISA):**

Manufacturer means any person who designs, manufactures, assembles or processes finished devices, including those who only perform sterilization process, labeling and packaging [RDC ANVISA 665/2022: Art. 3º, section IX].

For a domestic manufacturer, confirm that the establishment has ANVISA's authorization to manufacture medical devices (AFE - Autorização de Funcionamento da Empresa). For domestic and international manufacturers, verify that the products already distributed in the Brazilian market are registered/notified with ANVISA [Brazilian Federal Law nº 6360/76].

According to Brazilian Legislation, the Good Manufacturing Practice (GMP) certification is a prerequisite for medical device registration. Therefore, the facility site inspection precedes the device registration request. Medical devices subject to notification do not need the GMP certificate, but even not being certified, their manufacturers shall comply with the GMP requirements.

#### **Medical devices registration/notification**

Device marketing authorization shall be requested to ANVISA by the domestic manufacturer or importer (legal representative) formally established in Brazil. Registration is a comprehensive process for market authorization, applied to medical devices in classes III and IV. [ANVISA RDC nº 36/2015, RDC nº 40/2015]

Notification is a simplified market authorization process, applied to all medical device classes I and II. [ANVISA RDC nº 36/2015, RDC nº 40/2015]. Registration is valid for 10 years, while notification has no expiry date. Renewal of the registration shall be requested upon time defined at Brazilian Law 6360/1976.

#### Establishment license

Domestic manufacturer: shall be authorized by ANVISA, at a minimum, as a manufacturer of medical devices. This license includes authorization to store and distribute medical devices.

Importer: the importer is considered the legal representative of the international manufacturer in Brazil and shall be authorized by ANVISA to import, store, and distribute medical devices. In the case of outsourcing the storage, the importer does not need authorization for this activity.

#### **Canada (HC):**

Manufacturer means a person who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 1 – Submission for Device Marketing Authorization and Facility Registration

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modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf [CMDR 1].

No person shall import or sell a Class II, III or IV medical device unless the manufacturer of the device holds a license in respect of that device or, if the medical device has been subjected to a change described in section 34, an amended medical device license [CMDR 26].

An application for a medical device license shall be submitted to the Minister by the manufacturer of the medical device in a format established by the Minister [CMDR 32].

An application for a medical device license shall include a copy of a quality management system certificate certifying that the quality management system under which the medical device is manufactured (class II) or designed and manufacturer (class III or IV) satisfies National Standard of Canada CAN/CSA-ISO 13485:2016. [CMDR 32(2)(f); 32(3)(j); 32(4)(p)].

#### ***Japan (MHLW):***

"Marketing Authorization Holder" means a person who resides in Japan and is granted a license for marketing from a prefectural government [PMD Act 23-2.1].

#### **Application or Notification for marketing**

*Class 2, class 3, and class 4 medical devices except for the ones specified by the requirement of PMD Act 23-2-23.1.*

An "Application for Marketing Approval" shall be submitted to PMDA by the Marketing Authorization Holder to get authorization for marketing a medical device in Japan. [PMD Act 23-2-5.1]

An "Application for QMS Audit" shall also be submitted to PMDA by the Marketing Authorization Holder, when they do not have an effective QMS Certificate for the device. [PMD Act 23-2-5.6, 7]

*Class 2 and class 3 medical devices which are specified by the requirement of PMD Act 23-2-23.1*

An "Application for Marketing Certification" shall be submitted to a Registered Certification Body (RCB) by the Marketing Authorization Holder to get authorization for marketing a medical device in Japan. [PMD Act 23-2-23.1].

An "Application for QMS Audit" shall also be submitted to an RCB by the person, when the person does not have a valid QMS Certificate for the device. [PMD Act 23-2-23.3, 4].

#### ***Class 1 medical device***

A "Notification for Marketing" shall be submitted to PMDA by the Marketing Authorization Holder for marketing a class 1 device in Japan [PMD Act 23-2-12].

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 1 – Submission for Device Marketing Authorization and Facility Registration

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A class 1 medical device doesn't need any QMS Certificate for marketing.

#### **Facility Registration (Registered Manufacturing Site)**

A medical device manufacturing site which conducts one of the designated manufacturing processes listed below shall be registered:

- Main Designing
- Main assembly
- Sterilization
- Domestic storage before final release.

The site is called "Registered Manufacturing Site". It has to submit an application to PMDA for registration by itself [PMD Act 23-2-3.1, 23-2-4].

#### ***United States (FDA):***

21 CFR 807 - Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices.

Establishment means a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed.

Owner or operator means the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering establishment.

Owner or operator must register the establishment and submit listing information to Food and Drug Administration (FDA) for those devices in commercial distribution, regardless of classification.

The registration and listing requirements must pertain to any person who:

- Initiates or develops specifications for a device that is to be manufactured by a second party for commercial distribution by the person initiating specifications
- Manufactures for commercial distribution a device either for itself or for another person; regardless of whether the manufacturer places the device into commercial distribution or returns the device to the customer
- Repackages or relabels a device
- Acts as an initial importer, except that initial importers may fulfill their listing obligation for any device for which they did not initiate or develop the specifications for the device or repackage or relabel the device by submitting the name and address of the manufacturer
- Manufactures components or accessories which are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such purpose

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 2 – Evidence of Marketing Clearance or Approval

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- Sterilizes or otherwise makes a device for or on behalf of a specification developer or any other person
  - Acts as a complaint file establishment
  - Is a device establishment located in a foreign trade zone.

#### **Links**

##### **Management**

During audit of the Management process, confirm that management is aware of and has made arrangements for device marketing authorization and facility registration.

### **Task 2 – Evidence of Marketing Clearance or Approval**

**Confirm the medical device organization has received appropriate marketing clearance or approval in the regulatory jurisdictions where the medical device organization markets their devices.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3

#### ***Country specific requirements***

##### ***Australia (TGA):***

Marketing authorization (inclusion in the Australian Register of Therapeutic Goods [ARTG]) is granted to the Australian Sponsor. The Sponsor cannot apply for marketing authorization until the Manufacturer has completed a conformity assessment procedure that is relevant for the Class of the device. Non-Australian Manufacturers will need to assist the Sponsor through the provision of information to support an application for marketing authorization and to meet the relevant conditions for on-going supply. A Sponsor is provided with a Certificate of Inclusion in the ARTG to identify the products that have been granted marketing authorization. Products with marketing authorization may be identified from the public facing ARTG database.

A Sponsor is not normally permitted to import, supply, export, or manufacture (in Australia) a medical device unless; the device complies with the essential principles, the Manufacturer has applied a relevant conformity assessment procedure, and the Sponsor has included the device in the ARTG. An exemption to allow importation and supply may be approved and granted to the Sponsor by the TGA, in cases where the TGA is satisfied that the device is to be used under a clinical trial scheme or the special access or authorized prescriber schemes. An exemption approval may contain conditions in

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 2 – Evidence of Marketing Clearance or Approval

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relation to the manufacture of the product. The Manufacturer should verify with the Australian Sponsor if any such conditions have been applied to the exemption approval.

A Manufacturer must maintain a list of their Australian Sponsors and the products those Sponsors have included in the Australian Register of Therapeutic Goods.

A Manufacturer's procedures should ensure that product is not released for supply to the Australian market unless the Sponsor has been issued with a "Certificate of Inclusion in the Australian Register of Therapeutic Goods", that identifies each kind of medical device that has been approved for supply to the Australian market [TG Act s41FJ], or the Sponsor holds a relevant exemption (TG Act Part 4-7).

As part of an application for marketing authorization a Sponsor commits to certain requirements that are identified in s41FD - "Matters to be certified". These matters include establishing a written agreement with the manufacturer about the provision of information and establishing effective communication channels for post-market activities. See [Annex 4](#) for further guidance.

#### ***Brazil (ANVISA):***

In Brazil there are two kinds of marketing clearance, registration and notification:

- Device market clearance shall be requested to ANVISA by the domestic manufacturer or importer (legal representative) formally established in Brazil. Registration is a comprehensive process for market authorization, applied to medical devices in classes III and IV. [ANVISA RDC nº 36/2015, RDC nº 40/2015].
- Notification is a simplified market authorization process, applied to all medical devices classes I and II. [ANVISA RDC nº 36/2015, RDC nº 40/2015] Registration is valid for 10 years, while notifications have no expiry date - renewal of the registration shall be requested upon time defined at Brazilian Law 6360/1976.

#### ***Canada (HC):***

No person shall import or sell a Class II, III or IV medical device unless the Manufacturer of the device holds a license in respect of that device or, if the medical device has been subjected to a change described in section 34 - an amended medical device license [CMDR 26].

#### ***Japan (MHLW):***

Any person who intends to market a medical device for business in Japan shall have a license for marketing granted by the prefectural government. This person is called a "Marketing Authorization Holder" (MAH) and shall reside in Japan [PMD Act 23-2.1]. The person has to submit an Application for Marketing Approval/Certification (class 2, 3 or 4 medical device) or a Notification for Marketing (class 1 medical device) to get marketing clearance for the medical device. No person shall market a

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 3 – Notification of Changes to Marketed Devices or to the QMS

medical device in Japan, unless the Marketing Authorization Holder of the device has been granted the marketing clearance [PMD Act 23-2-5.1, 23-2-23.1, 23-2-12].

#### ***United States (FDA):***

##### **21 CFR 807.81- Premarket Notification:**

Each person who is required to register his establishment pursuant to 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

- The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to, (i) a device in commercial distribution before May 28, 1976, or (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.
- The device is being introduced into commercial distribution for the first time by a person required to register.

##### **21 CFR 814 – Premarket Approval**

A Premarket approval is required for any FDA class III device that was not on the market (introduced or delivered for introduction into commerce for commercial distribution) before May 28, 1976, and is not substantially equivalent to a device on the market before May 28, 1976, or to a device first marketed on, or after that date, which has been classified into class I or class II.

#### ***Links***

##### **Management, Design and Development**

During the audit of the Management and Design and Development processes, ensure that management is aware of requirements for device marketing authorization and facility registration, and that these are considered when designing the device.

Confirm that management obtains marketing authorization in the appropriate jurisdictions prior to commercial distribution of the device.

### **Task 3 – Notification of Changes to Marketed Devices or to the QMS**

**Verify the medical device organization has identified changes to marketed devices or the quality management system which require notification to regulatory authorities.**

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 3 – Notification of Changes to Marketed Devices or to the QMS

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**The audit team should pay special attention to situations observed in the audit of the Design and Development process (specifically design changes) that may require notification to the jurisdictions to which the changed devices are marketed.**

#### *Clause and Regulation*

**ISO:** ISO 13485:2016: 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3, 7.3.9

#### *Country specific requirements*

##### **Australia (TGA):**

The Manufacturer is required to notify their auditing organization body of:

- A proposed change to their QMS, including the name or location of the manufacturer
- A proposed change to critical suppliers or the goods and services they provide
- A proposed change to a validated manufacturing process
- A proposed change to the kinds of medical devices to which the system is to be applied
- For Class III or AIMD, a proposed change to the design, intended performance, intended user, packaging, storage or transport conditions of a device.

Changes are to be evaluated by the Auditing Organization to determine whether a special audit is required to verify the continuing integrity of the quality management system, or whether verification of the change may occur at the next routine audit. The Auditing Organization should also verify the continuing adequacy of technical documentation as a result of the change ([see Annex 1](#))

If the Manufacturer is a holder of a TGA Conformity Assessment Certificate, then the Manufacturer is also required to notify the TGA of these changes, prior to implementation. For changes that are not considered substantial by the Manufacturer or applicant, they should be notified to the TGA at the time of recertification of an existing conformity assessment certificate, included within the scope of another conformity assessment application, or made available for the auditor during the next on site audit; whichever occurs earlier.

Examples of substantial changes that may require notification to the TGA include, but are not limited to, the following:

- Name and/or address of the Manufacturer
- Scope of existing manufacturing facilities, including manufacturing steps
- Addition or removal of a manufacturing facility along with associated activities
- Critical manufacturing process (e.g. a drug coating process, a sterilization method etc.)
- Critical supplier and/or relevant scope
- Type of conformity assessment procedure
- Device category

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 3 – Notification of Changes to Marketed Devices or to the QMS

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- Product design (e.g. materials for medical devices, storage, shelf-life, and packaging)
- Information to be provided with a medical device (e.g. intended purpose of the device in the IFU, removal of warnings, contraindications, or other information regarding safety etc.)

Refer to:

*Therapeutic Goods (Medical Devices) Regulations 2002*

- Regulation 3.5 – Medical devices manufactured outside Australia
- Schedule 3 - The relevant conformity assessment procedure chosen by the Manufacturer

**Note:** An entry in the Australian Register of Therapeutic Goods (inclusion) in the name of the Australian Sponsor is in effect until cancelled.

#### **Brazil (ANVISA):**

Changes involving medical devices already approved by ANVISA, shall be submitted for a new approval [Brazilian Law nº 6360/76 - Art. 13]. Changes/modifications that shall be submitted are those ones classified as significant change, which affects:

- features of safety and effectiveness, including measures to communicate information (ex. residual risk)
- identification of the device or its manufacturer or manufacturing site
- indication for use, including its purpose, patient type (adult, pediatric, newborn) or environment to be used (domestic, hospital, ambulance, etc.)
- device classification
- technical specification of the device, including composition and other operational/technical/physical features
- manufacturing method.

Examples of modifications that may require a submission include, but are not limited to, the following:

- Sterilization method
- Structural material / composition
- New or additional manufacturer
- Manufacturing method
- Manufacturing site
- Operating parameters or conditions for use
- Patient or user safety features
- Sterile barrier packaging material
- Stability or expiration claims
- Design

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 3 – Notification of Changes to Marketed Devices or to the QMS

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- Labels and instructions of use (if modification is regarding information)
- Commercial name
- Indication for use
- New software version
- Commercial presentation
- Inclusion of a new device in a family of medical devices already approved
- Inclusion of new accessories.

#### ***Canada (HC):***

If the Manufacturer proposes to make one or more changes, the Manufacturer shall submit to the Minister, in a format established by the Minister, an application for a medical device license amendment including the information and documents set out in section 32 that are relevant to the change [CMDR 34].

Every Manufacturer of a licensed medical device shall, annually before November 1 and in a form authorized by the Minister, furnish the Minister with a statement signed by the Manufacturer or by a person authorized to sign on the Manufacturer's behalf describing any change to the information and documents supplied by the Manufacturer with respect to the device, other than those to be submitted under section 34 or 43.1 [CMDR 43].

If the holder of a medical device license discontinues the sale of the medical device in Canada, the licensee shall inform the Minister within 30 days after the discontinuance, and the license shall be cancelled at the time that the Minister is informed [CMDR 43(3)].

Subject to section 34, if a new or modified quality management system certificate is issued in respect of a licensed medical device, the Manufacturer of the device shall submit a copy of the certificate to the Minister within 30 days after it is issued [CMDR 43.1].

#### ***Japan (MHLW):***

A change to a medical device which is approved/certified by PMDA/a Registered Certification Body may require the Marketing Authorization Holder to submit a new application, a change application, or a change notification [PMD Act 23-2-5.1, 23-2-5.11, 23-2-5.12, 23-2-23.1, 23-2-23.6, 23-2-23.7].

Changes that require the application or the notification are those ones which directly impact the safety and efficacy of the device and/or the substantial identity of the fact approved during marketing approval / certification.

The Registered Manufacturing Site shall communicate with the Marketing Authorization Holder about the change when the Registered Manufacturing Site plans such changes, so that the Marketing

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 3 – Notification of Changes to Marketed Devices or to the QMS

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Authorization Holder could take any necessary regulatory actions mentioned above [MHLW MO169: 29].

Examples of changes that may require an application or a notification include, but are not limited to, the following:

- Design
- Composition
- Raw material
- Sterilization method
- Manufacturing method
- Manufacturing site
- Patient or user safety features
- Operating Parameters or conditions for use
- Indication for use
- Shelf life
- Performance Specification.

#### ***United States (FDA):***

21 CFR 807 - Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices.

Update the device listing information during each June and December or, at its discretion, at the time the change occurs. Conditions that require updating and information to be submitted for each of these updates are as follows:

- If an owner or operator introduces into commercial distribution a device identified with a classification name not currently listed by the owner or operator
- If an owner or operator discontinues commercial distribution of all devices in the same device class

Update registration if changes in individual ownership, corporate or partnership structure, or location of at the time of annual registration, or by letter if the changes occur at other times. This information must be submitted within 30 days of such changes. Changes in the names of officers and/or directors of the corporation(s) must be filed with the establishment's official correspondent and must be provided to the Food and Drug Administration upon receipt of a written request for this information.

#### 21 CFR 807.81- Premarket Notification:

A new complete 510(k) application is usually required for changes or modifications to an existing device, where the modifications could significantly affect the safety or effectiveness of the device, or

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

### Task 3 – Notification of Changes to Marketed Devices or to the QMS

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the device is to be marketed for a new or different indication. Most changes in indications for use require the submission of a 510(k).

Examples of modifications that may require a 510(k) submission include, but are not limited to, the following:

- Sterilization method
- Structural material
- Manufacturing method
- Operating parameters or conditions for use
- Patient or user safety features
- Sterile barrier packaging material
- Stability or expiration claims
- Design.

### **21 CFR 814.39 – PMA Supplements**

After FDA's approval of a PMA, an applicant must submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:

- New indications for use of the device
- Labeling changes
- The use of a different facility or establishment to manufacture, process, or package the device
- Changes in sterilization procedures
- Changes in packaging
- Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device
- Extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol that has not been approved by FDA
- An applicant may make a change in a device after FDA's approval of a PMA for the device without submitting a PMA supplement if the change does not affect the device's safety or effectiveness and the change is reported to FDA in post approval periodic reports required as a condition to approval of the device, e.g., an editorial change in labeling which does not affect the safety or effectiveness of the device.

## **Chapter 2 - Device Marketing Authorization and Facility Registration**

Task 3 – Notification of Changes to Marketed Devices or to the QMS

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### ***Links***

#### **Design and Development**

During the audit of the Design and Development process, the audit team should confirm the medical device organization has considered regulatory requirements for device marketing authorization and facility registration; and has complied with these requirements prior to marketing the changed device in the applicable regulatory jurisdictions.

## **Chapter 3 - Measurement, Analysis and Improvement**

### **Chapter 3 - Measurement, Analysis and Improvement**

One of the most important activities in the quality management system is the identification of existing and potential causes of product and quality problems. Such causes must be identified so that appropriate and effective corrective or preventive actions can take place. These activities are carried out under the Measurement, Analysis and Improvement process.

The purpose of a medical device organization's Measurement, Analysis and Improvement process is to collect and analyze information, identify and investigate existing and potential causes of product and quality problems, and take appropriate and effective corrective or preventive action to prevent recurrence or occurrence. It is essential that a medical device organization verify or validate these actions, communicate corrective and preventive action activities to responsible people, provide relevant information for management review, and document these activities. These activities will help the medical device organization deal effectively with existing or potential product and quality problems, prevent their recurrence and/or occurrence, and prevent or minimize device failures or other quality problems.

The **management representative** is responsible for ensuring that the requirements of the quality management system have been effectively defined, documented, implemented, and maintained. Prior to the audit of a process, it may be helpful to interview the management representative (or designee) to obtain an overview of the process and a feel for management's knowledge and understanding of the process.

The Measurement, Analysis and Improvement process is the second primary process to be audited per the MDSAP audit sequence. When applicable, information regarding device or identified quality management system nonconformities observed during the audit of the Measurement, Analysis and Improvement process should be used to make decisions as to design projects or design changes to assess during audit of the Design and Development process, suppliers to evaluate during audit of the Purchasing process, and processes to review during audit of the Production and Service Controls process.

### **Auditing the Measurement, Analysis and Improvement Process**

**Purpose:** The purpose of auditing the Measurement, Analysis and Improvement process is to verify that the medical device organization's processes ensure that information related to products, process/es, or the quality management system is collected and analyzed to identify actual and potential product, process, or quality system nonconformities, that problems and potential problems are investigated, and that appropriate and effective corrective actions and preventive actions are taken.

## **Chapter 3 - Measurement, Analysis and Improvement**

Task 1 – Procedures for Measurement, Analysis, and Improvement of QMS Effectiveness and Product Conformity

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**Outcomes:** As a result of the audit of the Measurement, Analysis and Improvement process, objective evidence will show whether the medical device organization has:

- A) Defined, documented, and implemented procedures for measurement, analysis and improvement that address the requirements of the quality management system standard and participating MDSAP regulatory authorities
- B) Identified, analyzed, and monitored appropriate sources of quality data to identify nonconformities or potential nonconformities and determined the need for corrective or preventive action
- C) Ensured investigations are conducted to identify the underlying cause(s) of nonconformities and potential nonconformities, where possible
- D) Implemented appropriate corrective action to eliminate the recurrence or preventive action to prevent the occurrence of product or quality system nonconformities, commensurate with the risks associated with the nonconformities or potential nonconformities encountered
- E) Reviewed the effectiveness of corrective action and preventive action
- F) Utilized information from the analysis of production and post-production quality data to amend the analysis of product risk, as appropriate

Links to Other Processes:

Design and Development; [\*\*Production and Service Controls\*\*](#); [\*\*Purchasing\*\*](#); Medical Device Adverse Events and Advisory Notices Reporting; Management

### **Task 1 – Procedures for Measurement, Analysis, and Improvement of QMS Effectiveness and Product Conformity**

**Verify that procedures for measurement, analysis and improvement which address the requirements of the quality management system standard and regulatory authorities have been established and documented.**

**Confirm the medical device organization maintains and implements procedures to monitor and measure product conformity throughout product realization, as well as procedures that provide for mechanisms for feedback to provide early warnings of quality problems and the implementation of corrective action and preventive action.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 8.1, 8.2.1, 8.2.6, 8.5

**TGA:** TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f)

## **Chapter 3 - Measurement, Analysis and Improvement**

Task 1 – Procedures for Measurement, Analysis, and Improvement of QMS Effectiveness and Product Conformity

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**ANVISA:** RDC ANVISA 665/2022: Art. 88, Art. 120, Art. 121

**MHLW/PMDA:** MO169: 6, 54, 55-1, 58, 59, 62, 63, 64; [Old: 6, 54, 55, 58, 59, 62, 63, 64]

**FDA:** 21 CFR 820.100(a)]

### ***Additional country-specific requirements:***

#### **Brazil (ANVISA):**

Verify that the manufacturer has ensured that information about quality problems or nonconforming products are properly disseminated to those directly involved in the maintenance of product quality and to prevent occurrence of such problems [RDC ANVISA 665/2022: Art. 120 section VI].

#### **United States (FDA):**

Verify procedures ensure that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of problems [21 CFR 820.100(a)(6)].

Confirm procedures provide for the submission of relevant information on identified quality problems, as well as corrective and preventive actions, for management review [21 CFR 820.100(a)(7)].

## **Assessing conformity**

### **Procedures**

Each medical device organization must establish and maintain procedures for analyzing data and implementing corrective action and preventive action. The procedures must include requirements for:

- Analyzing feedback, conformity to product requirements, characteristics and trends of processes and products (including opportunities for preventive action), and conformity of suppliers
- Reviewing nonconformities, including customer complaints
- Evaluating the need for action to prevent recurrence or occurrence of nonconformities
- Recording the results of any investigations and of actions taken
- Identifying the action(s) needed to correct and prevent recurrence or occurrence of nonconforming product and other quality problems
- Ensure that action is effective and does not adversely affect the finished device
- Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems
- Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 2 – Sources of quality data

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#### **Task 2 – Sources of quality data**

**Determine if appropriate sources of quality data have been identified and analyzed according to a documented procedure for use the use of valid statistical methods (where appropriate) for input into the measurement, analysis and improvement process, including customer complaints, feedback, service records, returned product, internal and external audit findings, nonconformities from regulatory audits and inspections, and data from the monitoring of products, processes, nonconforming products, and suppliers.**

**Information from the organization's analysis of quality data should be used to inform the audit team's decision as to specific complaint records to review in Task 12, and products and processes to audit during the Design and Development, Production and Service Controls, and Purchasing processes.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 7.5.4, 8.1, 8.2.1, 8.2.6, 8.4

**TGA:** TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f)

**ANVISA:** RDC ANVISA 665/2022: Art. 120 section I, Art. 131

**MHLW/PMDA:** MO169: 43, 54, 55-1, 58, 59, 61; [Old: 43, 54, 55, 58, 59, 61]

**FDA:** 21 CFR 820.100(a)]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Quality data sources**

Complaints, records of acceptance activities and concessions, nonconformities identified in internal audits, service records, acceptability of supplied product and supplier performance, and data presented in management review are common quality data sources that are useful in identifying quality problems, among others.

Some sources of quality data that may be useful in identifying potential problems are acceptance activities, such as component, in-process, or finished device testing; environmental monitoring, and statistical process control (SPC). Results of acceptance activities may indicate an unfavorable trend that left unattended may result in product nonconformity.

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 2 – Sources of quality data

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During the audit of the Measurement, Analysis and Improvement process, it is recommended that the auditor(s) review the previous audit report if there is one for the medical device organization. If this information is available, the audit team should use the information in the report when selecting some quality data sources to review during the audit. For example, if service records were reviewed during the previous audit and the medical device organization handled the data appropriately, the audit team may wish to select a different data source for review during the audit.

However, if the previous audit documented that the data from service records were not being entered into the Measurement, Analysis and Improvement process appropriately, the audit team should consider reviewing service records again to determine whether the previous deficiency was effectively addressed:

- Select some sources of quality data
- Determine if the data from these sources were entered into the medical device organization's Measurement, Analysis and Improvement process for analysis and whether the information was complete, accurate, and entered in a timely fashion
- Be mindful of quality problems that appear in more than one data source. For example, device nonconformities noted in complaints should be compared with similar nonconformities noted during the medical device organization's analysis of data from other data sources such as product reject reports, or nonconforming product or process reports.

This comparison will help the medical device organization and the audit teams understand the full extent of the quality problem.

### **Analysis of data**

A medical device organization should use data from a variety of quality data sources to identify the causes of existing product and quality problems. Not all organizations will have the same sources of quality data. For example, service records and installation reports are quality data sources that may not be found at every medical device organization.

As the audit team is conducting the audit, determine what sources of quality data the medical device organization has identified. The audit team will also determine whether the sources identified by the medical device organization are appropriate and if the medical device organization is analyzing quality data from these sources to identify existing product problems as well as existing problems within its quality system.

Later in the evaluation of the Measurement, Analysis and Improvement process, the audit team will be sampling raw quality data to determine how the medical device organization analyzed the quality data and responded to the results of its analysis.

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 3 – Investigation of Nonconformity

A medical device organization should also use data from a variety of quality data sources to identify the causes of potential product and quality problems. The medical device organization should be looking for trends or other indications of potential problems before the problems actually occur. The medical device organization may choose to perform analysis of competing devices, including reviewing advisory notices related to competing devices, to determine whether similar nonconformities could occur in the medical device organization's devices.

Determine whether the medical device organization can identify potential product and quality problems that may require preventive action.

A medical device organization has the flexibility to use whatever methods of analysis are appropriate to identify existing and potential causes of nonconforming product or other quality problems. However, a medical device organization must use appropriate statistical methodology where necessary to detect recurring quality problems.

A medical device organization must also use appropriate statistical tools when it is necessary to use statistical methodology. It should not misuse statistics in an effort to minimize the problem or avoid addressing the problem.

#### **Links**

##### **Purchasing**

During the audit of the Measurement, Analysis and Improvement process, the audit team may encounter data involving product nonconformities, including complaints involving finished devices, where the underlying cause of the quality problem has been traced to supplied product.

During the audit of the Purchasing process, the audit team should consider selecting suppliers to audit that have corrective action indicators of nonconformities with supplied components or processes.

### **Task 3 – Investigation of Nonconformity**

**Determine if investigations are conducted to identify the underlying cause(s) of detected nonconformities, where possible.**

***Confirm investigations are commensurate with the risk of the nonconformity.***

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 8.5.2

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 3 – Investigation of Nonconformity

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**TGA:** TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii),(f), TG(MD)R Sch1 P1 2

**ANVISA:** RDC ANVISA 665/2022: Art. 116, Art. 120 section II

**MHLW/PMDA:** MO169: 63

**FDA:** 21 CFR 820.100 (a)(2)]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Investigations of nonconformities**

Organizations must define and implement a process for investigations. The process should consist of a structured, risk-based approach (in a mature QS) intended to determine the root or underlying cause(s) of a quality problem. Criteria should be defined to determine when an investigation is necessary and the extent of the investigation. The investigation should be based on a pre-approved plan or other defined approach, timelines should be defined, roles and responsibilities should be assigned, and the course of action should be assessed when the underlying cause cannot be determined. The results of the investigation must be recorded. The depth of the medical device organization's investigation of a process, product, or other quality system nonconformity should be commensurate with the significance and risk of the nonconformity. The process for determining the extent of an investigation may be linked to the medical device organization's risk management system and the design outputs essential to the proper functioning of the device.

A correction is not the same as a corrective action.

In order for a medical device organization to take a corrective action (i.e., action taken to prevent recurrence of an existing nonconformity), an investigation must be conducted to determine the cause of the nonconformity. Often a medical device organization will only make a correction to handle the immediate problem (e.g. relabeling a lot of mislabeled finished devices). Determining the cause of the lot of mislabeled finished devices is more difficult and may be overlooked. Where possible, the medical device organization should identify the underlying cause or causes of the nonconformity so that appropriate corrective action can be taken.

### **Selecting records**

When selecting records of investigations to review, be mindful of the risk of the nonconformity to the product or process. Select records of investigations where the nonconformity has a higher risk of adversely affecting the ability of the finished device to meet its essential design outputs or the nonconformity affects the safety and efficacy of the product.

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 4 – Investigation of Potential Nonconformity

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#### ***Links***

None

### **Task 4 – Investigation of Potential Nonconformity**

**Determine if investigations are conducted to identify the underlying cause(s) of potential nonconformities, where possible.**

***Confirm investigations are commensurate with the risk of the potential nonconformity.***

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 8.5.3

**TGA:** TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii),(f),TG(MD)R Sch1 P1 2

**ANVISA:** RDC ANVISA 665/2022: Art. 120 section I

**MHLW/PMDA:** MO169: 64

**FDA:** 21 CFR 820.100(a)(2)]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Investigations of potential nonconformities**

The depth of the medical device organization's investigation into potential process, product, or other quality system nonconformities should be commensurate with the risk of the nonconformity if it were to occur. The process for determining the extent of an investigation may be linked to the medical device organization's risk management system and outputs essential to the proper functioning of the device.

### **Selecting records**

When selecting records of investigations to review, be mindful of the risk of the potential nonconformity to the product or process. Select records of investigations where the potential nonconformity has a higher risk of adversely affecting the ability of the finished device to meet its essential design outputs or the potential nonconformity could affect the safety and efficacy of the product.

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 5 – Correction, Corrective Action, and Preventive Action

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#### **Links**

None

### **Task 5 – Correction, Corrective Action, and Preventive Action**

**Confirm that corrections, corrective actions, and preventive actions were determined, implemented, documented, effective, and did not adversely affect finished devices.**

**Ensure corrective action and preventive action is appropriate to the risk of the nonconformities or potential nonconformities encountered.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 8.2.1, 8.2.5, 8.3.1, 8.5.2, 8.5.3

**TGA:** TG(MD)R Sch1 P1 2, TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f)

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 116, Art. 120 sections II, II, IV, V

**MHLW/PMDA:** MO169: 55-1, 57, 60-1, 63, 64; [Old: 55, 57, 60, 63, 64]

**FDA:** 21 CFR 820.100(a)(3), 820.100 (a)(4), 820.100(a)(6), 820.100(b)]

#### ***Additional country-specific requirements***

None

### **Assessing conformity**

#### **Determining the extent of actions**

Corrective actions taken by a medical device organization can vary depending on the situation.

Corrective actions are intended to correct and also prevent recurrence of not only nonconforming product but also poor practices, such as inadequate training.

In developing corrective action addressing nonconforming product, the medical device organization should consider corrections to be taken regarding the affected products, whether distributed or not. Corrections and corrective actions must be commensurate with the risk associated with the nonconformity.

The audit team may encounter situations where a quality problem has been identified, but the medical device organization's management has decided not to undertake corrective actions. Confirm that the medical device organization's decision not to take corrective action has been made using appropriate risk-based decision making, including a determination that the finished device meets risk acceptability criteria.

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 6 – Assessment of Design Change resulting from Corrective or Preventive Action

#### **Determining the effectiveness of actions**

During the audit of the Measurement, Analysis and Improvement process, review the mechanisms by which the medical device organization assessed effectiveness of the corrective and preventive actions. Compare the records of significant and/or higher risk corrective actions and preventive actions to the medical device organization's product and quality data analyses, such as trend results. Look for product or quality problems or trends that continued or began after the actions were implemented. This may indicate that the corrective actions or preventive actions were not effective.

Review how the medical device organization has determined that the actions do not adversely affect the finished device(s).

#### **Links**

##### **[Medical Device Adverse Events and Advisory Notices Reporting](#)**

Determine whether any of the medical device organization's corrective actions require reporting to participating MDSAP authorities.

## **Task 6 – Assessment of Design Change resulting from Corrective or Preventive Action**

***When a corrective or preventive action results in a design change, verify that any new hazard(s) and any new risks are evaluated under the risk management process.***

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 7.1, 7.3.9

**TGA:** TG(MD)R Sch1 P1 2

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 60

**MHLW/PMDA:** MO169: 26, 36-1; [Old: 26, 36]

**FDA:** 21 CFR 820.30(i), 820.30(g)

#### ***Additional country-specific requirements***

None

## **Chapter 3 - Measurement, Analysis and Improvement**

Task 7 – Assessment of Process Change resulting from Corrective or Preventive Action

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### **Assessing conformity**

#### **Design change**

Completing this audit task may involve linkages to other subsystems. Verification and validation are important elements in assuring that corrective actions and preventive actions that result in design changes are effective and do not introduce new hazards.

#### **Links**

##### **Design and Development**

If the corrective action or preventive action involves changing the design, design controls should be applied to the change where applicable.

When necessary, confirm that design controls were applied to the change according to the medical device organization's procedures.

In addition, design changes should be evaluated under the medical device organization's risk management process to ensure that changes do not introduce new hazards.

## **Task 7 – Assessment of Process Change resulting from Corrective or Preventive Action**

***When a corrective or preventive action results in a process change, confirm that the process change is assessed to determine if any new risks to the product are introduced.***

**Verify the medical device organization has performed revalidation of processes where appropriate.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.1.2, 4.1.4, 4.1.6, 4.2.1, 7.1, 7.5.2, 7.5.6, 7.5.7

**TGA:** TG(MD)R Sch1 P1 2; Sch3 P1 1.5(4)

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 106, Art. 120

**MHLW/PMDA:** MO169: 5-2, 5-4, 5-6, 6, 26, 41, 45, 46; [Old: 5, 6, 26, 41, 45, 46]

**FDA:** 21 CFR 820.100(a)(4), 820.100(a)(5), 820.70(b), 820.75(c)

#### ***Additional country-specific requirements***

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 7 – Assessment of Process Change resulting from Corrective or Preventive Action

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#### **Australia (TGA):**

Confirm that the Manufacturer's procedure for dealing with substantial changes to a critical process (e.g. sterilization, processing materials of animal origin, processing materials of microbial or recombinant origin, or processes that incorporate a medicinal substance in a medical device), requires the Manufacturer to notify the Auditing Organization of their plans before implementing a change to a critical process. The Auditing Organization is to assess the proposed change before implementation by the Manufacturer, to determine if the requirements of the relevant conformity assessment procedure will still be met after the change. [TG(MD)R Sch3 P1 1.5(2)].

If the Manufacturer is also a holder of a TGA Conformity Assessment Certificate, then the Manufacturer is also required to notify the TGA of these changes, prior to implementation.

#### **Canada (HC):**

Verify that the Manufacturer has a process or procedure for identifying a "significant change" to a class III or IV device. Verify that information about "significant changes" is submitted in a medical device license amendment application [CMDR 1, 34].

#### **Japan (MHLW):**

Confirm that when the Registered Manufacturing Site plans to make a significant change to a manufacturing processes (e.g. sterilization site change, manufacturing site change), the Registered Manufacturing Site notifies the Marketing Authorization Holder so as the Marketing Authorization Holder can take appropriate regulatory actions [MHLW MO169: 29].

## **Assessing conformity**

### **Process changes**

Completing this audit task may involve linkages to other quality management system processes. Production processes require at least some degree of qualification, verification, or validation. If the change involves a validated process, review the medical device organization's evaluation of the process change to determine if re-validation is needed.

For changes to production processes that are performed by suppliers, the audit team should consider selecting those suppliers for evaluation during audit of the Purchasing process. In cases where the medical device organization makes a change to a validated process performed by a supplier, the audit team should evaluate whether re-validation is required. If re-validation of production processes is required, confirm the results show the process meets the planned result.

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 8 – Identification and Control of Nonconforming Product

#### **Links**

##### **Production and Service Controls, Purchasing**

If the corrective action or preventive action involves changing a production process, the audit team should consider selecting this change for evaluation during audit of Production and Service Controls.

### **Task 8 – Identification and Control of Nonconforming Product**

**Verify that controls are in place to ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.**

**Confirm that an appropriate disposition was made, justified, and documented and that any external party responsible for the nonconformity was notified.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 8.3.1, 8.3.2

**TGA:** TG(MD)R Sch3 P1 1.4(5)(b)(iii)

**ANVISA:** RDC ANVISA 665/2022: Art. 117, Art. 118, Art. 120 section VI

**MHLW/PMDA:** MO169: 60-1, 60-2; [Old: 60]

**FDA:** 21CFR 820.90(a)

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Nonconforming product**

The audit team should review procedures and controls for preventing the unintended distribution of nonconforming product. The auditor(s) may choose to select a sample of records involving nonconforming product that was in stock or returned to review how the procedures and controls were applied to control the nonconforming product.

Confirm the medical device organization has established and maintained procedures that define the responsibility for review and the authority for the disposition of nonconforming product, as well as the

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 9 – Action Regarding Nonconforming Product Detected After Delivery

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execution of the review and disposition process. Disposition of nonconforming product must be documented.

The audit team may encounter situations where the medical device organization's management has decided to authorize the use of nonconforming product under concession. Documentation must include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use. Confirm that the medical device organization's decision to use nonconforming product under concession has been made using appropriate risk-based decision making, including a determination that the finished device meets specified requirements. Be mindful of instances where the use of nonconforming product under concession has led to devices not meeting specifications.

#### **Selecting records**

When selecting records of nonconforming products to review, be mindful of the risk of the nonconformity to the finished device and the patient or user. Select records of nonconforming products to review where the nonconformity has a higher risk of adversely affecting the ability of the finished device to meet its essential design outputs or the nonconformity affects the safety and efficacy of the product.

#### **Links**

None

### **Task 9 – Action Regarding Nonconforming Product Detected After Delivery**

**Confirm that when nonconforming product is detected after delivery or use, appropriate action is taken commensurate with the risk, or potential risks, of the nonconformity.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 8.3.3, 8.5.2

**TGA:** TG(MD)R Sch1 P1 2, TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f)

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 120 section VIII

**MHLW/PMDA:** MO169: 60-3, 63; [Old: 60, 63]

**FDA:** 21 CFR 820.100(a)]

#### ***Additional country-specific requirements***

None

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 10 – Internal Audit

#### **Assessing conformity**

##### **Control and action based on risk**

During this audit task, confirm that the medical device organization has determined the control and actions to be taken on nonconforming products detected after delivery or use, commensurate with the risk associated with a product failure.

While it may not be necessary for the medical device organization to recall nonconforming product from distribution as part of its identified actions needed to correct and prevent recurrence of the problem, confirm that the decision is made using an adequate risk justification.

#### **Links**

##### **Medical Device Adverse Events and Advisory Notices Reporting**

If the medical device organization has taken field action on products already distributed, confirm that the appropriate MDSAP regulatory authorities have been notified, as necessary.

### **Task 10 – Internal Audit**

**Verify that internal audits of the quality management system are being conducted according to planned arrangements and documented procedures to ensure the quality management system is in compliance with the established quality management system requirements and applicable regulatory requirements, and to determine the effectiveness of the quality system.**

**Confirm that the internal audits include provisions for auditor training and independence over the areas being audited, corrections, corrective actions, follow-up activities, and the verification of corrective actions.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 6.2, 8.2.4

**TGA:** TG(MD)R Sch3 P1 1.4(5)(b)(iii)

**ANVISA:** RDC ANVISA 665/2022: Art. 122, Art. 123, Art. 124

**MHLW/PMDA:** MO169: 22, 23, 56

**FDA:** 21 CFR 820.22, 820.100

#### ***Additional country-specific requirements***

None

MDSAP AU P0002.007

# **Chapter 3 - Measurement, Analysis and Improvement**

## Task 10 – Internal Audit

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### **Assessing conformity**

#### **Internal audits**

Internal audits are systematic, independent examinations of a medical device organization's quality management system that are performed at defined intervals and at sufficient frequency to determine whether both quality management system activities and the results of such activities comply with quality management system procedures. Internal audits should also determine whether these procedures are implemented effectively and whether they are suitable to achieve quality management system objectives.

#### **Auditors**

Internal audits are to be conducted according to established procedures by appropriately trained individuals not having direct responsibility for the matters being audited. If possible, interview auditors and ask how audits are conducted, how long audits typically last, what documents are typically reviewed, etc.

#### **Requirements**

Internal audit procedures typically include requirements for auditor qualifications, requirements for the frequency of audits, specified functional areas to be audited, and audit plans (or the requirement to establish audit plans prior to the audit). Procedures should also include requirements for:

- How audit activities and results are to be communicated, addressed, and followed up (including re-audit, if necessary) and,
- How audit activities are to be documented.

#### **Review and documentation**

Management having responsibility for the matters audited must review the report of the quality audit. The dates and results of all quality audits (and subsequent re-audits, if necessary) must be documented, as well as any corrective or preventive actions resulting from the internal audits.

#### **Links**

##### **Management**

During the audit of the Management process, the audit team should confirm that the output of internal audits is an input to management review.

## **Chapter 3 - Measurement, Analysis and Improvement**

Task 11 – Information Supplied for Management Review

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### **Task 11 – Information Supplied for Management Review**

**Determine if relevant information regarding nonconforming product, quality management system nonconformities, corrections, corrective actions, and preventive actions has been supplied to management for management review.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 5.6.2

**TGA:** TG(MD)R Sch3 P1 1.4(5)(b)(iii)

**ANVISA:** RDC ANVISA 665/2022: Art. 12, Art. 120 section VII

**MHLW/PMDA:** MO169: 19

**FDA:** 21 CFR 820.100 (a)(7)]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Management review**

During the performance of this audit task, the auditor(s) may choose to select a recent, significant corrective or preventive action and determine which records or information regarding the event was submitted for management review.

#### ***Links***

##### **Management**

During the audit of the Management process, the audit team should have confirmed that the status of corrective and preventive actions is an input to the management review.

During the audit of the Measurement, Analysis and Improvement process, determine if top management is aware of higher-risk quality problems, as well as significant corrective and preventive actions, when necessary.

## **Chapter 3 - Measurement, Analysis and Improvement**

Task 12 – Evaluation of Information from Post-Production Phase, Including Complaints

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### **Task 12 – Evaluation of Information from Post-Production Phase, Including Complaints**

**Confirm that the medical device organization has made effective arrangements for gaining experience from the post-production phase, including postmarket surveillance, handling complaints, and investigating the cause of nonconformities related to advisory notices with provision for feedback into the Measurement, Analysis and Improvement process.**

**Select records of complaints for review that represent the highest risk to the user or have the largest impact on the ability of the device to meet its essential design outputs.**

***Verify that information from the analysis of production and post-production quality data was considered for amending the analysis of product risk, as appropriate.***

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 7.2.3, 7.5.4 (a), 8.2.1, 8.2.2, 8.5.1

**TGA:** TG(MD)R Sch1 P1 2, Sch3 P1 1.4(3), 1.4(5)(b)(iii) &1.4(5)(f)

**ANVISA:** RDC ANVISA 665/2022: Art. 121

**HC:** CMDR 57-58, 61.4-61.6

**MHLW/PMDA:** MO169: 6, 29, 43, 55-1, 55-2, 62; [Old: 6, 29, 43, 55, 62]

**FDA:** 21 CFR 820.198]

#### ***Additional country-specific requirements***

##### ***Australia (TGA):***

Verify that the medical device organization has procedures for a post-marketing system that includes a systematic review of post-production experience (e.g. from; expert user groups, customer surveys, customer complaints and warranty claims, service and repair information, literature reviews, post-production clinical trials, user feedback other than complaints, device tracking and registration schemes, user reactions during training, adverse event reports). Investigation should take place in a timely manner to ensure that reporting timeframes for adverse events or the implementation of advisory notices (recalls) may be met by the Australian Sponsor [TG(MD)R Sch3 P1 1.4(3)(a)].

**Note:** In Australia the conduct of a recall is the responsibility of the Australian Sponsor in accordance with the Australian Uniform Recall Procedure for Therapeutic Goods.

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 12 – Evaluation of Information from Post-Production Phase, Including Complaints

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#### **Brazil (ANVISA):**

Verify that each manufacturer has established and maintains procedures to receive, examine, evaluate, investigate and document complaints. Such procedures must ensure that:

- Complaints are received, documented, analyzed, evaluated, investigated and documented by a formally designated unit
- Where applicable, complaints must be reported to the competent health authority
- Complaints must be examined to determine whether an investigation is necessary. When an investigation is not done, the unit must maintain a record that includes the reason that the investigation was not performed and the name of the persons responsible for the decision.
- Each manufacturer must examine, evaluate and investigate all complaints involving possible nonconformities of the product. Any claim for death, injury or threat to public health must be immediately reviewed, evaluated and investigated.
- The records of the investigation must include:
- Product name
- Date of receipt of the complaint
- Any control number used
- Name, address and telephone number of the complainant
- Nature of complaint
- Data and research results including actions taken [RDC ANVISA 665/2022: Art. 121].

#### **Canada (HC):**

Verify that the Manufacturer maintains records of reported problems related to the performance characteristics or safety of a device, including any consumer complaints received by the Manufacturer after the device was first sold in Canada, and all actions taken by the Manufacturer in response to the problems referred to in the complaints [CMDR Section 57].

Verify that the Manufacturer has established and implemented documented procedures that will enable it to carry out an effective and timely investigation of the problem reports through the customer complaints, and to carry out an effective and timely recall of the device [CMDR Section 58].

Verify that the Manufacturer has established and implemented documented procedures for preparing summary reports with respect to information received or of which they became aware:

- During the previous 24 months for class II medical devices; and

During the previous 12 months for class III and IV medical devices. CMDR 61.4(1)]

## **Chapter 3 - Measurement, Analysis and Improvement**

Task 12 – Evaluation of Information from Post-Production Phase, Including Complaints

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Verify that summary reports cover:

- Adverse effects;
- Reported problems and complaints;
- Reportable incidents in accordance with section 59(1);

Serious risks of injury to human health that are relevant to the safety of the medical device in accordance with section 61.2(2). [CMDR 61.4(2)]

Verify that the summary report includes a concise critical analysis of the information required in section 61.4(2)

[CMDR 61.4(3)]

Verify that the manufacturer has determined, based on the analysis of data, whether what is known about the benefits and risks associated with the medical device has changed as follows:

- Any of the benefits that may be obtained by patients through the use of the medical device could be less;
- In respect of any of the risks:
  - the risk is more likely to occur; or,
  - if the risk occurs, the consequences for the health and safety of patients, users or other persons could be more serious.
- a new risk has been identified.

Verify that the manufacturer has included the conclusions drawn from the above-mentioned analysis in the summary report.

[CMDR 61.4(4)&(5)]

Verify that the manufacturer has notified the Minister in writing within 72 hours after concluding that what is known about the benefits and risks associated with the medical device has changed. [Note: Refer to the guidance document "[\*\*Guidance on summary reports and issue-related analyses for medical devices: Summary reports\*\*](#)" for instructions for reporting to the Minister.]

[CMDR 61.4(6)]

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 12 – Evaluation of Information from Post-Production Phase, Including Complaints

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Verify that the manufacturer retains records of the summary reports, the information used in the preparation of the reports, and any associated notification to the Minister for seven years after the day on which they are created.

[CMDR 61.6]

#### ***Japan (MHLW/PMDA):***

Confirm that the person operating the Registered Manufacturing Site has determined and implemented effective arrangement for communicating with the Japanese Marketing Authorization Holder in relation to customer feedback, including customer complaints, and advisory notices [MHLW MO169: 29].

#### ***United States (FDA):***

Verify procedures have been defined, documented, and implemented for receiving, reviewing, and evaluating complaints by a formally designated unit. Procedures must ensure that:

- All complaints are processed in a uniform and timely manner
- Oral complaints are documented upon receipt
- Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA

Each manufacturer must review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer must maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

Any complaint of the failure of the device, labeling, or packaging to meet any of its specifications must be reviewed, evaluated, and investigated, unless such investigation has already been made for a similar complaint and another investigation is not necessary.

Any complaint that represents an event which must be reported to FDA must be promptly reviewed, evaluated, and investigated by a designated individual(s) and must be maintained in a separate portion of the complaint files or otherwise clearly identified. Records of investigation must include a determination of:

- Whether the device failed to meet specifications
- Whether the device was being used for treatment or diagnosis
- The relationship, if any, of the device to the reported incident or adverse event

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 12 – Evaluation of Information from Post-Production Phase, Including Complaints

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When an investigation is made, a record of the investigation must be maintained by the formally designated unit. The record of investigation must include:

- The name of the device
- The date the complaint was received
- Any unique identifier (UDI), or Universal Product Code (UPC) or any other device identification(s) and control number(s) used
- The name, address, and telephone number of the complainant
- The nature and details of the complaint
- The dates and results of investigation
- Any corrective action taken

When the manufacturer's formally designated unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation must be reasonably accessible to the manufacturing establishment [21 CFR 820.198].

## **Assessing conformity**

### **Evaluation of post-production data**

During the review of quality data sources that serve as inputs to the Measurement, Analysis and Improvement process, the audit team may choose to review complaints and customer feedback. Confirm that complaints are handled as required by the MDSAP participating regulatory authorities. Complaints can be an important source of information regarding quality problems and are often indicative that distributed devices (or their packaging or labeling) did not meet specified requirements.

### **Selecting records**

One method to analyze complaints and customer feedback is to review the analysis of complaint data and postmarket surveillance activities and select one or more complaint failure modes, **preferably failure modes associated with higher risk to the patient or user**. Once the audit team has selected complaint failure modes, the auditor(s) can select a sample of complaints from those failure modes and confirm the complaints are handled appropriately, including investigation and implementation of corrective action when necessary.

### **Risk management**

Information from post-production sources, including complaints, customer feedback, and postmarket surveillance can provide important information for the risk management activities for the device. In particular, previously unidentified risks discovered during the post-production monitoring may indicate a need for improving the risk management process or may indicate a need for design

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 13 – Communications with External Parties Involved on Complaints

changes. Additionally, on the basis of post-production quality data, the medical device organization may choose to enact new or more stringent controls to maintain an acceptable level of product risk.

#### **Links**

##### **[Medical Device Adverse Events and Advisory Notices Reporting; Design and Development; Production and Service Controls](#)**

During the review of complaints and feedback, confirm that individual medical device reports were made to the appropriate regulatory authorities when necessary.

Information from reviewing post-production sources, including complaints and postmarket surveillance reports, should guide the audit team in selecting designs to review and production processes to audit.

### **Task 13 – Communications with External Parties Involved on Complaints**

**Where investigation determines that activities outside the medical device organization, contributed to a customer complaint, verify that records show that relevant information was exchanged between the organizations involved.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.1.5, 7.4.1, 8.3.1

**ANVISA:** RDC ANVISA 665/2022: Art. 120 section VI

**MHLW/PMDA:** MO169: 5-5, 37, 60-1; [Old: 5, 37, 60]

**FDA:** 21 CFR 820.100(a)(6)

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Complaints and nonconformities attributed to supplied product**

Confirm that information related to quality problems or nonconforming product, including complaints, is disseminated to those directly responsible for assuring the quality of product. This includes instances where investigation reveals the underlying cause of the complaint or nonconforming product to be related to the supplied product. The medical device organization should notify the supplier of the quality problem and appropriate corrective action must be taken when necessary. Failure of an

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 14 – Evaluation of Complaints for Adverse Event Reporting

outside medical device organization to provide products that meet specified requirements may disqualify them as an acceptable or approved supplier.

#### **Links**

##### **Purchasing**

During the audit of the Measurement, Analysis and Improvement process, if significant nonconformities are related to the supplied product, the audit team should consider selecting those suppliers for evaluation during the audit of the medical device organization's Purchasing process.

### **Task 14 – Evaluation of Complaints for Adverse Event Reporting**

**Verify that the medical device organization has defined and documented procedures for the evaluation of complaints for adverse event reporting.**

**Confirm that decisions to not report complaints were made according to established procedures and a documented rationale.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 7.2.3, 8.2.3

**TGA:** TG(MD)R Sch3 P1 1.4(3)(c)

**ANVISA:** RDC ANVISA 665/2022: Art. 120 section VIII, RDC ANVISA 67/2009

**HC:** CMDR 59-61.1

**MHLW/PMDA:** MO169: 6, 29, 55-3; [Old; 6, 29, 62]

**FDA:** 21 CFR 803

#### ***Additional country-specific requirements***

Refer to MDSAP process Medical Device Adverse Events and Advisory Notices Reporting

## **Assessing conformity**

### **Individual adverse event reports**

An output of the activities associated with the Measurement, Analysis and Improvement process, such as complaint handling, is the evaluation of individual adverse events to determine whether individual adverse event reports are required to be submitted to the regulatory authorities. During review of complaint records, assess whether the complaint was evaluated to determine whether the criteria for

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 15 – Evaluation of Quality Problems for Advisory Notices

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reporting was met and confirm the appropriate reports and information was provided to the regulatory authority when appropriate. Ensure the individual adverse event reports contain accurate information by comparing the submitted reports to the associated complaint and complaint investigation.

Reportable events are often an important Measurement, Analysis and Improvement process quality data source since these events are indicative that the finished device has caused death, serious injury, or has malfunctioned in a manner such that if the malfunction were to recur, the result could be death or serious injury. Any death, even if the medical device organization attributes it to user error, is considered to have potentially high risk associated with it. Confirm that reportable events were evaluated for corrective action when necessary.

#### ***Links***

None

### **Task 15 – Evaluation of Quality Problems for Advisory Notices**

**Confirm that the manufacturer has made effective arrangements for the timely evaluation of quality problems involving distributed product for potential issuance and implementation of advisory notices.**

**Select records for review of quality problems that were evaluated for potential issuance of advisory notices (include records where a decision was made not to issue an advisory notice as well as records of decision to issue advisory notices) and assess whether the organization has taken actions appropriately based on risk and documented the rationale.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 7.2.3, 8.3.3

**TGA:** TG(MD)R Sch3 P1 1.4(3)(c)

**ANVISA:** RDC ANVISA 665/2022: Art. 120 section VIII, RDC ANVISA 551/2021

**HC:** CMDR 63-65.1

**MHLW/PMDA:** MO169: 6, 29, 60-3; [Old: 6, 29, 60]

**FDA:** 21 CFR 806, 820.100(a)]

#### ***Additional country-specific requirements***

Refer to MDSAP process Medical Device Adverse Events and Advisory Notices Reporting

## **Chapter 3 - Measurement, Analysis and Improvement**

### Task 15 – Evaluation of Quality Problems for Advisory Notices

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## **Assessing conformity**

### **Advisory notices**

An output of the activities associated with the Measurement, Analysis and Improvement process, including complaint handling and the discovery of nonconforming product that has been distributed, may be the determination of whether an advisory action is necessary. When applicable, select quality issues that were evaluated for potential advisory actions and assess whether appropriate actions were taken and the organization's decisions were justified, based on the risk of the quality problem to device users. This may include assessing whether the organization appropriately determined the scope of the quality issue. For example, if the organization determined that a product is distributed in three MDSAP jurisdictions, but the advisory notice was only issued in one MDSAP jurisdiction, the audit team should determine whether the organization has an appropriate documented justification for the scope of the advisory action.

The quality problems that led to an advisory notice is often an important quality data source for the corrective actions process since these events are indicative that the finished device does not meet specified requirements and has the potential for unreasonable risk to the user. Confirm that quality problems that were evaluated by the organization for potential advisory actions were evaluated for corrective action. If corrective action was taken, evaluate the mechanism by which the medical device organization assured the action is effective and does not adversely affect the ability of the device to meet specified requirements. If corrective action was not taken for quality problems associated with a correction, removal, or advisory notice; or action appears unduly delayed considering the risk of the quality problem, review the medical device organization's rationale for not undertaking corrective action and confirm that the decision is appropriate using a risk-based decision making process.

### **Decisions to not report a correction, removal, or advisory notice**

The audit team may encounter instances where the medical device organization has performed activities involving issuance of advisory notices without notifying regulatory authorities in the markets in which the device is marketed. In these situations, review the medical device organization's rationale for not reporting these actions and ensure that the rationale is appropriate. Verify that records of the action are maintained.

### ***Links***

None

## **Chapter 3 - Measurement, Analysis and Improvement**

Task 16 – Top Management Commitment to Measurement, Analysis, and Improvement Process

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### **Task 16 – Top Management Commitment to Measurement, Analysis, and Improvement Process**

**Determine, based on the assessment of the Measurement, Analysis and Improvement process overall, whether management provides the necessary commitment to detect and address product and quality management system nonconformities, and ensure the continued suitability and effectiveness of the quality management system.**

#### *Clause and Regulation*

**ISO:** ISO 13485:2016: 4.1.3, 5.2, 8.1, 8.5.1

**ANVISA:** RDC ANVISA 665/2022: Art. 5°, Art. 6°, Art. 7°

**MHLW/PMDA:** MO169: 5-3, 11, 54, 62; [Old: 5, 11, 54, 62]

#### *Additional country-specific requirements*

None

#### *Links*

None

## **Chapter 4 - Medical Device Adverse Events and Advisory Notices Reporting**

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### **Chapter 4 - Medical Device Adverse Events and Advisory Notices Reporting**

The Medical Device Adverse Events and Advisory Notices Reporting process may be audited as a linkage from the Measurement, Analysis and Improvement process.

#### **Auditing the Medical Device Adverse Events and Advisory Notices Reporting**

**Purpose:** The purpose of auditing the Medical Device Adverse Events and Advisory Notices Reporting is; to verify that the medical device organization's processes ensure that individual device-related adverse events and, advisory notices involving medical devices are reported to regulatory authorities within required timeframes.

**Outcomes:** As a result of the audit of the Medical Device Adverse Events and Advisory Notices Reporting process, objective evidence will show whether the medical device organization has:

- A) Defined processes to ensure individual device-related adverse events are reported to regulatory authorities as required
- B) Ensured that advisory notices are reported to regulatory authorities and authorized representatives when necessary
- C) Maintained appropriate records of individual device-related adverse events and advisory notices

Links to Other Processes:

[\*\*Measurement, Analysis and Improvement\*\*](#)

#### **Task 1 – Notification of Adverse Events**

**Verify that the medical device organization has a process in place for identifying device-related events that may meet reporting criteria as defined by participating regulatory authorities.**

**Verify that the complaint process has a mechanism for reviewing each complaint to determine if a report to a regulatory authority is required.**

**Confirm that the medical device organization's processes meet the timeframes required by each regulatory authority where the product is marketed.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 7.2.3, 8.2.2, 8.2.3

## **Chapter 4 - Medical Device Adverse Events and Advisory Notices Reporting**

### Task 1 – Notification of Adverse Events

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#### ***Country-specific requirements***

##### **Australia (TGA):**

Manufacturers are required to implement a post-marketing system that includes provisions for adverse event reporting – e.g. *Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 3 Part 1 Clause 1.4(3)(c)(i)*. In view of the written agreement between Manufacturers and the Australian Sponsor [TG Act 41FD], events must be reported by the Manufacturer to the TGA, or to the Sponsor, in a timely manner to ensure that a Sponsor can meet their reporting obligations under the *Therapeutic Goods (Medical Devices) Regulation 5.7*:

- Verify that the Manufacturer or other person becoming aware of an event that represents a serious threat to public health provides information as soon as practicable. The Sponsor is to report the event within 48 hours.
- Verify that the Manufacturer or other person becoming aware of an event that led to the death or serious deterioration in the state of health of a patient, a user, or other person provides information as soon as practicable. The Sponsor is to report the event within 10 days.
- Verify that the manufacturer or other person becoming aware of an event that the recurrence of which might lead to the death or serious deterioration in the state of health of a patient, a user, or other person provides information as soon as practicable. The Sponsor is to report the event within 30 days.

**Note:** An event that leads to a serious threat to human health is a hazard arising from a systematic failure of the devices or an event or other occurrence that may lead to death or serious injury.

**Note:** Adverse events may be reported on-line to the TGA, by the Manufacturer or Sponsor, at <https://www.tga.gov.au/reporting-problems>.

**Note:** It is a condition on Australian Sponsors of Class AIMD, Class III and Implantable Class IIb devices that they provide three consecutive annual reports to the TGA following inclusion of the device in the ARTG. Annual reports are due 1 October each year. Reports should be for the period 1 July to 30 June. The report is to include:

- ARTG no.
- Product name
- Model no(s)
- Number supplied in Australia
- Number supplied worldwide (Numbers should include devices that are the same but supplied under a different name in another jurisdiction)
- Number of complaints in Australia
- Number of complaints worldwide

## **Chapter 4 - Medical Device Adverse Events and Advisory Notices Reporting**

### Task 1 – Notification of Adverse Events

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- Number of adverse events and incident rates in Australia (Rate= No. of events/ No. Supplied x 100 = Rate%)
- Number of adverse events and incident rates worldwide
- A list of the more common complaints and all of the adverse events
- Device Incident Report (DIR) number of those adverse events reported to the TGA
- Regulatory/corrective action/notification by Manufacturer

**Note:** Australian Sponsors are required to provide Manufacturers with any information that will assist the Manufacturer to comply with the obligations of a conformity assessment procedure (e.g. information in relation to adverse events) [TG(MD)R Reg 5.8].

#### ***Brazil (ANVISA):***

Verify that a post-market surveillance system is established and implemented in the medical device organization and integrated into the Quality System, with procedures and workflows established to ensure the correct and the prompt identification of adverse events, the performance of investigations and use of the results to improve the safety and effectiveness of the device when necessary [RDC ANVISA 67/2009 – Art. 6º].

For domestic manufacturers (also applies to legal representatives in Brazil) - verify that top management has designated a professional to be responsible for the post-market surveillance system. This designation shall be documented [RDC ANVISA 67/2009 – Art. 5º].

Verify that the medical device organization has mechanisms for processing and recording complaints, conducting investigations, and providing feedback directly to the complainant, or in the case of an international manufacturer, to their legal representative in Brazil, as necessary [RDC ANVISA 67/2009 – Art. 6º, Art. 7º, Art. 9º].

Verify that the medical device organization has notified the regulatory authority about problems associated with their devices, including adverse events (critical or non-critical), any technical defect that was identified regarding products already marketed, anything that can cause a serious hazard to public health, or cases of counterfeit [RDC ANVISA 67/2009 – Art. 8º].

For international manufacturer, verify that the legal representative in Brazil is aware about the occurrence of possibility of death, serious hazard to public health or cases of counterfeit, associated with their products exported to Brazil [RDC ANVISA 67/2009 – Art. 8º].

#### ***Canada (HC):***

CMDR 59-61.1, 61.2-61.3

## **Chapter 4 - Medical Device Adverse Events and Advisory Notices Reporting**

### Task 1 – Notification of Adverse Events

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Verify that the Manufacturer and the importer of a medical device make a preliminary and final report to the minister concerning any incident occurring inside Canada involving a device sold (authorized for sale) in Canada that:

- Is related to the failure of the device or deterioration in its effectiveness or any inadequacy in its labeling or in its directions for use; and
- Has led to death or serious deterioration in the state of health of a patient, user, or other person, or could do so if it were to recur [CMDR 59(1)].

[Note: the requirement to report incidents occurring outside of Canada no longer applies to class II-IV devices authorized for sale in Canada. The requirement nonetheless still applies for class I devices.[CMDR 59(1.1)]]

Verify that the Manufacturer or other person becoming aware of an event that led to the death or serious deterioration in the state of health of a patient, a user, or other person provides information in a preliminary report within 10 days after the person becomes aware of the event or occurrence [CMDR 60 (1)(a)(i)].

Verify that the Manufacturer or other person becoming aware of an event that the recurrence of which might lead to the death or serious deterioration in the state of health of a patient, a user, or other person provides information in a preliminary report within 30 days after the person becomes aware of the event or occurrence [CMDR 60 (1)(a)(ii)].

Verify that Manufacturer has made effective arrangements to submit preliminary reports to the Minister and that the reports contain [CMDR 60 (2)]:

- the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family
- if the report is made by:
  - the Manufacturer:
    - the name and address of that Manufacturer and of any known importer, and
    - the name, title and telephone and facsimile numbers of a representative of the Manufacturer to contact for any information concerning the incident, or
  - the importer of the device:
    - the name and address of the importer and of the Manufacturer, and
    - the name, title and telephone and facsimile numbers of a representative of the importer to contact for any information concerning the incident.
- the date on which the incident came to the attention of the Manufacturer or importer
- the details known in respect of the incident, including the date on which the incident occurred
- and the consequences for the patient, user or other person
- the name, address and telephone number, if known, of the person who reported the incident to the Manufacturer or importer
- the identity of any other medical devices or accessories involved in the incident, if known
- the Manufacturer's or importer's preliminary comments with respect to the incident

## **Chapter 4 - Medical Device Adverse Events and Advisory Notices Reporting**

### Task 1 – Notification of Adverse Events

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- the course of action, including an investigation, that the Manufacturer or importer proposes to follow in respect of the incident and a timetable for carrying out any proposed action and for submitting a final report
- a statement indicating whether a previous report has been made to the Minister with respect to the device and, if so, the date of the report.

If a preliminary report required by section 60 is submitted to the Minister and/or Importer, verify that the Manufacturer has submitted a final report to the Minister in writing in accordance with the timetable established under CMDR 60(2)(h) and the final report contains [CMDR 61(1)(2)]:

- a description of the incident, including the number of persons who have experienced a serious deterioration in the state of their health or who have died
- a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident
- any actions taken as a result of the investigation, which may include:
  - increased post-market surveillance of the device
  - corrective and preventive action respecting the design and manufacture of the device, and
  - recall of the device.

Manufacturers and Importers can use the [\*\*"Mandatory Medical Device Problem Reporting Form for Industry"\*\*](#) to submit preliminary and final incident report.

If the reports required by section 60 and 61 are submitted to the Minister just by the Importer, verify that the Manufacturer has advised the Minister in writing that the reports the Manufacturer and importer would have submitted were identical and that the Manufacturer has permitted the importer to prepare and submit reports to the Minister on the Manufacturer's behalf [CMDR 61.1]. This notification is to be done using [\*\*Health Canada form "FRM-0090"\*\*](#).

[Note: additional guidance on Mandatory Problem Reporting, including these modified requirements, is available in the associated [\*\*Guidance Document\*\*](#).]

Verify that the Manufacturer of a medical device submits to the Minister information regarding serious risk of injury to human health related to the safety of the device that it becomes aware of or receives, regarding:

- (a) Risks that have been communicated by any Regulatory Agency that is set out in the [\*\*List of Regulatory Agencies for the Purposes of Section 61.2 of the Medical Devices Regulations\*\*](#), or by any person who is authorized to manufacture or sell a medical device within the jurisdiction of such a Regulatory Agency, and the manner of the communication;
- (b) changes that have been made to the labelling of any medical device and that have been communicated to or requested by any Regulatory Agency that is set out in the list referred to in paragraph (a); and

## **Chapter 4 - Medical Device Adverse Events and Advisory Notices Reporting**

### Task 1 – Notification of Adverse Events

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- (c) recalls, reassessments and suspensions or revocations of authorizations, including licences, in respect of any medical device, that have taken place within the jurisdiction of any Regulatory Agency that is set out in the list referred to in paragraph (a). [CMDR 61.2(2)]

For greater clarity, serious risk of injury to human health is defined as a hazard associated with the medical device that is relevant to the safety of the medical device and that, without risk mitigation, would likely:

- be life-threatening
- result in persistent or significant disability or incapacity
- require inpatient hospitalization or prolonged hospitalization
- result in a serious health consequence such as loss of function or debilitating chronic pain
- result in death

Verify that manufacturers submit notifications of foreign risks within 72 hours after receiving or becoming aware that a notifiable action has been taken in response to a serious risk, whichever comes first. [CMDR 61.2(3)]

Foreign Risk Notifications can be submitted using the "[\*\*Medical Device Foreign Risk Notification Form for Industry\*\*](#)".

If the notification required by section 61.2 is submitted to the Minister just by the Importer, verify that the Manufacturer has advised the Minister in writing that the report the Manufacturer and importer would have submitted were identical and that the Manufacturer has permitted the importer to prepare and submit reports to the Minister on the Manufacturer's behalf [CMDR 61.3(2)]. This notification is to be done using [\*\*Health Canada form "FRM-0090"\*\*](#).

Additional information and guidance on Foreign Risk Notification can be found in the associated [\*\*Guidance Document\*\*](#).

#### ***Japan (MHLW):***

Marketing Authorization Holders are required to implement post market safety activities in accordance with domestic (Japanese) regulatory requirements in addition to the QMS requirements.

The persons operating the Registered Manufacturing Sites are not required to report any adverse event directly to a Regulatory Authority but shall report any adverse event which meets the criteria specified by the Ordinance for Enforcement of PMD Act Article 228-20 to the Marketing Authorization Holder [MHLW MO169: 55-3; (Old: 62.6)].

Verify that the person operating the Registered Manufacturing Site provides events which meets the following criteria defined by the Ordinance for Enforcement of PMD Act Article 228-20.2 (see below), to the Marketing Authorization Holder in a timely manner.

- The following malfunction events which may cause or may have caused health damage:

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### Task 1 – Notification of Adverse Events

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- Serious event (domestic and foreign)
- Unlabeled non-Serious event (domestic)
- The following Adverse Reaction events which was caused or might have been caused by the malfunction of a medical device:
  - Serious event (domestic and foreign)
  - Unlabeled non-Serious event (domestic)
  - Any action taken for preventing the occurrence or expansion of public health hazard in relation to a medical device which is marketed in foreign countries and is equivalent to the one marketed in Japan. The action includes but not limited to:
    - Suspension of manufacturing, importing or selling
    - Recall and
    - Abolishment.
    - Study report that indicates:
    - Possibility of event of cancer and other serious illness, injury or death caused by malfunction of a medical device (domestic and foreign), or by infectious disease arising from usage of a device (domestic and foreign)
    - Significant occurrence rate change of event etc. caused by malfunction of a medical device (domestic and foreign)
    - Significant occurrence rate change of infectious disease caused by usage of a medical device (domestic and foreign)
    - The fact that a medical device is less effective than claimed when approved.

#### ***United States (FDA):***

21 CFR 803: Medical Device Reporting

Determine whether the manufacturer has developed a process for reporting to FDA incidents involving device-related deaths, serious injuries, and reportable malfunctions that occur within and outside the United States if the same or similar device is marketed to the United States.

Confirm that the manufacturer has developed, maintained, and implemented written medical device reporting (MDR) procedures for the following:

- Internal processes that provide for:
- Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements
- A standardized review process or procedure for determining when an event meets the criteria for reporting
- Timely transmission of complete medical device reports to FDA
- Documentation and recordkeeping requirements for:

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### Task 1 – Notification of Adverse Events

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- Information that was evaluated to determine if an event was reportable;
- All medical device reports and information submitted to FDA
- Processes that ensure access to information that facilitates timely follow-up and audit.

Verify that reports are made within 30 calendar days after the day that the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device that is marketed may have caused or contributed to a death or serious injury:

- Confirm the manufacturer's MDR files contain the following:
- Information (or references to information) related to the adverse event, including all documentation of deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable to FDA
- Copies of all MDR forms and other information related to the event submitted to FDA.

If a device has malfunctioned and this device or a similar device that is marketed would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, quarterly summary reporting is acceptable for most device product codes.

If the manufacturer maintains MDR event files as part of the complaint file, ensure that the manufacturer has prominently identified these records as MDR reportable events. FDA will not consider a submitted MDR report to comply with 21 CFR 803 unless the manufacturer evaluates an event in accordance with the quality management system requirements. Confirm that the manufacturer has documented and maintained in the MDR event files an explanation of why the manufacturer did not submit or could not obtain any information required by 21 CFR 803, as well as the results of the evaluation of each event.

Compare the information submitted on the individual medical device report to the information contained in the associated complaint and confirm the medical device report contains all information related to the event that is reasonably known to the manufacturer.

Verify the manufacturer has submitted reports to FDA no later than 5 work days after the day that the manufacturer becomes aware that:

- An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer may become aware of the need for remedial action from any information, including any trend analysis; or
- FDA has made a written request for the submission of a 5-day report. If the manufacturer receives such a written request from FDA, the manufacturer must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. FDA may extend the time

## **Chapter 4 - Medical Device Adverse Events and Advisory Notices Reporting**

### Task 2 – Notification of advisory notices

period stated in the original written request if FDA determines it is in the interest of the public health.

Verify the manufacturer submitted supplemental reports within one month of obtaining information that was not submitted in an initial report.

Confirm that medical device reports include the unique device identifier (UDI) that appears on the device label or on the device package.

Medical device reports submitted to FDA must be submitted electronically via the Electronic Submissions Gateway (ESG) using eSubmitter or the AS2 Gateway-to-Gateway using HL7 ICSR XML software.

#### **Links**

##### **Measurement, Analysis and Improvement**

Reports of individual adverse events are a form of feedback and must be analyzed as appropriate for trends requiring improvement or corrective action.

During the audit of the Measurement, Analysis and Improvement process, confirm that the medical device organization has considered individual adverse events and trends of adverse events in the analysis of data.

### **Task 2 – Notification of advisory notices**

**Verify that advisory notices are reported to regulatory authorities when necessary and comply with the timeframes and recordkeeping requirements established by participating regulatory authorities.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 7.2.3, 8.2.3, 8.3.3

#### ***Country specific requirements***

##### ***Australia (TGA):***

Manufacturers are required to implement a post-marketing system that includes provisions for the recall of devices – e.g. *Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 3 Part 1 Clause 1.4 (3A)*. Under the MDSAP, and in view of the written agreement between Manufacturers and the Australian Sponsor [TG Act 41FD] (see [Annex 4](#)), proposed recalls must be reported by the Manufacturer to the MDSAP AO, and to the TGA or Sponsor in a timely manner to ensure that a

## **Chapter 4 - Medical Device Adverse Events and Advisory Notices Reporting**

### Task 2 – Notification of advisory notices

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Sponsor can meet their reporting obligations [*Therapeutic Goods (Medical Devices) Regulation 5.7 and 5.8, Therapeutic Goods Act Part 4-9 and the Uniform Recall Procedure for Therapeutic Goods (URPTG)*].

**Note:** Further information concerning the Australian requirements for advisory notices and the recovery of devices is available at <https://www.tga.gov.au/recalls>

**Note:** Australian Sponsors are required to provide Manufacturers with any information that will assist the Manufacturer to comply with the obligations of a conformity assessment procedure (e.g. information in relation to the recovery of devices) [TG(MD)R Reg 5.8].

#### **Brazil (ANVISA):**

Verify that procedures and work flows were established in order to identify when field actions (recalls and corrections) are necessary, in accordance with the medical device organization's post-market surveillance system and quality system [RDC ANVISA 67/2009 - Art. 6º, RDC ANVISA 551/2021 – Art. 1º, Art. 5º].

Verify that the medical device organization keeps records regarding field actions performed, including those that do not need to be reported to regulatory authorities [RDC ANVISA 551/2021 – Art. 4º; Art. 6º, Art. 10, Art. 11, Art. 16].

For domestic manufacturers (also applies to legal representatives in Brazil) - verify that the medical device organization has sent to the regulatory authority the reports requested, according to Brazilian regulation [RDC ANVISA 551/2021– Art. 10, Art. 11].

Verify that the medical device organization has performed field actions based on potential or concrete evidence that their product does not comply with essential requirements of safety and effectiveness [RDC ANVISA 551/2021 – Art. 4º, Art. 6º, Art. 7º, Art. 13, Art. 14, Art. 15].

For domestic manufacturers (also applies to legal representatives in Brazil) - verify that the medical device organization has performed field actions when required by the regulatory authority [RDC ANVISA 551/2021 – Art. 6º].

For domestic manufacturers (also applies to legal representatives in Brazil) - verify that the medical device organization notified the regulatory authority regarding field actions, in accordance with requirements and deadlines established per Brazilian regulation [RDC ANVISA 551/2021 – Art. 7º, Art. 8º].

For international manufacturers, verify that the legal representative in Brazil was aware about the occurrence of field actions performed on products exported to Brazil [RDC ANVISA 67/2009 – Art. 8º].

#### **Canada (HC):**

Medical Device Regulations SOR/98-282, Section 63 – 65.1:

MDSAP AU P0002.007

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## **Chapter 4 - Medical Device Adverse Events and Advisory Notices Reporting**

### Task 2 – Notification of advisory notices

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Verify that the Manufacturer and the importer of a medical device, on or before undertaking a recall of a device provide the minister with the following information [CMDR 64]:

- the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family
- the name and address of the Manufacturer and importer, and the name and address of the establishment where the device was manufactured, if different from that of the Manufacturer
- the reason for the recall, the nature of the defectiveness or possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered
- an evaluation of the risk associated with the defectiveness or possible defectiveness
- the number of affected units of the device that the Manufacturer or importer:
  - manufactured in Canada,
  - imported into Canada,
  - sold in Canada.
- the period during which the affected units of the device were distributed in Canada by the Manufacturer or importer
- the name of each person to whom the affected device was sold by the Manufacturer or importer and the number of units of the device sold to each person
- a copy of any communication issued with respect to the recall
- the proposed strategy for conducting the recall, including the date for beginning the recall, information as to how and when the Minister will be informed of the progress of the recall and the proposed date for its completion
- the proposed action to prevent a recurrence of the problem
- the name, title and telephone number of the representative of the Manufacturer or importer to contact for any information concerning the recall.

Verify that as soon as possible after the completion of the recall the Manufacturer and the importer reports to the minister the results of the recall and the action taken to prevent a recurrence of the problem [CMDR 65].

If the reports required by section 64 and 65 are submitted to the Minister just by the Importer, verify that the Manufacturer has advised the Minister in writing that the reports the Manufacturer and importer would have submitted were identical and that the Manufacturer has permitted the importer to prepare and submit reports to the Minister on the Manufacturer's behalf [CMDR 65.1].

For greater clarity and consistency with [\*\*section 4.1.1 of Health Canada's Recall Policy for Health Products \(POL-0016\)\*\*](#), AOs and auditors are advised of the following interpretations of the timelines in sections 64 and 65 of the *Medical Devices Regulations*:

## **Chapter 4 - Medical Device Adverse Events and Advisory Notices Reporting**

### Task 2 – Notification of advisory notices

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*Section 64 of the Medical Devices Regulations requires the manufacturer and importer of a medical device to provide Health Canada with information concerning a recall "on or before undertaking a recall". This is interpreted to mean that the manufacturer and importer must submit to Health Canada as much recall information as is known **within 24 hours of having made the decision to recall**. This initial notification may be made verbally or in writing. This must be followed by a written report containing full information as required by section 64 **within three business days of starting the recall**. As per section 65 of the Medical Devices Regulations, a report on the results of the recall and the action taken to prevent a recurrence of the problem must be submitted **as soon as possible after the completion of a recall**.*

#### **Japan (MHLW):**

Marketing Authorization Holders are required to report advisory notices to Regulatory Authorities [PMD Act 68-11].

Confirm that the person operating the Registered Manufacturing Site has determined and implemented effective arrangement for communicating with the Marketing Authorization Holder in relation to advisory notices [MHLW MO169: 29].

**Note:** Persons operating Registered Manufacturing Sites are not required to report any advisory notice directly to regulatory authority, but shall communicate with the Marketing Authorization Holder, so they can take necessary regulatory actions.

#### **United States (FDA):**

21 CFR 806: Medical Devices; Reports of Corrections and Removals

Verify that the manufacturer has a process in place to notify FDA in the event of actions concerning device corrections and removals and to maintain records of those corrections and removals.

Verify that the written report to FDA of any correction or removal initiated to reduce a risk to health or remedy a violation of the U.S. Food, Drug and Cosmetic Act is reported within 10 working days of initiating the correction or removal. Confirm that the report contains the unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, Universal Product Code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

Confirm that the manufacturer maintains records of any correction and removal not required to be reported to FDA (e.g. corrections and removals conducted to correct a minor violation of the U.S. Food, Drug and Cosmetic Act or no risk to health). Confirm that records of corrections and removals not required to be reported contain the unique device identifier (UDI) that appears on the device label

## **Chapter 4 - Medical Device Adverse Events and Advisory Notices Reporting**

### Task 2 – Notification of advisory notices

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or on the device package, or the device identifier, Universal Product Code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

#### ***Links***

##### **Measurement, Analysis and Improvement**

Corrections and removals are indicative that the product or process does not meet specified requirements or planned results and the nonconformity was not detected prior to distribution. When specified requirements or planned results are not achieved, correction and corrective action must be taken as necessary.

During the audit of the Measurement, Analysis and Improvement process, confirm the medical device organization has taken appropriate correction regarding devices already distributed, and taken appropriate corrective action to prevent recurrence of the condition(s) that caused the nonconformity.

## **Chapter 5 - Design and Development**

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### **Chapter 5 - Design and Development**

The purpose of the Design and Development process is to control the design of a medical device and to assure that the device meets user needs, intended use, and its specified requirements. Attention to design and development planning, identifying design inputs, developing design outputs, verifying that design outputs meet design inputs, validating the design, controlling design changes, reviewing design results, transferring the design to production, and compiling the appropriate records will help a medical device organization assure that resulting designs will meet user needs, intended uses, and requirements.

The **management representative** is responsible for ensuring that the requirements of the quality management system have been effectively defined, documented, implemented, and maintained. Prior to the audit of a process, it may be helpful to interview the management representative (or designee) to obtain an overview of the process and a feel for management's knowledge and understanding of the process.

Audit of the Design and Development process will follow audit of the Measurement, Analysis and Improvement process per the MDSAP audit sequence. Information regarding product or quality system nonconformities noted during audit of the Measurement, Analysis and Improvement process should be considered when making decisions as to the design and development projects, including design changes resulting from corrective actions, to be reviewed during the audit of the Design and Development process.

Review of the Design and Development process will also provide an opportunity to evaluate how the medical device organization has utilized risk management activities to ensure design inputs are comprehensive and meet user needs, to confirm that risk control measures that were planned have been implemented in the design, and to verify that risk control measures are effective in controlling or reducing risk.

Additionally, review of design and development activities will assist the audit team during the audit of the medical device organization's Purchasing process because the auditor(s) has an opportunity to select suppliers for review whose activities are associated with higher risk to the product or whose activities are critical to the essential design outputs. The review of design and development activities also provides information to assist the audit team in performing a final evaluation of the Management process at the conclusion of the audit.

### **Auditing the Design and Development Process**

**Purpose:** The purpose of auditing the Design and Development process is to verify that the medical device organization establishes, documents, implements, and maintains controls to ensure that medical devices meet user needs, intended uses, and specified requirements.

**Outcomes:** As a result of the audit of the Design and Development process, objective evidence will show whether the medical device organization has:

- A) Defined, documented and implemented procedures to ensure medical devices are designed according to specified requirements
- B) Effectively planned the design and development of a device

## **Chapter 5 - Design and Development**

Task 1 – Identification of devices subject to design and development procedures; technical documentation

- 
- C) Established mechanisms, including systematic review, for addressing incomplete, ambiguous or conflicting requirements
  - D) Determined the internally or externally imposed requirements for safety, function, and performance for the intended use, including regulatory requirements, risk management, and human factors requirements
  - E) Verified that design outputs satisfy design input requirements
  - F) Identified and mitigated, to the extent practical, the risks associated with the device, including the device software
  - G) Ensured that changes to the device design are controlled, the risks associated with the design change are identified and mitigated, to the extent practical, and that the device will continue to perform as intended
  - H) Performed design validation to ensure devices conform to user needs and intended use
  - I) Confirmed that the design is correctly translated into production methods and procedures

Links to Other Processes:

**Purchasing; Production and Service Controls; Measurement, Analysis and Improvement;  
Device Marketing Authorization and Facility Registration**

### **Task 1 – Identification of devices subject to design and development procedures; technical documentation**

**Verify that those devices that are, by regulation, subject to design and development procedures have been identified. (See [Annex 1](#))**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.1.1, 4.2.1, 7.1, 7.3.10

**TGA:** TG(MD)R Division 3.2

**MHLW/PMDA:** MO169: 5-1, 6, 26, 36-2; [Old: 5, 6, 26]

**FDA:** 21 CFR 820.30(a)]

#### ***Additional country-specific requirements***

##### ***Australia (TGA):***

When a Manufacturer applies TG(MD)R Division 3.2 and selects the Full Quality Assurance conformity assessment procedures [TG(MR)R Schedule 3, Part1, (excluding or including clause 1.6)], quality management system procedures for design and development must be available.

## **Chapter 5 - Design and Development**

Task 1 – Identification of devices subject to design and development procedures; technical documentation

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In addition, for all classes of devices, the guidance provided for the audit of technical documentation in [Annex 1](#) is to be followed to ensure the availability of objective evidence that demonstrates compliance with the Essential Principles of Safety and Performance.

### ***Brazil (ANVISA):***

According to Brazilian legislations, there is no exception to design control.

If design activities are outsourced, verify that the manufacturer has a complete device master record for the device and records of the design transfer to production [RDC ANVISA 665/2022: Art. 52, Art. 63].

### ***Canada (HC):***

With respect to Class II devices that are not subject to Design and Development controls, verify that the manufacturer has objective evidence to establish that Class II devices meet the safety and effectiveness requirements of section 10 to 20 [CMDR 9, 10 to 20].

### ***Japan (MHLW):***

Class 1 devices are not required to comply with the requirements of MHLW MO169:30-36-2, which are equivalent to the requirements of design and development in ISO13485 [MHLW MO169: 4.1].

## **Assessing conformity**

### **Absence of design activity**

The audit team may encounter situations where the medical device organization has not completed any design projects, has no ongoing or planned design projects, and has not made any design changes (i.e., there has been no design activity). At the minimum, verify that the medical device organization maintains a defined and documented design change procedure. A medical device organization may also have defined and documented other design control procedures. For that type of medical device organization — a medical device organization with no design activity, including no design changes — assess the procedures the medical device organization has in place. The audit team can then proceed to the audit of the next process.

### **Outsourced design activities**

In cases where design activities (development and changes) are completely outsourced by the medical device organization, the audit team must verify (at a minimum) that the controls and records related to the design transfer to production have been determined and that the production line, implemented in the medical device organization's site, meets the production requirements established during the design and development of the device.

In these cases, the medical device organization shall ensure that the supplier complies with the requirements of design and development, established by Medical devices – Quality management systems – Requirements for

## **Chapter 5 - Design and Development**

### Task 2 – Selection of a completed design and development project

regulatory purposes (ISO 13485:2016), the Quality Management System requirements of the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch3), Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022), Japanese QMS Ordinance (MHLW MO 169), the Quality System Regulation (21 CFR Part 820), and any other specific requirements of medical device regulatory authorities participating in the MDSAP program.

#### **Links**

##### Purchasing

If the medical device organization outsources design and development activities, or any portion of the design and development, confirm that the medical device organization treats the outsourced medical device organization as a supplier, has appropriately qualified and maintains control over the supplier, communicates requirements to the supplier, including regulatory requirements, and has arrangements to verify that the design and development activities satisfy those requirements.

### **Task 2 – Selection of a completed design and development project**

#### **Select a completed (where applicable) design and development project for review.**

Priority criteria for selection:

1. complaints or known problems with a particular device
2. product risk
3. recent design changes, particularly design changes made to correct quality problems associated with the device design
4. age of design (prefer most recent)
5. designs that have not been recently audited

## **Chapter 5 - Design and Development**

### Task 3 – Design and development planning

#### **Links**

##### **Measurement, Analysis and Improvement**

At this point in the audit, the audit team will have already reviewed the Measurement, Analysis and Improvement process. If the auditors noted corrective actions that resulted in design changes, or noted product nonconformities that have been attributed to the design of the device, the audit team should consider selecting those designs for review.

The audit team should be particularly mindful of how the identified quality problems from the Measurement, Analysis and Improvement process are related to specific aspects of the design and development of the device. For example, if the auditors review complaints related to a safety feature of the device that is not performing as intended, the audit team should consider selecting for review the design verification of that safety feature and determine whether appropriate risk control methods were confirmed to be effective.

### **Task 3 – Design and development planning**

**Verify that the design and development process is planned and controlled.**

**Review the design plan for the selected design and development project to understand the design and development activities; including the design and development stages, the review, verification, validation, and design transfer activities that are appropriate at each stage; and the assignment of responsibilities, authorities, and interfaces between different groups involved in design and development.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 7.1, 7.3.2

**TGA:** TG(MD)R Sch3 P1 Cl 1.4(4)&(5)(c)

**ANVISA:** RDC ANVISA 665/2022: Art. 44, Art. 61

**MHLW/PMDA:** MO169: 6, 26, 30

**FDA:** 21 CFR 820.30(b), 820.30(j)]

#### ***Additional country-specific requirements***

##### ***Australia (TGA):***

Verify that effective planning for design and development is documented, typically as part of a Quality Plan [TG(MD)R Sch3 P1 Cl 1.4(4)].

## **Chapter 5 - Design and Development**

Task 4 – Implementation of the design and development process

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### ***Canada (HC):***

Verify that Manufacturers of Class IV devices maintain a quality plan that sets out the specific quality practices, resources, and sequence of activities relevant to the device [CMDR 32].

## **Assessing conformity**

### **Reviewing the design plan**

Review the design plan for the selected project to understand the layout of the design and development activities, including assigned responsibilities and interfaces.

The design plan for the selected project can be used by the audit team as a roadmap for the review of the project.

Plans may vary depending on the type or size of the project. Some design plans may be expressed as simple flowcharts, or for larger projects, Gantt or Program Evaluation Review Technique (PERT) charts may be used. Plans do not have to show starting or completion dates for activities covered. However, plans must define responsibility for implementation of the design and development activities and describe the interfaces with different groups or activities.

Expect to see interfacing between research and development, marketing, regulatory, manufacturing, and quality departments. The audit team might also see interfacing with purchasing, installers, and servicers. When external institutions (e.g. universities or research and development centers) are involved in the design and development activities, the interfaces between the medical device organization and those external institutions must also be defined.

Design and development plans may change while the design and development process evolves; however, all changes on the plan must be documented and approved.

### ***Links***

None

## **Task 4 – Implementation of the design and development process**

**For the device design and development record(s) selected, verify that design and development procedures have been established and applied.**

**Confirm the design and development procedures address the design and development stages, review, verification, validation, design transfer, and design changes.**

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 7.3.1, 7.3.10

## **Chapter 5 - Design and Development**

Task 4 – Implementation of the design and development process

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**TGA:** TG(MD)R Sch3 P1 Cl 1.4(4)&(5)(c)

**ANVISA:** RDC ANVISA 665/2022: Art. 43

**MHLW/PMDA:** MO169: 6, 30, 36-2; [Old: 6, 30]

**FDA:** 21 CFR 820.30(a), 820.30(j)]

### ***Additional country-specific requirements***

#### ***United States (FDA):***

Verify that the design input procedures contain a mechanism for addressing incomplete, ambiguous, or conflicting requirements [21 CFR 820.30(c)].

## **Assessing conformity**

### **Review of procedures**

Design and development procedures set the structure, provide the framework, and support the medical device organization's Design and Development process. The purpose of auditing the procedures is to determine if the medical device organization has that framework in place. If procedures have not been defined and documented, or are deficient, the medical device organization's devices may not meet user needs and intended use.

In accomplishing this audit task, the audit team is to review the medical device organization's procedures and verify that the procedures address the requirements of the Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016), the Quality Management System requirements of the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch3), Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022), Japanese QMS Ordinance (MHLW MO 169), the Quality System Regulation (21 CFR Part 820), and specific requirements of medical device regulatory authorities participating in the MDSAP program. For example:

- verify that the design input procedure includes a mechanism for addressing incomplete, ambiguous, or conflicting requirements
- Verify that the output procedure ensures that essential outputs are identified
- Verify that the design review procedure ensures that each design review includes an individual who does not have responsibility for the design stage being reviewed.

### **Minimum requirement**

If the medical device organization has no ongoing or planned design projects, has not made any design changes, then ensure that, at a minimum, the medical device organization maintains defined and documented design change procedures.

## **Chapter 5 - Design and Development**

### Task 5 – Design and development input

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#### **Links**

None

### **Task 5 – Design and development input**

**Verify that design and development inputs were established, reviewed and approved; and that they address customer functional, performance and safety requirements, intended use, applicable regulatory requirements, and other requirements including those arising from human factors issues, essential for design and development.**

***Verify that any risks and risk mitigation measures identified during the risk management process are used as an input in the design and development process.***

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 5.2, 7.2.1, 7.3.3, 8.2.1

**TGA:** TG(MD)R Sch1 P1 2, Sch3 P1 Cl 1.4(2)&(5)(c), Sch 3 P1 1.4(3)(a)&(b)

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 46, Art. 61

**HC:** CMDR 10-20, 21-23, 66, 67, 68

**MHLW/PMDA:** MO169: 6, 11, 27, 31, 55-1; [Old: 6, 11, 27, 31, 55]

**FDA:** 21 CFR820.30(c), 820.30(g)]

#### ***Additional country-specific requirements***

##### ***Australia (TGA):***

Verify that the Manufacturer has identified the relevant Essential Principles that apply to the medical device [TG(MD)R Sch1 Essential Principles].

Verify that Manufacturer has taken into account post-production feedback as an input to monitoring and maintaining product requirements and improving product realization processes.

##### ***United States (FDA):***

For the selected device(s), verify that the medical device organization has the appropriate marketing clearance [510(k)] or pre-market approval (PMA) if distributing the devices in the United States [21 CFR 807].

## **Chapter 5 - Design and Development**

### Task 5 – Design and development input

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#### **Assessing conformity**

##### **Design inputs**

Inputs are the physical and performance requirements of a device that are used as a basis for device design. Inputs must be documented and approved by appropriate personnel. The audit team should review the sources used to develop the inputs and determine that relevant aspects of the requirements for the device were covered. These sources must include the relevant regulations where safety and performance criteria have been defined (e.g. safety and efficacy requirements or Essential Principles of Safety and Performance).

Examples of relevant aspects include:

- intended use, performance characteristics
- intended user
- risk mitigation
- biocompatibility
- compatibility with the environment of intended use (including electromagnetic compatibility)
- software
- radiation protection
- human factors
- sterility.

Organizations must take into account the current thinking of experts where published information is available (e.g. Standards).

Design inputs may also relate to manufacturing processes particularly where validation, revalidation, the periodic monitoring of critical process parameters, or the implementation of specified controls, is required to assure the quality of product (e.g. sterilization, injection molding, control on the source, or inactivation of transmissible agents in, materials of animal origin, or GMP controls on the handling, processing or incorporation of a medicinal substance in a medical device).

Design inputs are the basis of the design verification and validation; therefore, design inputs need to be defined and recorded as formal requirements that allow for confirmation to the design outputs.

Relevant information for design input can also come from post-production data or experience from similar devices. Complaints, adverse events, feedback, and post-market surveillance form a feedback system that can help drive quality improvements in new designs and changes to current designs.

## **Chapter 5 - Design and Development**

Task 6 – Completeness, coherence, and unambiguity of design and development input

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### **Links**

#### **Device Marketing Authorization and Facility Registration**

Confirm the medical device organization has considered regulatory requirements for registration, listing, notification and licensing; and has complied with these requirements prior to marketing the device in the applicable regulatory jurisdictions.

## **Task 6 – Completeness, coherence, and unambiguity of design and development input**

**Confirm that the design and development inputs are complete, unambiguous, and not in conflict with each other.**

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 7.3.3

**TGA:** TG(MD)R Sch 3 Part 1.4(4)

**ANVISA:** RDC ANVISA 665/2022: Art. 46

**MHLW/PMDA:** MO169: 31

**FDA:** 21 CFR820.30(c)]

### ***Additional country-specific requirements***

#### ***Australia (TGA):***

Confirm that design inputs include the relevant Essential Principles [TG(MD)R – Schedule 1].

Solutions adopted by the Manufacturer for the design and construction of a medical device are to conform to safety principles that are derived from the generally acknowledged state of the art. [TG(MD)R – Sch 1 – EP2] Safety principles are usually identified in internationally recognized standards.

Compliance with any given standard is not mandatory under Australian legislation however it is one way to demonstrate compliance with the Essential Principles.

The TGA is to presume compliance with the relevant Essential Principles if the Manufacturer has applied, in full, a relevant standard that is identified in a Medical Device Standards Order. (See TGA website - For example, ISO 10993).

## **Chapter 5 - Design and Development**

### Task 7 – Design and development output and design verification

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If relevant standards have not been identified as design inputs, ensure that the Manufacturer has documented a rationale to explain why alternatives have been applied to demonstrate compliance with the Essential Principles [TG(MD)R Sch3 Part 1.4(5)(c)(iii)(C)].

## **Assessing conformity**

### **Design inputs**

Design inputs must be defined and recorded as verifiable requirements, approved by the appropriate personnel. If the medical device organization does not have accurate and complete design inputs, the final design may not meet user needs and intended use.

A common method for a medical device organization to confirm the design inputs for a design and development project are complete, unambiguous, and not in conflict with each other is to perform a design review after the initial requirements are determined.

### **Links**

None

## **Task 7 – Design and development output and design verification**

**Review medical device specifications to confirm that design and development outputs are traceable to and satisfy design input requirements.**

**Verify that the design and development outputs essential for the proper functioning of the medical device have been identified.**

Outputs include, but are not limited to:

- device specifications
- specifications for the manufacturing process
- specifications for the sterilization process (if applicable)
- the quality assurance testing
- device labeling and packaging.

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 4.2.3, 7.3.4

**TGA:** TG(MD)R Sch3 P1 Cl 1.4(5)(c)

**ANVISA:** RDC ANVISA 665/2022: Art. 48, Art. 49, Art. 61

**MHLW/PMDA:** MO169: 6, 7-2, 32; [Old: 6, 32]

## **Chapter 5 - Design and Development**

### Task 7 – Design and development output and design verification

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**FDA:** 21 CFR 820.30(d), 820.30(f)]

#### ***Additional country-specific requirements***

##### **Australia (TGA):**

If relevant standards have not been applied, or not been applied in full, ensure that the Manufacturer has documented a rationale to explain why alternative methods have been applied to demonstrate compliance with the Essential Principles [TG(MD)R Sch3 Part 1.4(5)(c)(iii)(C)].

For devices incorporating a medicinal substance, verify that documentation also identifies the data to be derived from tests conducted in relation to the substance, and its interaction with the device [TG(MD)R Sch 3 Part 1.4(5)(c)(v)].

## **Assessing conformity**

### **Design outputs**

Design outputs are the work products or deliverables of a design stage. Design outputs can include documents such as diagrams, drawings, specifications, and procedures for both products and processes. The outputs from one stage may become inputs to the next stage. The total finished design output consists of the specifications for the device, its packaging and labeling (including implant cards and leaflets, where applicable), quality management system requirements, the manufacturing process, and if applicable, installation and servicing requirements.

During this design stage, a tremendous number of records, or outputs, can be produced. Only the approved outputs need to be retained. However, if a medical device organization chooses to retain other records, for historical or other purposes, they may do so.

### **Essential outputs**

Outputs that are essential for the proper functioning of the device must be identified. Typically, a medical device organization can use a risk management tool to determine the essential outputs. To verify that this has been done, the auditor(s) may review the medical device organization's process for determining how the essential outputs were identified and if it was done in accordance with their design output procedures.

The identification of essential outputs may influence other quality system activities. For example, the establishment of manufacturing process controls and tolerances, the degree of purchasing controls and acceptance activities applied to a supplier or the priority and depth of a failure investigation may be influenced by whether or not the component (assembly, material, etc.) is considered an output essential for the proper functioning of the device.

## **Chapter 5 - Design and Development**

Task 7 – Design and development output and design verification

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### **Design outputs for sterile devices**

Design and development of medical devices that are intended to be sterile should ensure compatibility of the sterilization process with the device, compatibility of the device packaging and the sterilization process, ability of the device to be sterilized or re-sterilized, and (if applicable), rationale for adding the device to a product family covered by a validated sterilization process.

### **Design verification**

In design verification, the medical device organization obtains objective evidence (i.e., data) that design outputs meet design inputs. A medical device organization generates this objective evidence by conducting verification activities such as tests, measurements, and analyses. These activities should be explicit and thorough in their execution. A medical device organization's verification activities should be predictive, not empiric. In other words, acceptance criteria need to be stated in advance of the verification activity. The establishment of pre-determined acceptance criteria should be documented in a verification protocol or similar document. During the review of design verification activities, the auditor(s) will determine if the design verification data confirms that design outputs met the design input requirements.

### **Verification techniques**

Complex designs will require more and different types of verifications than simple designs. Sometimes a medical device organization has to use its own expertise to develop (in-house) a way to verify a particular aspect of a design. Any approach selected by a medical device organization is acceptable as long as it provides reliable objective evidence that the output met the input.

### **Choosing verification activities for review**

In accomplishing this audit task, select records generated from design verification activities associated with a number of design inputs and design outputs. The review of these records will determine whether design outputs met design input requirements. When possible, select documentation of design verification activities that are associated with outputs that are considered essential for the proper functioning of the device or are associated with the highest risk to the user or patient.

## Chapter 5 - Design and Development

Task 8 – Risk management activities applied throughout the design and development project

### Links

#### Purchasing, Production and Service Controls

During the review of a design project, the audit team should be mindful of production processes and supplied products that are essential to the proper functioning of the device. Production processes can include not only the manufacturing instructions, but also internal controls, such as the type and extent of acceptance activities, equipment calibration and maintenance intervals, environmental controls, and personnel controls. For suppliers that provide products and services related to the essential design outputs, the degree of purchasing controls necessary is commensurate with the effect of the supplied product on the proper functioning of the finished device.

During the audits of the Purchasing process and Production and Service Controls process, the audit team should consider reviewing production processes and supplied products that have the highest risk or greatest effect on the essential design outputs.

## Task 8 – Risk management activities applied throughout the design and development project

***Verify that risk management activities are defined and implemented for product and process design and development.***

***Confirm that risk acceptability criteria are established and met throughout the design and development process.***

***Verify that any residual risk is evaluated and, where appropriate, communicated to the customer (e.g., labeling, service documents, advisory notices, etc.).***

**Note:** In some instances, it may be necessary for the medical device organization to conduct a risk/benefit analysis to justify a risk that cannot be mitigated to an acceptable level. ***Additionally, it may be necessary to audit other processes (e.g. Production and Service Controls, Purchasing) to verify that risk acceptability criteria are met, risk is controlled or reduced, and residual risk is communicated if necessary.***

### Clause and Regulation

**ISO:** ISO 13485:2016: 4.2.1, 7.1, 7.3.3, 7.3.4

**TGA:** TG(MD)R Sch1 P1 2, Sch3 P1 Cl 1.4(5)(c)(iii)

## **Chapter 5 - Design and Development**

Task 8 – Risk management activities applied throughout the design and development project

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**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 61, RDC ANVISA 56/2001

**HC:** CMDR 10, 11, 15, 16

**MHLW/PMDA:** MO169: 6, 26, 31, 32

**FDA:** 21 CFR 820.30(g)]

### ***Additional country-specific requirements***

#### ***Brazil (ANVISA):***

Verify that the manufacturer has established and maintains a continuous process of risk management which covers the entire life cycle of the product. Possible hazards must be identified in both normal and fault conditions, including those arising from human factors issues. The risk associated with those hazards, shall be calculated. Risks must be analyzed, evaluated and controlled, as necessary. Effectiveness of risk controls implemented shall be evaluated [RDC ANVISA 56/2001, RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20].

#### ***United States (FDA):***

Confirm that the manufacturer has identified the possible hazards associated with the device in both normal and fault conditions. The risks associated with the hazards, including those resulting from user error, should be calculated in both normal and fault conditions. If any risk is judged to be unacceptable, it should be reduced to acceptable levels by the appropriate means. Ensure changes to the device to eliminate or minimize hazards do not introduce new hazards [21 CFR 820.30(g); preamble comment 83].

## **Assessing conformity**

### **Risk management**

Each medical device organization must determine and document how much risk is acceptable. The actual use of any medical device includes some measure of risk to users or patients. Determining an acceptable level of risk depends on the intended use of the device, including the particular health concern of the patient population, the training of the users involved, and the use environment. For example, pediatric patients may have less ability to detect a device malfunction. A device used by consumers generally has less medical oversight than a device used in a hospital setting. The goal of a risk management program is to ensure the device is as safe as practical and the safety of the device is acceptable for the intended use.

Effective risk management usually starts in conjunction with the design and development process, proceeds through product realization, including the selection of suppliers, and continues until the time the product is decommissioned. Risk management should be initiated at a point early in the design and development process. This includes defining the intended use of the device, considering risk under normal use and reasonably foreseen misuse. Starting the risk management process after the design has progressed beyond a point where reasonable risk mitigation features can be included in the design can lead to devices that do not

## **Chapter 5 - Design and Development**

Task 9 – Design verification or design validation to confirm effectiveness of risk control measures

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meet customer needs and the medical device organization's requirements for safety. Records of risk management should demonstrate that risks that have been identified as unacceptable have been mitigated to an acceptable level.

### **Mitigation of risks**

There are a number of mechanisms that can be used to mitigate product risk. These risk mitigation mechanisms, in descending order of effectiveness, include safety features inherent in the device design, protective measures in the design (e.g. alarms), and user notifications (e.g. labeled warnings).

### **Review of risk management activities**

During the review of the design project selected, verify that risk management is initiated early in the design and development process. Confirm that the medical device organization's risk management process involves the proactive evaluation, control, and monitoring of product risk, followed by the reactive response to quality data that indicates new or changing product risk.

### **Links**

None

## **Task 9 – Design verification or design validation to confirm effectiveness of risk control measures**

**Confirm that design verification and/or design validation includes assurances that risk control measures are effective in controlling or reducing risk.**

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 7.1, 7.3.6, 7.3.7

**TGA:** TG(MD)R Sch1 P1 2, Sch3 P1 Cl 1.4(5)(c)

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 48

**HC:** CMDR 10,11, 15, 16

**MHLW/PMDA:** MO169: 26, 34, 35-1, [Old: 26, 34, 35]

**FDA:** 21 CFR 820.30(f), 820.30(g)]

### ***Additional country-specific requirements***

None

# **Chapter 5 - Design and Development**

## Task 10 – Design validation

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### **Assessing conformity**

#### **Verification of risk control measures**

During the review of design verification activities for the chosen design project, confirm that the identified risk control measures are actually effective in reducing or controlling risk. For example, a design for an enteral feeding tube may have a unique connector to prevent the potential for misconnection to other types of devices, such as suction catheters. Design verification should show that it is difficult or impossible to connect non-related devices to the enteral feeding tube.

#### **Links**

None

### **Task 10 – Design validation**

**Verify that design and development validation data show that the approved design meets the requirements for the specified application or intended use(s).**

***Verify that design validation testing is adjusted according to the nature and risk of the product and element being validated.***

#### **Clause and Regulation**

**ISO:** ISO 13485:2016: 4.2.1, 7.3.7

**TGA:** TG(MD)R Sch1 P1 2; Sch3 P1 Cl1.4(5)(d)

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 49, Art. 53, Art. 54, Art. 55, Art. 56, Art. 57, Art. 58, Art. 61

**HC:** CMDR 12, 18, 19

**MHLW/PMDA:** MO169: 6, 35-1; [6, 35]

**FDA:** 21 CFR 820.30(g)]

#### **Additional country-specific requirements**

##### **Australia (TGA):**

For devices contain temperature sensitive material, environmental conditions should be considered for country specific requirement. For example, test samples should be conditioned as per ISTA 2A to cover Australian climate zone (extreme temperature range -29C-50C) for packaging validation.

## **Chapter 5 - Design and Development**

Task 11 – Clinical evaluation and/or evaluation of medical device safety and performance

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### **Assessing conformity**

#### **Design validation**

Design validation is performed to provide objective evidence that design specifications (outputs) conform to user needs and intended uses. Design validation must be completed before commercial distribution of the product. The design validation activities should be predictive, not empiric. In other words, acceptance criteria need to be stated in advance of the validation activity. The establishment of pre-determined acceptance criteria may be found in a validation protocol or similar document.

Design validation must be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and includes testing of production units under actual or simulated use conditions. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, must be recorded.

#### **Needs, environment and uses**

Design validation must address the needs of all relevant parties, such as the patient, healthcare worker, biomedical engineer, and storage clerk. Consideration must be given to the environment in which the device will be stored, transported, and used.

Design validation needs to be performed for each intended use. Design validation must also confirm that user needs and intended uses associated with the device's packaging and labeling are met. These outputs have human factors implications and unless they are adequately considered during design validation, they may adversely affect the device and its use. Confirm that design validation data show that the approved design met the predetermined user needs and intended uses. The intended uses must include the purpose of the device, patient type (adults, pediatrics or newborn) and the environment in which the device is to be transported and used (domestic use, hospitals, ambulances, etc.).

#### **Links**

None

### **Task 11 – Clinical evaluation and/or evaluation of medical device safety and performance**

**Verify that clinical evaluations and/or evaluation of the medical device safety and performance were performed as part of design validation if required by national or regional regulations.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 7.3.7

**TGA:** TG(MD)R Reg 3.11, Sch1 EP14, Sch3 P1 Cl 1.4(5)(c)(vii), Sch3 P8

MDSAP AU P0002.007

## **Chapter 5 - Design and Development**

### Task 12 – Software design and development

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**ANVISA:** RDC ANVISA 665/2022: Art. 53, Art. 54, Art. 55, Art. 56, Art. 57, Art. 58, Art. 61, RDC ANVISA 56/2001

**HC:** CMDR 12, 18, 19

**MHLW/PMDA:** MO169: 6, 35-1; [Old: 6, 35]

**FDA:** 21 CFR 820.30(g)]

#### ***Additional country-specific requirements***

##### **Australia (TGA):**

Verify that records of the validation include clinical evidence as required by the clinical evidence procedures [TG(MD) Sch3 P1 Cl 1.4(5)(c)(vii) and TG(MD) Sch3 P8].

For more information about the sources and types of clinical evidence and how they may be used to demonstrate compliance with the Australian EPs, auditors may refer to the clinical evidence guidelines (medical devices)

## **Assessing conformity**

### **Clinical evaluations and testing**

Design validation may involve the performance of some sort of clinical evaluation, including testing under actual or simulated use conditions. Clinical evaluations may involve full clinical studies. Clinical evaluations may also consist of other evaluations in a clinical or non-clinical setting, provision of historical evidence that similar designs are clinically safe, or reviews of scientific literature.

The audit team should limit their review of clinical evaluations to verifying whether clinical evaluations have been performed as part of design validation, when necessary, and whether the medical device organization has established acceptance criteria for the results in order to validate the device and that the results obtained meet the defined acceptance criteria.

When applicable, review the clinical evaluations, if performed, to validate the design. The audit team should confirm that the data from clinical evaluations demonstrates that the user needs and intended uses for the device and its packaging and labeling were met.

### ***Links***

None

## **Task 12 – Software design and development**

**If the medical device contains software, verify that the software was subject to the design and development process.**

## **Chapter 5 - Design and Development**

### Task 12 – Software design and development

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***Confirm that the software was included within the risk management process.***

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 7.3.2, 7.3.10

**TGA:** TG(MD)R Sch1 P1 2, Sch1 EP12.1

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 53, Art. 54, Art. 55, Art. 56, Art. 57, Art. 58, Art. 61

**HC:** CMDR 20

**MHLW/PMDA:** MO169: 30, 36-2; [Old: 30]

**FDA:** 21 CFR 820.30(g)]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Software development**

Many devices are at least partially controlled by software. Some devices consist almost entirely of software. For the device software, confirm that the software is part of the design and development plan for the device. The life cycle requirements for medical device software must be defined, including the intended use.

### **Software verification**

“Software verification” is a term often used to describe the testing of the software. During the review of the software development, confirm that the medical device organization has conducted appropriate verification activities. Verification is often accomplished by performing test cases at the unit, subsystem, and integration levels; as well as system functional testing.

Software verification can include the testing of the software product installed on the target hardware. As with other types of design verification, verification of software is a predictive activity. The acceptance criteria must be determined prior to performing the testing.

The predetermined acceptance criteria are often found in a verification protocol or similar document. Confirm that the predetermined acceptance criteria have been met by reviewing the actual results of the selected software tests. The risk management activities for the device and software can help guide the audit team as to which verification tests involve the essential design outputs of the device and software.

## **Chapter 5 - Design and Development**

### Task 13 – Design and development change

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#### **Software validation**

Software validation is a “confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.” It involves checking for proper operation of the software in its actual or simulated use environment, including integration into the final device where appropriate. Testing of device software functionality in a simulated use environment, and user site testing are typically included as components of an overall design validation program for a software automated device.

The audit team may encounter times when the software has been installed at user sites as part of validation, often referred to as “beta testing”. Beta testing can be a method to confirm the device, including the software, meets the user needs and intended uses.

#### **Links**

None

### **Task 13 – Design and development change**

**Verify that design and development changes were controlled, verified (or where appropriate validated), and approved prior to implementation.**

***Confirm that any new risks associated with the design change have been identified and mitigated to the extent practical.***

#### **Clause and Regulation**

**ISO:** ISO 13485:2016: 4.2.1, 4.2.3, 7.1, 7.3.9, 7.3.10, 8.2.1

**TGA:** TG(MD)R Sch1 P1 2, Sch3 P1 Cl 1.4(5)(f), Sch3 P1Cl1.5(4), Sch3 P1 1.4(3)(a)&(b)

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 49, Art. 53, Art. 54, Art. 55, Art. 56, Art. 57, Art. 58, Art. 60, Art. 61, Brazilian Law 6360/76 - Art. 13

**HC:** CMDR 1, 34

**MHLW/PMDA:** MO169: 6, 7-2, 26, 36-1, 36-2, 55-1; [Old: 6, 26, 36]

**FDA:** 21 CFR 820.30(i)]

#### **Additional country-specific requirements**

##### **Australia (TGA):**

Verify that the Manufacturer has a process or procedure for notifying the Auditing Organization of a substantial change to the design process or the range of products to be manufactured [TG(MD)R Sch3 Cl1.5].

## **Chapter 5 - Design and Development**

### Task 13 – Design and development change

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Verify that the Manufacturer has a process or procedure for identifying a proposed substantial change to the design, or the intended performance, of a Class AIMD or Class III device, and to notify the assessment body prior to implementing the change [TG(MD)R Sch3 P1 CI 1.6(4)].

If the Manufacturer is also a holder of a TGA Conformity Assessment Certificate, then the Manufacturer is also required to notify the TGA of these changes.

Verify that Manufacturer has taken into account post-production feedback as an input to monitoring and maintaining product requirements and improving product realization processes.

#### ***Brazil (ANVISA):***

If the medical device evaluated is already registered/notified with ANVISA, verify that the design change was correctly and promptly submitted to ANVISA for approval, when applicable [Brazilian Law 6360/76 - Art. 13].

#### ***Canada (HC):***

Verify that the manufacturer has a process or procedure for identifying a "significant change" to a Class III or IV medical device. Verify that information about "significant changes" is submitted in a medical device license amendment application [CMDR 1, 34].

#### ***Japan (MHLW):***

For the Marketing Authorization Holder, confirm if the Marketing Authorization Holder has submitted a new application, a change application, or a change notification to PMDA/ a Registered Certification Body, when applicable [PMD Act 23-2-5.1, 23-2-5.11, 23-2-5.12, 23-2-23.1, 23-2-23.6, 23-2-23.7].

For the Registered Manufacturing Site, confirm if the site has a mechanism to communicate with the Marketing Authorization Holder about device modifications, so the Marketing Authorization Holder can take appropriate actions. If a critical medical device modification has happened in the Registered Manufacturing Site, confirm if the Registered Manufacturing Site has communicated with Marketing Authorization Holder about the change [MHLW MO169: 29].

#### ***United States (FDA):***

Verify that the medical device organization obtained a new 510(k) or supplement to the pre-market approval if required [21 CFR 807].

## **Assessing conformity**

### **Procedures**

A medical device organization may have separate change control procedures to handle the post-production and pre-production changes, or a medical device organization may have one procedure that handles both.

# **Chapter 5 - Design and Development**

## Task 14 – Design review

### **Nature of change**

The documentation and control of changes begins when the initial design inputs are approved and continues for the life of the product. Design change control applies to changes to inputs or outputs as a result of design verification or design validation, changes to labeling or packaging, changes to enhance a product's performance, changes of production process/es, and changes that result from product complaints. Change can be acceptable as long as it is controlled.

### **Records**

The control of changes is not complete until the results of the review of changes and any updates to product specifications or changed processes are documented or amended.

### **Communication and consequential actions**

Changes need to be effectively communicated and requirements for any consequential actions should be defined (e.g. training or communication to design or production staff)

### **Links**

[\*\*Measurement, Analysis and Improvement\*\*](#) process (if a design change was made to correct a quality problem with the device); [\*\*Device Marketing Authorization and Facility Registration\*\*](#)

During the audit of the Measurement, Analysis and Improvement process, the auditors may encounter corrective actions or preventive actions that resulted in design changes. When corrective action or preventive action involves changing the design, confirm that design controls have been applied to the change, in accordance with the medical device organization's procedures. Confirm these design changes were effective in addressing the quality issues or potential quality issues identified in corrective or preventive action. In addition, the design change should be evaluated under the medical device organization's risk management process to ensure that changes do not introduce new hazards. Some changes may require revalidation where it is not possible to verify that requirements have been met after the change has been implemented.

The audit team should also confirm the medical device organization has considered regulatory requirements for registration, listing, notification and licensing; and has complied with these requirements prior to marketing the changed device in the applicable regulatory jurisdictions.

## **Task 14 – Design review**

**Verify that design reviews were conducted at suitable stages as required by the design and development plan.**

## **Chapter 5 - Design and Development**

### Task 14 – Design review

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**Confirm that the participants in the reviews include representatives of functions concerned with the design and development stage being reviewed, as well as any specialist personnel needed.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 7.3.2, 7.3.5

**TGA:** TG(MD)R Sch3 P1 C1.4(5)(c)(i)

**ANVISA:** RDC ANVISA 665/2022: Art. 50, Art. 61

**MHLW/PMDA:** MO169: 6, 30, 33

**FDA:** 21 CFR 820.30(e)]

#### ***Additional country-specific requirements***

##### ***United States (FDA):***

Verify that procedures ensure that participants include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed [21 CFR 820.30(e)].

## **Assessing conformity**

### **Design reviews**

Design reviews typically occur at the end of each design stage or phase or after the completion of project milestones. The number of design reviews can vary, but at a minimum, one formal review must be conducted. Reviews should provide feedback to the design team on emerging problems, assess the progress of the design and development project, and confirm that the design is ready to move to the next phase of development or for transfer to the manufacturing phase.

It is not necessary to have fully convened meetings for all design reviews. For simple designs or minor changes, desk reviews and sign-offs may be adequate. Design reviews must include an individual who does not have direct responsibility for the design stage being reviewed and representation from manufacturing to ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.

During the review of design review activities for the selected design project, confirm that the reviews included an individual who did not have direct responsibility for the design stage being reviewed. The audit team should also confirm that outstanding action items are being resolved or have been resolved.

### ***Links***

None

## **Chapter 5 - Design and Development**

Task 15 – Impact review of design and development changes on previously made and distributed devices

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### **Task 15 – Impact review of design and development changes on previously made and distributed devices**

**Verify that design changes have been reviewed for the effect on products previously made and delivered, and that records of review results are maintained.**

#### *Clause and Regulation*

**ISO:** ISO 13485:2016: 7.3.9

**ANVISA:** RDC ANVISA 665/2022: Art. 60

**MHLW/PMDA:** MO169: 36-1; [Old: 36]

**FDA:** 21 CFR 820.30(i)]

#### *Additional country-specific requirements*

None

## **Assessing conformity**

### **Effects on constituent parts and products already delivered**

There are situations where a design change can affect constituent parts. For example, a change to a disposable portion of an aspiration system might affect the ability of the disposable to connect to the console. When necessary, ensure the design change does not negatively impact products in distribution.

#### *Links*

None

## **Task 16 – Design transfer**

**Determine if the design was correctly transferred to production.**

#### *Clause and Regulation*

**ISO:** ISO 13485:2016: 4.2.1, 4.2.3, 7.3.8

**ANVISA:** RDC ANVISA 665/2022: Art. 52, Art. 54, Art. 55, Art. 56, Art. 57, Art. 58, Art. 61

**MHLW/PMDA:** MO169: 6, 7-2, 35-2; [Old: 6, 30]

**FDA:** 21 CFR 830.30(h)]

#### *Additional country-specific requirements*

## **Chapter 5 - Design and Development**

### Task 16 – Design transfer

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#### **Brazil (ANVISA):**

Confirm that the manufacturer ensures that the design is not released for production until its approval by the persons assigned by the manufacturer and that the person/s assigned review all records required to the design history file in order to ensure it is complete and the final design is compatible with the approved plans, prior to its release. Confirm that this release, including date and manual or electronic signature of the responsible is documented [RDC ANVISA 665/2022: Art. 58, Art. 61].

## **Assessing conformity**

### **Transferring the design to production**

During this phase, the design is translated into production specifications. This can take place in steps or phases. The audit team should review how the design for the selected project was transferred into production specifications. Based on the medical device organization's identification of essential outputs and risk management activities, review significant elements of the manufacturing processes, including products from suppliers and the established tolerances for processes, and compare them with the approved design outputs contained within the design records. These activities can confirm whether or not the design was correctly transferred.

Design transfer is a process that may be initiated not only at the end of the design and development process, but may also be initiated immediately before validation stages and may continue as design and development evolves. This early initiation of design transfer is helpful in order to have production processes and device validations conducted properly and allow for corrections during the process. At the end, design and development process is "finalized" by a "final design transfer."

### **Links**

#### **Production and Service Controls, Purchasing**

Verify that production processes for the device, including process validation (if required) have been defined, documented, and implemented. Confirm that potential hazards that could be introduced or exacerbated by the production process have been identified, and production controls have been established. Production processes include not only the manufacturing instructions, but also internal controls, such as the type and extent of acceptance activities, equipment calibration and maintenance intervals, environmental controls, and personnel controls.

Confirm that the medical device organization has determined the type and extent of supplier controls based on the relationship between the supplied products and services and product risk.

## **Chapter 5 - Design and Development**

Task 17 – Top management commitment to design and development process

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### **Task 17 – Top management commitment to design and development process**

**Determine, based on the assessment of the design and development process overall, whether management provides the necessary commitment to the design and development process.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.1.3, 5.1, 5.5.1

**TGA:** TG(MD)R Sch3 P1 Cl 1.4(5)(b)(ii)

**ANVISA:** RDC ANVISA 665/2022: Art. 5°, Art. 6°, Art. 7°

**MHLW/PMDA:** MO169: 5-3, 10, 15

#### ***Additional country-specific requirements***

None

#### ***Links***

None

## **Chapter 6 - Production and Service Controls**

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### **Chapter 6 - Production and Service Controls**

The purpose of the Production and Service Controls process is to manufacture products that meet specifications. Developing processes that are adequate to produce devices that meet specifications, validating (or fully verifying the results of) those processes, and monitoring and controlling those processes are all steps that help assure the result will be devices that meet specified requirements. After completing the audit of the medical device organization's Production and Service Controls process, the audit team will return to the Management process to make a final decision of whether top management ensures that an adequate and effective quality management system has been established and maintained at the medical device organization.

In order to meet the Production and Service Controls requirements of Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016), the Quality Management System requirements of the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch3), Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022), Japanese QMS Ordinance (MHLW MO 169), the Quality System Regulation (21 CFR Part 820), and specific requirements of medical device regulatory authorities participating in the MDSAP program, the medical device organization must understand when deviations from device specifications could occur as a result of the production process or environment.

The **management representative** is responsible for ensuring that the requirements of the quality management system have been effectively defined, documented, implemented, and maintained. Prior to the audit of a process, it may be helpful to interview the management representative (or designee) to obtain an overview of the process and a feel for management's knowledge and understanding of the process.

Audit of the Production and Service Controls process will follow audit of the Measurement, Analysis and Improvement process and the Design and Development process per the MDSAP audit sequence. Information the audit team has learned about device and quality management system nonconformities during audit of the Measurement, Analysis and Improvement process, as well as higher risk elements and essential design outputs from the design projects reviewed during audit of the Design and Development process, should be used to make decisions as to the production processes to be reviewed during the audit of the Production and Service Controls process.

### **Auditing the Production and Service Controls Process**

**Purpose:** The purpose of auditing the production and service controls process (including testing, infrastructure, facilities, equipment, and servicing) is to verify that the medical device organization's process/es are capable of ensuring that products will meet specifications.

**Outcomes:** As a result of the audit of the Production and Service Controls process, objective evidence will show whether the medical device organization has:

## **Chapter 6 - Production and Service Controls**

### Task 1 – Planning of production and service process

- 
- A) Defined, documented and implemented procedures to ensure production and service processes are planned, developed, conducted, controlled, and monitored to ensure conformity to specified requirements
  - B) Developed production and service process controls commensurate with the potential effect of the process on product risk
  - C) Ensured that when the results of a process cannot be verified by subsequent monitoring or measurement, the process is validated with a high degree of assurance that the process will consistently achieve the planned result
  - D) Implemented procedures for the validation of the application of computer software for production and service processes that affect the ability of the product to conform to specified requirements, including validation of computer software used in the quality management system
  - E) Maintained records for each batch of medical devices that provides information for traceability and confirmation that the batch meets specified requirements
  - F) Implemented controls to protect customer property, including intellectual property, confidential health information, and other forms of customer property that is used or incorporated into products

Links to Other Processes:

**Management; Design and Development; Measurement, Analysis and Improvement;**  
**Purchasing**

### **Task 1 – Planning of production and service process**

**Verify that the product realization processes are planned, including any necessary controls, controlled conditions, and risk management activities required for the product to meet the specified or intended uses, the statutory and regulatory requirements related to the product, and (when applicable) unique device identifier requirements.**

**Confirm that the planning of product realization is consistent with the requirements of the other processes of the quality management system and performed in consideration of the quality objectives.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 7.1, 7.2.1, 7.5.1

**TGA:** TG(MD)R Sch 1 P1 2, Sch3 P1 Cl1.4(4), Sch3 P1 Cl1.4(5)(d)&(e)

**ANVISA:** RDC ANVISA 665/2022: Art. 5°, Art. 6°, Art. 7°, Art. 44, Art. 52, Art. 64, Art. 65, Art. 66

**MHLW/PMDA:** MO169: 26, 27, 40

**FDA:** 21 CFR 801, 820.30(b), 820.20(a), 820.30(h), 820.70(a), 830]

## **Chapter 6 - Production and Service Controls**

Task 1 – Planning of production and service process

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### ***Additional country-specific requirements***

#### **United States (FDA):**

Confirm that the medical device organization has determined the applicability of unique device identifier requirements per 21 CFR 801 and 21 CFR 830, has obtained the unique device identifiers from an FDA-accredited UDI-issuing agency, and the required data elements have been entered in the Global Unique Device Identification Database (GUDID) [21 CFR 801, 830].

## **Assessing conformity**

### **Planning**

In planning product realization, the medical device organization must determine as appropriate the quality objectives and requirements for the product, the processes, documents, and resources specific to the product, the criteria for product acceptance, and the required verification, monitoring, inspection, and test activities specific to the product. Planning of product realization often begins in the design and development of the product, including the translation of the design into production specifications.

The planning of product realization should be consistent with the risk control and mitigation strategies identified by the medical device organization during risk management activities.

During the audit, be mindful of requirements for the product that relate to statutory and regulatory requirements, requirements necessary for the product to meet specified or intended uses, and requirements for safe and efficacious use of the product. The medical device organization must ensure their processes, and the monitoring of processes, inspection, and test activities are planned and developed to ensure these requirements are met.

### **Unique Device Identifier (UDI)**

A UDI is a coded representation of specified information. It appears on the device label, packaging, or in some cases on the device itself. The UDI should be presented in two forms: easily readable plain text, and Automated Identification and Data Capture (or AIDC) format. Many types of AIDC compliant codings are available and are permissible provided they can be entered into an electronic patient record or other computer system via an automated process.

The requirements of the rule are generally directed at labelers. Labeler is defined in 21 CFR 801.3.

Two main factors determine if a party is a labeler: (1) a labeler causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label, or (2) a labeler causes a label to be replaced or modified with the intent that the device will be commercially distributed.

## **Chapter 6 - Production and Service Controls**

### Task 2 – Selection of production and service process(es)

Manufacturers, contract manufacturers, private label distributors, and convenience kit assemblers are the most common types of organizations that are considered labelers. Some small exceptions apply, such as adding a name or contact information to the already existing label.

The UDI program requires labelers to work with an FDA accredited issuing agency to produce their UDIs. The issuing agency provides a portion of the UDI to identify the labeler, as well as providing a standards compliant format for the display of the UDI in easily readable plain text and AIDC code.

The UDI rule requires device labelers to meet two basic requirements: (1) the devices must bear a UDI in the appropriate location, (2) and certain data elements must be entered in the Global Unique Device Identification Database (GUDID). The GUDID is a database maintained by the UDI team at FDA that serves as a public facing repository for UDI related device information.

Under the UDI rule, all medical devices, regardless of class (and including unclassified devices) must comply with the requirements of the rule, unless covered by an exemption or enforcement discretion.

#### **Quality objectives**

Quality objectives are typically expressed as a measurable target or goal. The planning of product realization should include consideration of how the production processes, the criteria for product acceptance, and the required verification, validation, monitoring, inspection, and test activities specific to the product will achieve the quality objectives. Confirm that the medical device organization has defined quality objectives for the device.

#### **Links**

##### **Management**

Confirm when necessary that the quality objectives related to the product were considered for inclusion in management review.

### **Task 2 – Selection of production and service process(es)**

**Review production processes considering the following criteria.**

**Select one or more production processes to audit.**

**Reminder:** Information the audit team has learned about device and quality management system nonconformities during audit of the Measurement, Analysis and Improvement process, as well as higher risk elements and essential design outputs from the design projects reviewed during audit of the Design and Development process should be used to make decisions as to the production processes to be reviewed.

## **Chapter 6 - Production and Service Controls**

Task 3 – Controls for the implementation of selected production and service process(es)

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### **Priority criteria for selection:**

1. Corrective and preventive action indicators of process problems or potential problems
2. Use of the production process for higher risk products
3. Use of production processes that directly impact the ability of the device to meet its Essential design outputs
4. New production processes or new technologies
5. Use of the process in manufacturing multiple products
6. Processes that operate over multiple shifts
7. Processes not covered during previous audits

### **Links**

None

## **Task 3 – Controls for the implementation of selected production and service process(es)**

**For each selected process, determine if the production and service provision processes are planned and conducted under controlled conditions that include the following:**

- the availability of information describing product characteristics
- the availability of documented procedures, requirements, work instructions, and reference materials, reference measurements, and criteria for workmanship
- the use of suitable equipment
- the availability and use of monitoring and measuring devices
- the implementation of monitoring and measurement of process parameters and product characteristics during production
- the implementation of release, delivery and post-delivery activities
- the implementation of defined operations for labeling and packaging
- the establishment of documented requirements for changes to methods and processes

### **Clause and Regulation**

**ISO:** ISO 13485:2016: 7.5.1, 8.2.5, 8.2.6

**TGA:** TG(MD)R Sch3 P1 Cl1.4(5)(d)&(e)

**ANVISA:** RDC ANVISA 665/2022: Art. 30, Art. 63, Art. 62, Art. 64, Art. 65, Art. 66, Art. 84, Art. 88

**MHLW/PMDA:** MO169: 40, 57, 58, 59

**FDA:** 21 CFR 820.70(a), 820.70(b), 820.75, 820.120, 820.130]

# **Chapter 6 - Production and Service Controls**

## Task 4 – Control of product cleanliness

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### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Establishment of work instructions, procedures, and production processes**

Production processes that may cause a deviation to a device specification and all validated processes must be controlled and monitored. The planning of production includes the establishment of procedures and work instructions for the control and monitoring of the production processes, including service controls when necessary. Control and monitoring procedures may include in-process and finished device acceptance activities as well as environmental and contamination control measures. The establishment of procedures and work instructions to control the production of the device should provide the controls and tolerances necessary to ensure finished devices conform to product specifications.

### ***Links***

None

## **Task 4 – Control of product cleanliness**

**Determine if the medical device organization has established documented requirements for product cleanliness including any cleaning prior to sterilization, cleanliness requirements if provided non-sterile, and assuring that process agents are removed from the product if required.**

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 4.2.3, 6.4.2, 7.5.2

**TGA:** TG(MD)R Sch3 P1 CI1.4(5)(d)

**ANVISA:** RDC ANVISA 665/2022: Art. 69, Art. 75, Art. 79

**MHLW/PMDA:** MO169: 6, 7-2, 25-2, 41; [Old: 6, 25, 41]

**FDA:** 21 CFR 820.70(c), 820.70(d), 820.70(e), 820.70(h)]

### ***Additional country-specific requirements:***

#### ***Brazil (ANVISA):***

Confirm that a pest control program has been established and where chemicals are used as part of the pest control program, the company must ensure that they do not affect product quality [RDC ANVISA 665/2022: Art. 74].

# **Chapter 6 - Production and Service Controls**

## Task 4 – Control of product cleanliness

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Verify that the manufacturer has established and maintains housekeeping procedures and schedules for production areas and warehouses, in conformance with production specifications [RDC ANVISA 665/2022: Art. 69].

### **Assessing conformity**

#### **Cleanliness requirements**

The goal of establishing requirements for product cleanliness is to minimize contamination of the finished device and the manufacturing environment. Sterile devices may require a higher level of control in terms of minimizing the bioburden and particulate contamination in order to assure the desired sterility assurance level is met.

Each medical device organization must evaluate the extent of cleanliness required for the proper functioning and intended use of the finished device and implement the necessary control measures. Examples of control measures include, but are not limited to, cleaning procedures, environmental controls (e.g. cleanrooms, or other controlled environments), requirements for attire, and training of personnel. When necessary, confirm the medical device organization has identified the cleanliness requirements for the finished device and the proper controls to achieve the required level of cleanliness.

#### **Process agents**

Process agents, also known as manufacturing materials, are generally defined as materials or substances used to facilitate the manufacturing process, which are present in or on the finished devices as a residue or impurity. Examples of process agents include cleaning agents, mold- release agents, lubricating oils, latex proteins, sterilant residues, etc. The medical device organization must evaluate process agents used during the manufacturing process when the process agent could potentially have an adverse effect on the product. During the design of the product and the development of the manufacturing process, the potential effect of process agents should be considered.

If the audit team encounters situations where process agents are being utilized in the manufacturing of the product, and the process agent could potentially have an adverse effect on the product, confirm that the medical device organization has made effective arrangements to control the process agent in a manner commensurate with the risk the agent poses to the finished device. For example, the medical device organization may need to validate a cleaning process to ensure cutting oil is removed from an orthopedic implant prior to packaging and sterilization.

#### **Links**

None

## **Chapter 6 - Production and Service Controls**

### Task 5 – Infrastructure

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#### **Task 5 – Infrastructure**

**Verify that the medical device organization has determined and documented the infrastructure requirements to achieve product conformity, including buildings, workspace, process equipment, and supporting services.**

**Confirm that buildings, workspaces, and supporting services allow product to meet requirements.**

**Verify that there are documented and implemented requirements for maintenance of process equipment where important for product quality, and that records of maintenance are maintained.**

#### *Clause and Regulation*

**ISO:** ISO 13485:2016: 4.2.1, 6.3, 7.5.1

**ANVISA:** RDC ANVISA 665/2022: Art. 67, Art. 78

**HC:** CMDR 14

**MHLW/PMDA:** MO169: 6, 24, 40

**FDA:** 21 CFR 820.70(g), 820.70(f)]

#### *Additional country-specific requirements*

##### **Brazil (ANVISA):**

Verify that manufacturing facilities are configured in order to provide adequate means for people flow [RDC ANVISA 665/2022: Art. 67].

## **Assessing conformity**

### **Infrastructure requirements**

The medical device organization is responsible for evaluating the manufacturing facility to ensure that the buildings, utilities, and space allow for the achievement of product conformity. The medical device organization is responsible for ensuring adequate space to prevent mix-ups and ensure orderly handling of products.

### **Equipment maintenance**

The medical device organization must consider whether maintenance of production equipment may affect product quality. Procedures, including the frequency of maintenance and the records of maintenance must be available for these items of equipment.

# **Chapter 6 - Production and Service Controls**

## Task 6 – Work environment

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### **Links**

None

## **Task 6 – Work environment**

### **Verify documented requirements have been established, implemented and maintained for:**

- health, cleanliness, and clothing of personnel that could have an adverse effect on product quality
- monitoring and controlling work environment conditions that can have an adverse effect on product quality
- training or supervision of personnel who are required to work under special environmental conditions
- controlling contaminated or potentially contaminated product (including returned products) in order to prevent contamination of other product, the work environment, or personnel

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 6.4

**TGA:** TG(MD)R Sch1 P2 7.2, 8

**ANVISA:** RDC ANVISA 665/2022: Art. 68

**MHLW/PMDA:** MO169: 6, 25-1, 25-2; [Old: 6, 25]

**FDA:** 21 CFR 820.70(c), 820.70(d), 820.70(e)]

### ***Additional country-specific requirements***

#### ***Brazil (ANVISA):***

Verify that biosafety standards are used, when applicable [RDC ANVISA 665/2022: Art. 76].

## **Assessing conformity**

### **Contamination control**

The medical device organization is responsible for establishing and maintaining procedures to prevent contamination of products, equipment, and personnel by substances that could adversely affect the device. If contamination control measures are necessary to meet specified requirements, cleaning and sanitation procedures and schedules may be required to ensure the contamination control measures are properly functioning. The medical device organization should consider the segregation and decontamination of returned product.

## **Chapter 6 - Production and Service Controls**

### Task 7 – Identification of processes subject to validation

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#### **Personnel practices**

Personnel practices must address personnel health, cleanliness, and attire if these could adversely affect product quality or the work environment. In the event that maintenance or other personnel are required to work temporarily under special environmental conditions, these individuals must be appropriately trained or supervised by a trained individual.

#### **Links**

None

### **Task 7 – Identification of processes subject to validation**

**Determine if the selected process(es) and sub-process(es) have been reviewed, including any outsourced processes, to determine if validation of these processes is required.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 4.1.6, 7.5.6

**TGA:** TG(MD)R Sch1 P2 8.2, 8.3; Sch3 P1 1.4(5)(d)

**ANVISA:** RDC ANVISA665/2022: Art. 103, Art. 104, Art. 105, Art. 106

**MHLW/PMDA:** MO169: 6, 5-6, 45; [Old: 6, 45]

**FDA:** 21 CFR 820.75(a)]

#### ***Additional country-specific requirements***

##### **Brazil (ANVISA):**

Verify that analytical methods, supporting auxiliary systems for production and environmental control that can adversely affect product quality or the quality system are validated, periodically reviewed and, when necessary, revalidated according to documented procedures [RDC ANVISA 665/2022: Art. 103, Art. 104, Art. 105, Art. 106].

##### **United States (FDA):**

Process validation is required for sterilization, aseptic processing, injection molding, and welding [21 CFR 820.75; preamble comment 143].

## **Assessing conformity**

#### **Process validation**

During the planning of product realization, the medical device organization must determine which production processes require validation and which processes can be verified. Process validation may apply to processes that generate components, subassemblies, or finished devices. Process validation is required for processes

## **Chapter 6 - Production and Service Controls**

### Task 8 – Process validation

where the results of the process cannot be fully verified. Processes that cannot be fully verified include processes where clinical or destructive testing is necessary to show that the process produced the desired result, where routine inspection and/or testing does not examine quality attributes essential to the proper functioning of the finished device, or where routine testing has insufficient sensitivity to verify the desired safety and efficacy of the finished product.

Examples of processes that require validation include, but are not limited to sterilization, aseptic processing, welding, and injection molding. When applicable, confirm that the medical device organization has identified processes which require validation, including validation requirements for any outsourced processes.

When validating processes, organizations must take into account the current thinking of experts where published information is available (e.g. though the application of ISO standards for sterilization validation).

#### **Links**

##### **Purchasing**

The audit team may encounter situations where the medical device organization outsources processes that require validation.

During the review of the Purchasing process, review the controls the medical device organization has instituted over suppliers that perform validated processes. This can be particularly important for higher risk validated processes performed by suppliers, since the finished device manufacturer does not have immediate control over those processes.

### **Task 8 – Process validation**

**Verify that the selected process(es) have been validated according to documented procedures if the result of the process cannot be fully verified or can be verified, but is not.**

**Confirm that the validation demonstrates the ability of the process/es to consistently achieve the planned result.**

**In the event changes have occurred to a previously validated process, confirm that the process was reviewed and evaluated, and re-validation was performed where appropriate.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 7.5.6

**TGA:** TG(MD)R Sch1 P1 2(1), Sch3 P1 1.4(5)(d)

**ANVISA:** RDC ANVISA 665/2022: Art. 3º section 31, Art. 103

# **Chapter 6 - Production and Service Controls**

## Task 8 – Process validation

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**MHLW/PMDA:** MO169: 6, 45

**FDA:** 21 CFR 820.75(a), 820.75(c)]

### ***Additional country-specific requirements***

#### **Australia (TGA):**

Confirm that methods of validation have regard to the generally acknowledged state of the art (e.g. current Medical Device Standard Orders - MDSO, ISO/IEC Standards, BP, EP, USP etc.) [TG Act s41CB, TG(MD)R Sch 1 P1 2(1)].

## **Assessing conformity**

### **Process validation**

Process validation means establishing by objective evidence (i.e. data) that a process **consistently** produces a **result** (e.g., sterility assurance level) or **product** meeting predetermined specifications. Remember that the term "**product**" applies to components and in-process devices as well as finished devices. Therefore, process validation may apply to processes that generate components, in-process devices, or finished devices.

### **Process validation procedures**

Some organizations have general process validation procedures. Other organizations establish separate procedures for each individual process validation study. Both methods for establishing process validation procedures are acceptable.

### **Reviewing a validation**

During review of a validation study, determine when applicable whether:

- The instruments used to generate the data were properly calibrated and maintained
- Predetermined product and process specifications were established
- Sampling plans used to collect test samples are based on a statistically valid rationale
- Data demonstrates predetermined specifications were met consistently
- Process tolerance limits were challenged
- Process equipment was properly installed, adjusted, and maintained
- Process monitoring instruments were properly calibrated and maintained
- Changes to the validated process were appropriately challenged (if applicable)
- Process operators were appropriately qualified.

### **Achieving the planned result**

Process validation activities are predictive, rather than empiric. In order for a process validation study to show the process achieves the planned result, the acceptance criteria must be stated in advance of performing the

## **Chapter 6 - Production and Service Controls**

### Task 9 – Validation of sterilization process

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validation. The data from the process validation study must show the predetermined acceptance criteria have been met.

#### **Evidence of nonconformities**

Process validation studies may also provide valuable insight into process or product nonconformities. For example, the process validation study must demonstrate not only that the process can produce a result or product meeting predetermined specifications but also that the process will consistently produce a result or product meeting predetermined specifications. If process or product nonconformities related to a validated process are encountered at a higher than anticipated rate, it may indicate the process validation study did not confirm that the process could consistently produce a result or product meeting predetermined specifications. Unless the medical device organization recognized this during the process validation study, they may not have investigated the cause of the process inconsistency.

#### **Links**

None

### **Task 9 – Validation of sterilization process**

**If product is supplied sterile ([see Annex 2](#)):**

**Verify the sterilization process is validated, periodically re-validated, and records of the validation are available.**

**Verify that devices sold in a sterile state are manufactured and sterilized under appropriately controlled conditions.**

**Determine if the sterilization process and results are documented and traceable to each batch of product.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.2.1, 7.5.5, 7.5.6, 7.5.7

**TGA:** TG(MD)R Sch1 2(1) & 8.3, Sch3 P1 1.4(5)(d)

**ANVISA:** RDC ANVISA 665/2022: Art. 83, Art. 103, Art. 104, Art. 105, Art. 106

**HC:** CMDR 17

**MHLW/PMDA:** MO169: 6, 44, 45, 46

**FDA:** 21 CFR 820.75, 820.184(d)]

## **Chapter 6 - Production and Service Controls**

Task 10 – Monitoring and measurement of product conformity

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### ***Additional country-specific requirements***

#### **Australia (TGA):**

Verify that methods of sterilization validation have regard to the generally acknowledged state of the art (e.g. Australian Medical Device Standard Orders – MDSO e.g. [Medical Device Standards Order \(Endotoxin Requirements for Medical Devices\) 2018](#)) or Australian Conformity Assessment Standard Orders - [Conformity Assessment Standards Order \(Quality Management Systems\) 2019](#) that refer to the use of ISO 11135, ISO 11137 and other standards). [TG(MD)R Sch1 P1 2(1)].

## **Assessing conformity**

### **Validation of sterilization processes**

Sterilization processes include terminal sterilization methods (such as radiation and ethylene oxide) as well as aseptic processing methods. Sterilization processes must be validated, with periodic revalidation as required by established standards or requirements established by the medical device organization.

### **Control of the manufacturing processes for devices intended to be sterile**

In addition to ensuring the cleaning, packaging, and sterilization processes are validated, auditors should ensure the medical device organization maintains appropriate controls over the following:

- routine monitoring and measurement of the cleaning, packaging and sterilization processes
- routine acceptance criteria of the cleaning, packaging and sterilization processes
- (re-)qualification, (re-)verification, (re-)calibration and maintenance of the cleaning, packaging and sterilization equipment
- environmental control of production areas (cleanroom design and monitoring)
- storage of device parts, components, and packaging material
- storage of finished sterile product and management of shelf life
- handling processes for non-sterile devices for re-sterilization.

### **Links**

None

## **Task 10 – Monitoring and measurement of product conformity**

**Verify that the system for monitoring and measuring of product characteristics is capable of demonstrating the conformity of products to specified requirements.**

***Confirm that product risk is considered in the type and extent of product monitoring activities.***

## **Chapter 6 - Production and Service Controls**

Task 11 – Control, operation, and monitoring of the production and service process; risk controls

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### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 7.1, 7.5.1, 8.1, 8.2.6

**TGA:** TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e)

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 64, Art. 131

**MHLW/PMDA:** MO169: 26, 40, 54, 58, 59

**FDA:** 21 CFR 820.70(a), 820.250(a)]

### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Monitoring systems**

The general goal of monitoring processes and product characteristics during production is to ensure that products conform to the specified requirements defined and approved during the design and development of the device. The medical device organization has the flexibility to determine the controls that are necessary, commensurate with the risk to the finished device if processes or product characteristics do not meet specified requirements. During the audit of production processes, confirm that the control measures are suitable for detecting process or product nonconformities.

### ***Links***

None

## **Task 11 – Control, operation, and monitoring of the production and service process; risk controls**

**Verify that the processes used in production and service are appropriately controlled, monitored, operated within specified limits and documented in the product realization records.**

***In addition, verify that risk control measures identified by the medical device organization for production processes are implemented, monitored and evaluated.***

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 7.1, 7.5.1, 8.1, 8.2.5

**TGA:** TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e)

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 64, Art. 83, Art. 128, Art. 131

## **Chapter 6 - Production and Service Controls**

Task 11 – Control, operation, and monitoring of the production and service process; risk controls

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**MHLW/PMDA:** MO169: 26, 40, 54, 57

**FDA:** 21 CFR 820.70(a), 820.75(b), 820.250]

### ***Additional country-specific requirements***

#### **Australia (TGA):**

See [Annex 1](#)

## **Assessing conformity**

### **Process control and monitoring**

Processes that may cause a deviation to device specifications and validated processes must be controlled and monitored. Control and monitoring procedures may include in-process and finished device acceptance activities as well as environmental and contamination control measures.

Compare the process monitoring and acceptance procedures contained or referenced within the records of production specifications with those available to the production personnel. Confirm that the procedures available to the production personnel are the most current approved revisions.

While in the production area, verify that the building is of suitable design and contains sufficient space to perform necessary operations. Also, verify that the results of control and monitoring activities demonstrate that the process is currently operating in accordance with applicable procedures. This can be done by comparing work instructions with what is actually being done, comparing product acceptance criteria with acceptance activity results, reviewing control charts against specified requirements, etc.

### **Links**

#### **Design and Development**

The design outputs for a device include documents such as diagrams, drawings, specifications, procedures, and the production processes that are essential to the proper manufacturing of the device. Production processes can include not only the manufacturing instructions, but also internal controls, such as the type and extent of acceptance activities, equipment calibration and maintenance intervals, environmental controls, and personnel controls.

During the audit of the Production and Service Controls process, consider reviewing production processes that have the highest risk or greatest effect on the essential design outputs.

## **Chapter 6 - Production and Service Controls**

Task 12 – Competence of personnel

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### **Task 12 – Competence of personnel**

**Verify that personnel are competent to implement and maintain the processes in accordance with the requirements identified by the medical device organization.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 6.2

**ANVISA:** RDC ANVISA 665/2022: Art. 15

**MHLW/PMDA:** MO169: 22

**FDA:** 21 CFR 820.25, 820.70(d), 820.75(b)]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Personnel training and qualification**

Production processes must be performed by adequately trained personnel. The medical device organization must establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities.

This training must be documented. In addition, personnel who perform validated processes must be qualified.

It is management's responsibility to determine what qualifications are necessary for personnel who perform validated processes.

#### ***Links***

##### **Management**

During the audit of the Production and Service Controls process, ensure that employees who are involved in key operations that affect product realization and product quality have been trained in their specific job tasks, as well as the quality policy and objectives.

When appropriate, review the training records for those employees whose activities have contributed to process nonconformities.

## **Chapter 6 - Production and Service Controls**

Task 13 – Control of monitoring and measuring device

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### **Task 13 – Control of monitoring and measuring device**

**Confirm that the medical device organization has determined the monitoring and measuring devices needed to provide evidence of conformity to specified requirements.**

**Verify that the monitoring and measuring equipment used in production and service control has been identified, adjusted, calibrated and maintained, and capable of producing valid results.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 7.5.1, 7.6

**TGA:** TG(MD)R Sch3 P1 1.4(5)(e)

**ANVISA:** RDC ANVISA 665/2022: Art. 93, Art. 94, Art. 95

**MHLW/PMDA:** MO169: 40, 53

**FDA:** 21 CFR 820.70(g), 820.72]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Maintenance and calibration**

While reviewing the selected production process, make note of significant pieces of process equipment and significant pieces of measuring or test equipment. Consider selecting process and test equipment that, if not properly controlled, could cause devices to not meet specified requirements; or produce inaccurate results that could lead to unrecognized nonconformities. Confirm that the production and test equipment selected for review is suitable for its intended purpose and capable of giving valid results.

Review the maintenance, control, and calibration procedures (and records) for the equipment selected for review. The initial frequency with which measuring and test equipment is calibrated and maintained is usually based on the equipment manufacturer's recommendations. As the medical device organization gains experience with the piece of equipment, the frequency of calibration and maintenance may be adjusted, based on a documented rationale.

### **Accuracy and precision**

When accuracy and precision is a factor in the validity of the result of the measuring equipment, the required accuracy and precision should be defined during the planning of product realization to ensure the equipment is suitable and capable of providing valid results.

## **Chapter 6 - Production and Service Controls**

Task 14 – Impact analysis of monitoring and measuring device found out of specifications

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### **Reviewing records**

If production equipment or test equipment is found to be outside of its maintenance or calibration requirements, verify that the medical device organization made an assessment of the effect of the out-of-tolerance situation on in-process, finished, or released devices, based on risk. Equipment adjustment, calibration, and maintenance procedures and records may provide insight into nonconformities. Review these procedures and records to determine whether inadequate procedures or the medical device organization's failure to comply with adequate procedures contributed to the nonconformity. For example, determine whether the lack of specified equipment adjustment or maintenance contributed to the production of nonconforming product.

### **Links**

None

## **Task 14 – Impact analysis of monitoring and measuring device found out of specifications**

**Confirm that the medical device organization assesses and records, the validity of previous measurements when equipment is found not to conform to specified requirements and takes appropriate action on the equipment and any product affected.**

**Verify that the control of the monitoring and measuring devices is adequate to ensure valid results. Confirm that monitoring and measuring devices are protected from damage or deterioration.**

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 7.6

**TGA:** TG(MD)R Sch3 P1 1.4(5)(e)

**ANVISA:** RDC ANVISA 665/2022: Art. 102

**MHLW/PMDA:** MO169: 53

**FDA:** 21 CFR 820.72(a)]

### ***Additional country-specific requirements***

None

## **Chapter 6 - Production and Service Controls**

Task 15 – Validation of software used for the control of the production and service process

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### **Assessing conformity**

#### **Control of monitoring and measuring devices**

Organizations must maintain proper calibration, storage, and handling controls for measuring, monitoring, and test equipment used in the development, production, installation, and servicing of product. Calibration must be traceable to a national or international measurement standard if one is available. If calibration services are provided by a supplier, the supplier controls are to be applied to ensure calibration is performed competently. Proper controls will help instill confidence in results obtained from the use of the equipment.

#### **Procedures**

Organizations must define, implement, and maintain procedures for the control of monitoring and measuring devices. The medical device organization may choose to develop general policies for the control of monitoring and measuring devices, along with separate, more specific procedures for the actual calibration and control of each piece of equipment.

Procedures must account for any environmental controls necessary for the equipment to produce valid results, as well as any specific storage or handling requirements when necessary. For example, a set of calibrated calipers may require storage in a padded case to maintain the required accuracy and precision. Confirm that the medical device organization has the proper procedures and controls in place to preserve the proper functioning of monitoring, measuring, and test equipment.

#### **When equipment is found to be out-of-tolerance**

The medical device organization may discover that monitoring or measuring equipment is no longer within its adjustment or calibration tolerance. In these situations, the medical device organization must assess and record the validity of previous measuring results and take appropriate action on the equipment and any product affected.

#### **Links**

None

## **Task 15 – Validation of software used for the control of the production and service process**

**If the selected process is software controlled, or if software is used in production equipment or the quality management system, verify that the software is validated for its intended use.**

**Software validation may be part of equipment qualification.**

#### **Clause and Regulation**

**ISO:** ISO 13485:2016: 4.1.6, 7.5.6, 7.6

## **Chapter 6 - Production and Service Controls**

Task 15 – Validation of software used for the control of the production and service process

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**ANVISA:** RDC ANVISA 665/2022: Art. 104

**MHLW/PMDA:** MO169: 5-6, 45, 53; [Old: 45, 53]

**FDA:** 21 CFR 820.70(i)]

### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Validation of production and quality system software**

Production process control software (and any other software used in the medical device organization's quality system) must be validated for its intended use according to an established protocol. If the production process the audit team selected for review is controlled with software, review the software validation documents and records.

Software validation documents and records should include:

- A software requirements document describing the intended use(s) and user needs associated with the software.
- An established validation protocol or similar document describing the activities necessary to demonstrate that the software requirements can be met.
- Records of the results of the software validation activities described in the software validation protocol or similar document.
- Records that software changes are appropriately controlled (where applicable).

For off-the-shelf quality management system software and software-controlled production or test equipment, it may not be possible, practical, or necessary for the medical device organization to review the software code or the various software verification test cases that are typically performed by the software or equipment manufacturer. However, the medical device organization must still ensure the software is capable of functioning according to the device medical device organization's needs. The validation to confirm the software meets the medical device organization's needs must be performed according to a protocol or similar document with predetermined acceptance criteria.

If multiple software driven systems are used in the production process, be sure to assess the system(s) most likely to have an impact on the finished device's ability to meet specified requirements. Not all software driven systems used in a production process will need to be audited during each audit.

### ***Links***

None

## **Chapter 6 - Production and Service Controls**

### Task 16 – Device master file

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#### **Task 16 – Device master file**

**Determine if the medical device organization has established and maintained a file for each type of device that includes or refers to the location of device specifications, production process specifications, quality assurance procedures, traceability requirements, and packaging, labeling specifications, and when applicable requirements for installation and servicing.**

***Confirm that the medical device organization determined the extent of traceability based on the risk posed by the device in the event the device does not meet specified requirements.***

#### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 4.2.1, 4.2.3, 7.1, 7.5.8, 7.5.9.1

**TGA:** TG(MD)R, Sch1 EP13, Sch3 P1 1.4(5) (c),(d),(e) & 1.9

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 63, Art. 64, Art. 84, Art. 85, Art. 86, Art. 87

**HC:** CMDR 9(2), 21-23, 52-56, 66-68

**MHLW/PMDA:** MO169: 6, 7-2, 26, 47, 48; [Old: 6, 26, 47, 48]

**FDA:** 21 CFR 820.65, 820.181]

#### ***Additional country-specific requirements:***

##### ***Australia (TGA):***

Verify that the design and location of information to be provided with a medical device, including labelling and instructions for use, comply with Essential Principle 13 and implant cards and leaflets with Essential principle 13A.

##### ***Brazil (ANVISA):***

Verify that the manufacturer has established and maintains procedures to ensure integrity and to prevent accidental mixing of labels, instructions, and packaging materials [RDC ANVISA 665/2022: Art. 85].

Confirm that the manufacturer has ensured that labels are designed, printed and, where applicable, applied so that they remain legible and attached to the product during processing, storage, handling and use [RDC ANVISA 665/2022: Art. 86].

##### ***Canada (HC):***

Verify that the Manufacturer maintains objective evidence that devices meet the safety and effectiveness requirements. [CMDR 9(2)].

Verify that devices sold in Canada have labeling that conforms to Canadian English and French language requirements and contains the Manufacturer's name and address, device identifier, control number (for Class III MDSAP AU P0002.007

## **Chapter 6 - Production and Service Controls**

### Task 16 – Device master file

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and IV devices), contents of packaging, sterility, expiry, intended use, directions for use and any special storage conditions [CMDR 21-23].

Verify that the Manufacturer maintains distribution records in respect of a device that will permit a complete and rapid withdrawal of the device from the market [CMDR 52-56].

#### ***United States (FDA):***

If a control number is required for traceability, confirm that a control number is on, or accompanies the device throughout distribution [21 CFR 820.120(e)].

## **Assessing conformity**

### **Records**

The required records for each type or model of device include documents such as diagrams, drawings, specifications, and procedures associated with the device, its packaging and labeling; as well as, quality management system and production process requirements; and if applicable, installation and servicing requirements. Documents and records associated with production processes can include not only the manufacturing instructions, but also internal controls, such as the type and extent of acceptance activities, equipment calibration and maintenance intervals, environmental controls, and personnel controls.

These documents and records provide the requirements and instructions for the proper manufacturing, labeling, packaging, and testing of the device to assure specified requirements are met during the production of each batch of devices. For the device(s) the audit team has selected to review, confirm that the required records have been established.

### **General traceability**

It is the responsibility of the medical device organization to establish procedures for traceability. For devices that are not implanted and are not life-supporting or life-sustaining, the medical device organization has the flexibility to determine which raw materials and components are required to be traceable, commensurate with the risk posed by the device in the event the component does not meet specified requirements.

Traceability systems commonly include elements such as written procedures describing the control numbering system to be used, as well as the documentation of lot numbers, control numbers, or serial numbers identifying the batch of components, subassemblies, finished devices, packaging, and labeling in order to aid their identification in the manufacturing process.

## **Chapter 6 - Production and Service Controls**

Task 17 – Production record; evidence of compliance of released devices

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### **Links**

#### **Design and Development**

During the design and development of the device, the essential design outputs for the proper functioning of the device should have been identified. Raw materials, components, and subassemblies should have been considered for traceability if their nonconformity could result in the finished device not meeting its specified requirements and essential functions.

### **Task 17 – Production record; evidence of compliance of released devices**

**Determine if the medical device organization has established and maintained a record of the amount manufactured and approved for distribution for each batch of medical devices, the record is verified and approved, the device is manufactured according to the file referenced in Task 16, and the requirements for product release were met and documented.**

#### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 4.2.1, 7.5.1, 7.5.8, 7.5.9.1, 8.2.6

**ANVISA:** RDC ANVISA 665/2022: Art. 39, Art. 113, Art. 114

**MHLW/PMDA:** MO169: 6, 40, 47, 48, 58, 59

**FDA:** 21 CFR 820.120, 820.184]

#### ***Additional country-specific requirements***

##### ***Brazil (ANVISA):***

Verify that the device history record of the product includes or refers to the following information: date of manufacture; components used; quantity manufactured; results of inspections and tests; parameters of special processes; quantity released for distribution; labeling; identification of the serial number or batch of production; and final release of the product [RDC ANVISA 665/2022: Art. 40].

Verify that labeling has not been released for storage or use until a designated individual has examined the labeling for accuracy. The approval, including the date, name, and physical or electronic signature of the person responsible, must be documented in the device history record [RDC ANVISA 665/2022: Art. 87].

##### ***United States (FDA):***

Verify that labeling is not released for storage or use until a designated individual has examined the labeling for accuracy including, where applicable, the correct unique device identifier (UDI) or Universal Product Code

## **Chapter 6 - Production and Service Controls**

Task 17 – Production record; evidence of compliance of released devices

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(UPC), expiration date, control number, storage instructions, handling instructions, and any additional processing instructions [21 CFR 820.120(b)].

Confirm that labeling is stored in a manner that provides proper identification and prevents mix-ups. Verify labeling and packaging operations are controlled to prevent labeling mix-ups [21 CFR 820.120(c) and (d)].

Verify that the label and labeling used for each production unit, lot, or batch are documented in the batch record, as well as any control numbers used [21 CFR 820.120(e), 820.184(e)].

### **Assessing conformity**

#### **Verify manufacturing of the device**

Verify that each batch of devices was manufactured in accordance with product and production specifications, being mindful that in some instances, a batch can be a single device. This verification should include a review of the purchasing controls and receiving acceptance activities applied to at least one significant component or raw material, in-process and final finished device acceptance activities and results, environmental and contamination control records (if applicable), and sampling plans for process and environmental controls and monitoring.

The record for each batch of devices must include, or refer to the location of, the following information:

- The dates of manufacture
- The quantity manufactured
- The quantity released for distribution
- The acceptance records which demonstrate the device has been manufactured in accordance with the planned arrangements and defined product specifications
- The primary identification label and labeling used for each production unit
- Any device identification(s) and control number(s) used, including unique device identifiers when applicable
- A provision to indicate that the record has been verified and approved.

#### **Determine if there are problems**

If, during the accomplishment of this audit task, the audit team observes evidence that the process is outside the medical device organization's acceptance range for operating parameters or that product nonconformities exist, confirm that the nonconformities were handled appropriately, with input into the Measurement, Analysis and Improvement process when appropriate.

#### **Links**

None

## **Chapter 6 - Production and Service Controls**

Task 18 – Traceability applied to implantable, life-supporting or life-sustaining medical devices

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### **Task 18 – Traceability applied to implantable, life-supporting or life-sustaining medical devices**

**If the medical device organization manufactures active or non-active implantable medical devices, life-supporting or life-sustaining devices, confirm that the medical device organization maintains traceability records of all components, materials, and work environment conditions (if these could cause the medical device to not satisfy its specified requirements) in addition to records of the identity of personnel performing any inspection or testing of these devices.**

**Confirm that the medical device organization requires that agents or distributors of these devices maintain distribution records and makes them available for inspection.**

**Verify that the medical device organization records the name and address of shipping consignees for these devices.**

#### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 4.2.1, 7.5.9.2, 8.2.6

**MHLW/PMDA:** MO169: 6, 49, 59

**FDA:** 21 CFR 820.65]

#### ***Additional country-specific requirements***

##### ***Canada (HC):***

Verify that the Manufacturer has identified Schedule 2 implants and provides implant registration cards with devices or employs another suitable system approved by Health Canada [CMDR 66-68].

Verify that the Manufacturer of devices that are listed on Schedule 2 of the Medical Devices Regulations maintains distribution records of these devices as well as any information received on implant registration cards related to these Schedule 2 devices [CMDR 54].

##### ***United States (FDA):***

Verify that the manufacturer has implemented a tracking system for devices for which the manufacturer has received a tracking order from FDA. The tracking system must ensure the manufacturer is able to track the device to the end-user. The manufacturer must conduct periodic audits of the tracking system [21 CFR 821].

## **Assessing conformity**

### **Traceability of implantable, life-supporting or life-sustaining devices**

Medical device organizations that produce finished devices whose failure could result in serious injury or harm to the user must implement a traceability system. The traceability system must allow for each batch of finished

## **Chapter 6 - Production and Service Controls**

### Task 19 – Identification of product status

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devices to be traced by a control number or similar mechanism throughout the distribution chain.

Organizations must also provide for the control and traceability of components and materials used in the manufacture of the device, as well as documentation of the manufacturing conditions when manufacturing conditions could cause the finished device to not meet specified requirements (e.g. cleanroom conditions).

The determination of which components and raw materials may be required to be traceable may be made by the medical device organization using risk management tools, such as risk analysis, or by identification of the components and processes used to fulfill the essential design outputs.

#### **Medical Device Tracking**

Some regulatory authorities participating in the MDSAP have requirements for tracking certain types of devices to the end-user. For regulatory authorities that have tracking requirements, these requirements generally apply to a small subset of devices that are life-sustaining or life supporting, intended for implant longer than one year, or are considered by the regulatory authority to be high risk.

If the medical device organization manufactures or distributes a device that falls under a tracking requirement, confirm that the medical device organization has the necessary systems in place to provide for tracking each device to the end-user.

The medical device organization's tracking system must be periodically reviewed and audited by the medical device organization to confirm that the tracking system is effective. The tracking system must contain the unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices.

#### ***Links***

None

### **Task 19 – Identification of product status**

**Verify that product status identification is adequate to ensure that only product which has passed the required inspections and tests is dispatched, used, or installed.**

#### ***Clause and Regulation***

**ISO: ISO: 13485:2016: 7.5.8**

**ANVISA:** RDC ANVISA 665/2022: Art. 108, Art. 113

**MHLW/PMDA:** MO169: 47; [Old: 47, 50]

**FDA:** 21 CFR 820.86]

## **Chapter 6 - Production and Service Controls**

### Task 20 – Customer property

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#### *Additional country-specific requirements*

None

## **Assessing conformity**

### **Identification**

Identification is generally defined as the description of the product that distinguishes it from other product. Organizations must define, document, and implement processes for the identification and control of product, including components, process agents, subassemblies, finished devices, packaging, and labeling. This can be accomplished through the use of part numbers, lot numbers, batch numbers, work order numbers, quantities, supplier name, as well as other means. The extent of identification activities should be based on the complexity and risk of the product.

### *Links*

None

## **Task 20 – Customer property**

**Verify that the medical device organization has implemented controls to identify, verify, protect, and safeguard customer property provided for use or incorporation into the product.**

**Verify that the medical device organization treats patient information and confidential health information as customer property.**

### *Clause and Regulation*

**ISO:** ISO: 13485:2016: 7.5.10

**MHLW/PMDA:** MO169: 51

#### *Additional country-specific requirements*

None

## **Assessing conformity**

### **Safeguarding customer property**

The medical device organization is responsible for safeguarding customer property while it is under the medical device organization's control. If any customer property is lost, damaged, or otherwise unsuitable for use, this must be reported to the customer and records maintained.

### *Links*

None

## **Chapter 6 - Production and Service Controls**

### Task 21 – Acceptance activities

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#### **Task 21 – Acceptance activities**

**Verify that acceptance activities assure conformity with specifications and are documented.**

***Confirm that the extent of acceptance activities is commensurate with the risk posed by the device.***

**Note:** Acceptance activities apply to any incoming component, subassembly, or service, regardless of the medical device organization's financial or business arrangement with the supplier.

#### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 4.2.1, 7.4.3, 7.5.8, 8.2.6

**TGA:** TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(d)

**ANVISA:** RDC ANVISA 665/2022: Art. 88, Art. 89, Art. 90, Art. 131

**MHLW/PMDA:** MO169: 6, 39, 47, 58, 59

**FDA:** 21 CFR 820.80, 820.250(b)]

#### ***Additional country-specific requirements***

##### ***Brazil (ANVISA):***

Verify that sampling plans are defined and based on valid statistical rationale. Each manufacturer must establish and maintain procedures to ensure that sampling methods are suitable for their intended use and are reviewed regularly. A review of sampling plans should consider the occurrence of nonconforming product, quality audit reports, complaints and other indicators [RDC ANVISA 665/2022: Art. 132, Art. 133, Art.134].

##### ***United States (FDA):***

Verify that the manufacturer establishes and maintains procedures to ensure that sampling methods are adequate for their intended use and ensure that when changes occur, the sampling plans are reviewed [21 CFR 820.250(b)].

## **Assessing conformity**

### **Recognized acceptance activities**

Organizations are expected to define, document, and implement systems and procedures for acceptance activities to verify that products, including finished devices, in-process devices, components, packaging, and labeling conform to specified requirements. Recognized acceptance activities include, but are not limited to, inspections, tests, review of certificates of analysis, and supplier audits. Effective acceptance procedures and systems directly affect the ability of a medical device organization to demonstrate that the process and product meets specifications.

# **Chapter 6 - Production and Service Controls**

## Task 21 – Acceptance activities

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During the audit of acceptance activities for the devices selected for audit, confirm that the medical device organization has defined processes for receiving, in-process, and final acceptance activities. Determine if the acceptance activities have been implemented. One way to accomplish this audit task is to review a sample of batch records and confirm that the acceptance activities have been documented and that the acceptance activities show specified requirements have been met. Records should identify who conducted acceptance activities.

The acceptance status of incoming, in-process, and finished devices must be identified. The identification of acceptance status must be maintained throughout manufacturing, packaging, labeling, and where applicable, installation and servicing to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

### **Acceptance activities involving related firms**

The audit team may encounter situations where the medical device organization receives incoming product from a financial or corporate affiliate. It is the receiving medical device organization's responsibility to perform and record the necessary acceptance activities to ensure the received product conforms to specified requirements, as well as applying the necessary purchasing controls to the supplier. Acceptance activities and purchasing controls apply to all product received from suppliers outside of the scope of the medical device organizations quality management system, whether a payment occurs or not, and regardless of the corporate or financial relationship of the supplier to the medical device organization.

### **Sampling**

The audit team may encounter the use of sampling during acceptance activities. For example, a medical device organization might choose to use sampling to perform receiving acceptance on a large lot of incoming components. When used, sampling plans must be written and based on a valid statistical rationale and a risk-based methodology.

### **Combination of controls**

An important concept to remember is that quality cannot be inspected or tested into products. Organizations must establish an appropriate mix of acceptance activities and purchasing controls to ensure products will meet specified requirements. The type and extent of acceptance activities can be based in part on the amount of purchasing controls applied to the supplier, the demonstrated capability of the supplier to provide quality products, and the potential impact of the product on the finished device, including the risk the device poses to the patient or user if specified requirements are not met. Organizations that conduct quality control solely in-house must still assess the capability of suppliers to provide acceptable products.

### **Evidence of inadequate acceptance activities**

The audit team may encounter instances where product has been deemed acceptable by the successful completion of acceptance activities but the product is later shown to not meet specified requirements (i.e. failure of the device leading to product complaint). This can be an indication that the acceptance activities are MDSAP AU P0002.007

## **Chapter 6 - Production and Service Controls**

Task 22 – Identification, control, and disposition of nonconforming products

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not sufficient to identify nonconformities. Confirm that the medical device organization has taken the appropriate action to determine the suitability of the acceptance activities.

### **Links**

#### **Purchasing, Design and Development**

The audit team should consider reviewing the purchasing controls and requirements for suppliers of higher risk products. The audit team should also consider reviewing the purchasing controls and requirements for suppliers of products that undergo minimal acceptance activities at the medical device organization, particularly if the supplied product is manufactured using a process that requires validation. During the review of acceptance activities, if the audit team encounters situations where records of acceptance activities for supplied product reveal products that do not meet specified requirements, consider selecting those suppliers for review during the audit of the medical device organization's Purchasing process.

The establishment of the necessary purchasing controls and required acceptance activities is a design output. The degree of the purchasing controls necessary and extent of acceptance activities should be based on the risk posed by the product not meeting its specified requirements and essential design outputs.

## **Task 22 – Identification, control, and disposition of nonconforming products**

**Verify that the identification, control, and disposition of nonconforming products is adequate, based on the risk the nonconformity poses to the device meeting its specified requirements.**

### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 7.5.8, 8.3

**TGA:** TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(b)

**ANVISA:** RDC ANVISA 665/2022: Art. 115, Art. 116

**MHLW/PMDA:** MO169: 47, 60-1, 60-2, 60-3, 60-4; [Old: 47, 50, 60]

**FDA:** 21 CFR 820.60, 820.90(a), 820.86, 820.100(a)]

### ***Additional country-specific requirements***

None

## **Chapter 6 - Production and Service Controls**

Task 22 – Identification, control, and disposition of nonconforming products

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### **Assessing conformity**

#### **Procedures**

The purpose of controlling nonconforming product is to prevent the unintended use and distribution of nonconforming product, including components, processing agents, in-process devices, and finished devices. Confirm that the medical device organization has defined and implemented procedures for the identification, control, segregation, evaluation, and disposition of nonconforming product.

#### **Handling nonconforming product**

The medical device organization can address nonconforming product by taking action to eliminate the detected nonconformity (e.g. sorting an incoming lot of components to remove components that do not meet specifications), authorizing its use, release, or acceptance under concession, or by taking action to prevent its original intended use (e.g. allowing the components or devices to be used as demonstration units at marketing conferences).

Until a disposition can be made, the medical device organization must have a process to properly identify nonconforming product to prevent its accidental or unauthorized use. One example is tagging and moving the nonconforming product to a controlled enclosure away from the production area.

If nonconforming product is accepted under concession, the records of the identity of the person authorizing the concession must be maintained.

If nonconforming product has been detected after a product has been released and put into use the medical device organization must consider the risks associated with the device and may need to consider an advisory notice or recall.

#### **Evaluation of nonconforming product**

The evaluation of nonconformity must include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformity, such as a supplier. Ensure that the medical device organization has adequately established an interface / interaction between the processes for the identification of non-conforming product and the processes for corrective action. These interactions should be evident in the quality manual.

## Chapter 6 - Production and Service Controls

### Task 23 – Rework of nonconforming products

#### Links

##### [\*\*Measurement, Analysis and Improvement\*\*](#)

The audit team should be mindful of any instances where the acceptance of nonconforming product has led to finished devices not meeting specified requirements. This information can often be found in records of acceptance activities and complaint records.

During the review of the medical device organization's corrective and preventive actions, the auditors may have noted instances where nonconforming products were found to be the underlying cause of quality problems and complaints. The audit team should consider reviewing the medical device organization's handling and evaluation of nonconforming products that were determined to be the underlying cause of quality problems.

Ensure that the analysis of data regarding nonconforming product is considered as an input to the medical device organization's Measurement, Analysis and Improvement process and that corrective or preventive actions have been implemented when necessary.

### Task 23 – Rework of nonconforming products

**If a product needs to be reworked, confirm that the medical device organization has made a determination of any adverse effect of the rework upon the product.**

**Verify that the rework process has been performed according to an approved procedure, that the results of the rework have been documented, and that the reworked product has been re-verified to demonstrate conformity to requirements.**

#### *Clause and Regulation*

**ISO:** ISO: 13485:2016: 8.3.4

**ANVISA:** RDC ANVISA 665/2022: Art. 119

**MHLW/PMDA:** MO169: 60-4; [Old: 60]

**FDA:** 21 CFR 820.90(b)]

#### *Additional country-specific requirements*

None

## **Chapter 6 - Production and Service Controls**

### Task 24 – Preservation of the product

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#### **Assessing conformity**

##### **Reworking nonconforming product**

The audit team may encounter instances where the medical device organization has chosen to address nonconforming product by means of reworking the component, subassembly or finished device. The medical device organization must have suitable approved procedures in place to address nonconforming product destined for rework. Reworked product must be re-evaluated or re-tested to ensure it meets its original specified requirements. Rework must be documented.

Be mindful of instances where the underlying cause of quality problems, such as complaints that finished devices do not meet specified requirements, are traced to devices that have been reworked. This can be an indication that the rework process was not adequate to ensure the finished device meets specifications.

Additionally, rework of products manufactured using validated processes can be an indication that the process cannot consistently produce product that meets specified requirements. If the audit team notes a pattern of reworking products that are manufactured using a validated process, consider reviewing the process validation to confirm that the medical device organization has data to show the process is effective, reproducible, and stable; and that the medical device organization is operating the process within the validated parameters.

#### ***Links***

None

### **Task 24 – Preservation of the product**

**Verify that procedures are established and maintained for preserving the conformity of product and constituent parts of a product during internal processing, storage, and transport to the intended destination. This preservation encompasses identification, handling, packaging, storage, and protection, including those products with limited shelf-life or requiring special storage conditions.**

#### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 7.5.8, 7.5.11

**TGA:** TG(MD)R Sch1 P1 4&5

**ANVISA:** RDC ANVISA 665/2022: Art. 84, Art. 107, Art. 111

**HC:** CMDR 14

**MHLW/PMDA:** MO169: 47, 52

**FDA:** 21 CFR 820.130, 820.140, 820.150, 820.160(a)]

## **Chapter 6 - Production and Service Controls**

Task 25 – Review of customer requirements, distribution records

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### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Ensuring proper handling**

The medical device organization must have a documented system that defines product handling requirements at all stages of manufacturing to prevent mix-ups, damage, and deterioration. This can include specified requirements for storage and shipping to ensure the preservation of the product to its destination. For example, an in-vitro diagnostic device may need to be stored and shipped in a frozen state to maintain proper shelf-life of the reagents. or test samples may need to be conditioned as per ISTA 2A to cover Australian climate zone (extreme temperature range -29C-50C) for packaging validation. These handling requirements should have been considered during the planning of product realization for the device. When necessary, confirm that the needed control measures are implemented to ensure the conformity of product to its specified requirements.

### ***Links***

None

## **Task 25 – Review of customer requirements, distribution records**

**Confirm that the medical device organization performs a review of the customer's requirements, including the purchase order requirements, prior to the medical device organization's commitment to supply a product to a customer.**

**Verify that the medical device organization maintains documentation required by regulatory authorities regarding maintenance of distribution records.**

### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 4.2.1, 5.2, 7.2.2, 7.5.9

**ANVISA:** RDC ANVISA 665/2022: Art. 112

**MHLW/PMDA:** MO169: 6, 11, 28, 48, 49

**FDA:** 21 CFR 820.160(a)]

### ***Additional country-specific requirements***

## **Chapter 6 - Production and Service Controls**

### Task 26 – Installation activities

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#### ***Brazil (ANVISA):***

Verify that the manufacturer maintains distribution records which include or make reference to: the name and address of the consignee, the identification and quantity of products shipped, the date of dispatch, and any numerical control used for traceability [ANVISA RDC 6.3].

#### ***Canada (HC):***

Verify that the Manufacturer maintains distribution records that contain sufficient information to permit complete and rapid withdrawal of the medical device from the market [CMDR 52-53].

Verify that distribution records of a device are retained by the Manufacturer in a manner that will allow for timely retrieval, for the longer of (a) the projected useful life of the device; and (b) two years after the date the device was shipped [CMDR 55-56].

#### ***United States (FDA):***

Verify that the Manufacturer maintains distribution records which include or refer to the location of the name and address of the initial consignee, the identification and quantity of devices shipped; and any control numbers used [21 CFR 820.160(b)].

## **Assessing conformity**

### **Distribution records**

The medical device organization must maintain distribution records which include or refer to the location of the initial consignee, the identification and quantity of devices shipped, the date shipped, and any control numbers used.

### ***Links***

None

## **Task 26 – Installation activities**

**If installation activities are required, confirm that records of installation and verification activities are maintained.**

### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 7.5.3

**ANVISA:** RDC ANVISA 665/2022: Art. 125, Art. 126

**MHLW/PMDA:** MO169: 42

**FDA:** 21 CFR 820.170]

## **Chapter 6 - Production and Service Controls**

### Task 27 – Servicing activities

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#### *Additional country-specific requirements*

None

### **Assessing conformity**

#### **Installation activities**

When a device must be installed for suitable functioning, the medical device organization must establish procedures and instructions to ensure proper installation. These instructions must be made available to personnel performing the installation. Installation activities must be documented.

#### **Determining the extent of review**

In the absence of identified quality problems related to the installation of the selected device, the audit team may choose to limit the review of the installation process to confirming the necessary procedures are in place.

#### **Links**

None

### **Task 27 – Servicing activities**

**Determine if servicing activities are conducted and documented in accordance with defined and implemented instructions and procedures.**

**Confirm that service records are used as a source of quality data in the Measurement, Analysis and Improvement process.**

#### **Clause and Regulation**

**ISO:** ISO: 13485:2016: 4.2.1, 7.5.4, 8.4

**ANVISA:** RDC ANVISA 665/2022: Art. 130

**MHLW/PMDA:** MO169: 6, 43, 61

**FDA:** 21 CFR 820.200]

#### *Additional country-specific requirements*

#### **Brazil (ANVISA):**

Confirm that the manufacturer has established and maintains procedures to ensure that records of servicing activities are kept with the following information:

- the product serviced
- the control number of the product serviced

## **Chapter 6 - Production and Service Controls**

### Task 27 – Servicing activities

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- the date of completion of service
- identification of the service provider
- description of service performed
- results of inspections and tests performed [RDC ANVISA 665/2022: Art. 129].

Verify that the manufacturer periodically reviews the records of servicing activities. In cases where the analysis identifies trends that pose danger or records involving death or serious injury, a corrective or preventive action must be initiated [RDC ANVISA 665/2022: Art. 130].

#### ***United States (FDA):***

Verify that each manufacturer who receives a service report that represents an event that must be reported to FDA as a medical device report automatically considers the report a complaint [21 CFR 820.200(c)].

Confirm that service reports are documented and include the name of the device serviced, any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used; and the date of service [21 CFR 820.200(d)].

## **Assessing conformity**

### **Procedures**

When servicing is a specified requirement, the medical device organization must define and maintain procedures, instructions, and processes for performing and verifying that servicing activities meet specified requirements.

### **Servicing process**

When organizations implement servicing programs, the medical device organization must ensure components used for repair are acceptable for the intended use, inspection and test procedures are available, and test equipment is properly maintained to ensure serviced devices will perform as intended after servicing.

Personnel performing service activities must have the appropriate training.

The audit team may observe instances where nonconformities occurred and/or complaints were received after the servicing of the device. This can be an indication that the service activity was not properly controlled or that service personnel do not have the proper equipment, instructions, or training to perform the required service.

### **Analysis of service reports**

Service reports can be an important source of quality data for input into the medical device organization's Measurement, Analysis and Improvement process. When necessary, confirm data regarding service reports is analyzed for possible corrective action or preventive action. Service reports must also be analyzed to determine if the service event represents an adverse event that is reportable to regulatory authorities.

## **Chapter 6 - Production and Service Controls**

Task 28 – Risk controls applied to transport, installation, and servicing

In some instances, product complaints may be initially recorded by the medical device organization as a service report. For example, a user may report to the medical device organization that a patient blood parameter monitoring device is not working correctly and requires service. Upon receipt of the device from the user by the medical device organization's service function, the service function notes the reason the monitoring device is not working is that an essential component within the device failed prematurely. This service report should be considered by the medical device organization to be a complaint and analyzed by the medical device organization to determine if an adverse event report needs to be submitted to regulatory authorities.

### **Links**

#### **Measurement, Analysis and Improvement**

During the audit of the medical device organization's Measurement, Analysis and Improvement process, the audit team may have already confirmed that quality data from the analysis of servicing activities is analyzed for possible corrective or preventive action. When reviewing the medical device organization's service reports, the audit team should be mindful of service reports that appear to be product complaints. Ensure that service reports that appear to be complaints have been appropriately addressed.

In some instances, a similar quality problem for a particular device may be found in the service reports and the complaint records. In these instances, confirm that the medical device organization is taking appropriate corrections and/or corrective actions considering a similar quality problem is observed in multiple data sources.

## **Task 28 – Risk controls applied to transport, installation, and servicing**

***When appropriate, verify that risk control and mitigation measures are applied to transport, installation and servicing, in accordance with the medical device organization's risk management practices.***

### ***Clause and Regulation***

**ISO:** ISO: ISO 13485:2016: 7.1, 7.5.1, 7.5.3, 7.5.4, 7.5.11

**TGA:** TG(MD)R Sch1 P1 2&5

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20

**MHLW/PMDA:** MO169: 26, 40, 42, 43, 52

**FDA:** 21 CFR 820.160(a), 820.170(a), 820.200(a)]

## **Chapter 6 - Production and Service Controls**

Task 29 – Top management commitment to the production and service process

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### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Risk control**

The requirements for delivery, installation, and servicing of a particular device should have already been evaluated and addressed by the medical device organization during design and development and planning for product realization.

If risk control measures were identified involving the delivery, installation, and servicing for a particular device, confirm that the necessary processes have been implemented to ensure the risk control measures are in place. For example, a medical device organization may have identified that in order for a medical imaging device to give accurate images, servicing must be performed by trained personnel according to specific instructions.

Risk control measures might include warnings on the imaging device that only authorized personnel should service the device and the design of a unique tool to access the inside of the device that is only provided to authorized service personnel.

### ***Links***

None

## **Task 29 – Top management commitment to the production and service process**

**Determine, based on the assessment of the production and service control process overall, whether management provides the necessary commitment to the production and service control process to ensure devices meet specified requirements and quality objectives.**

### ***Clause and Regulation***

**ISO: ISO: 13485:2016: 5.1, 5.2**

**ANVISA: RDC ANVISA 665/2022: Art. 5°, Art. 6°, Art. 7°**

**MHLW/PMDA: MO169: 10, 11**

### ***Additional country-specific requirements***

None

### ***Links***

None

## **Chapter 7 - Purchasing**

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### **Chapter 7 - Purchasing**

The intent of the Purchasing process is to ensure that purchased, subcontracted, or otherwise received products and services conform to specified requirements. The medical device organization is expected to establish and maintain documented controls for planning and performing purchasing activities.

The controls necessary depend on the effect of the product on the quality, safety, and effectiveness of the finished device. Effective purchasing processes incorporate purchasing requirements and specifications, the selection of acceptable suppliers based on the capability of the suppliers to provide acceptable product, the performance of necessary acceptance activities, and maintenance of the required quality records.

The **management representative** is responsible for ensuring that the requirements of the quality management system have been effectively defined, documented, implemented, and maintained. Prior to the audit of a process, it may be helpful to interview the management representative (or designee) to obtain an overview of the process and a feel for management's knowledge and understanding of the process.

The Purchasing process is integral to the other processes of the MDSAP audit sequence. As the audit is being performed of the medical device organization's Measurement, Analysis and Improvement process, Design and Development process, and Production and Service Controls process, the audit team should be assessing the affect purchased product has on the quality of the finished device. The audit team should be using information learned about actual and potential product and process nonconformities during the audit of the Measurement, Analysis and Improvement process, higher risk elements and essential design outputs from the design projects reviewed during audit of the Design and Development process, in addition to significant outsourced product and production processes identified during the audit of the Production and Service Controls process to make decisions as to supplier evaluation files to be reviewed during the audit of the Purchasing process.

The medical device organization's purchasing process may be reviewed in conjunction with the Measurement, Analysis and Improvement process, the Design and Development process, and the Production and Service Controls process, being mindful of the MDSAP process linkages. The Purchasing process should be considered a critical process for those organizations that outsource essential activities such as design and development and/or production to one or more suppliers.

### **Auditing the Purchasing Process**

**Purpose:** The purpose of auditing the Purchasing process is to verify that the medical device organization's processes ensure that products (e.g. components, materials and services provided by suppliers, including contractors and consultants) are in conformance with specified purchase requirements, including quality management system requirements. This is particularly important for those organizations who outsource activities such as design and development and/or production to one or more suppliers, and when the supplied product or service cannot be verified by inspection (e.g. sterilization services). Suppliers include those providers of any product received from outside the medical device organization, including corporate or financial affiliates, where the product has an effect on subsequent product realization or the final product.

## Chapter 7 - Purchasing

Task 1 – Planning activities regarding purchased products and outsourced processes

**Outcomes:** As a result of the audit of the Purchasing process, objective evidence will show whether the medical device organization has:

- A) Defined, documented and implemented procedures to ensure purchased or otherwise supplied products conform to specified purchase requirements
- B) Established criteria for the selection, evaluation and re-evaluation of suppliers based on the type and significance of the product purchased and the impact of the supplied product on subsequent product realization or the quality of the finished device
- C) Performed the evaluation and selection of suppliers based on the capability of the supplier to meet specified requirements
- D) Ensured the continued capability of suppliers to provide quality products that meet specified purchase requirements through re-evaluation
- E) Determined and implemented an appropriate combination of controls applied to suppliers in conjunction with acceptance verification activities to ensure conformity to product and quality management system requirements, based on the impact of the supplied product on the finished device.

Links to Other Processes:

[\*\*Management; Design and Development; Measurement, Analysis and Improvement;\*\*](#)  
[\*\*Production and Service Controls\*\*](#)

### Task 1 – Planning activities regarding purchased products and outsourced processes

**Verify that planning activities describe or identify products to purchase and processes to outsource, the specified requirements for purchased products, the requirements for purchasing documentation and records, purchasing resources, the activities for purchased product acceptance, and *risk management* in supplier selection and purchasing.**

#### *Clause and Regulation*

**ISO:** ISO: 13485:2016: 4.1.2, 4.1.3, 4.1.5, 7.1, 7.4.1, 7.4.2, 7.4.3

**TGA:** TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(d)(ii)

**ANVISA:** RDC ANVISA665/2022: Art. 18, Art. 21

**MHLW/PMDA:** MO169: 5-2, 5-3, 5-5, 26, 37, 38, 39; [Old: 5, 26, 37, 38, 39]

**FDA:** 21 CFR 820.20, 820.50]

#### *Additional country-specific requirements*

None

MDSAP AU P0002.007

## **Chapter 7 - Purchasing**

### Task 2 – Selection of supplier file to audit

## **Assessing conformity**

### **Planning**

In planning product realization, the medical device organization must determine as appropriate the quality objectives and requirements for the purchased products, the processes, documents, and resources specific to the purchased products, the criteria for purchased product acceptance, and the required verification, monitoring, inspection, and test activities specific to the purchased products. Planning of product realization often begins in the design and development of the product, including the translation of the design into production specifications. The translation of the design into production specifications includes the establishment of specified requirements for purchased product.

### **Quality objectives**

Quality objectives are typically expressed as a measurable target or goal. The planning of product realization should include consideration of how the purchased product, the criteria for purchased product acceptance, and the required verification, monitoring, inspection, and test activities specific to the purchased product will achieve the quality objectives.

### **Links**

#### **Design and Development, Management**

During the review of a design project, confirm that the medical device organization has considered the effect of purchased product on the essential design outputs. For suppliers that provide product and services related to the essential design outputs, the degree of purchasing controls necessary is commensurate with the effect of the supplied product on the proper functioning of the finished device.

During the audit of the Purchasing process, confirm when necessary that the degree of control over suppliers of purchased product has been made based on the risk the supplied product poses to the ability of the finished device to meet specified requirements.

Additionally, confirm when necessary that the quality objectives related to the purchased product were considered for inclusion in management review.

## **Task 2 – Selection of supplier file to audit**

**Select one or more supplier evaluation files to audit.**

**Priority criteria for selection:**

## **Chapter 7 - Purchasing**

Task 3 – Procedure for the control of purchased products and outsourced processes

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1. Indications of problems with supplied products or processes from audit of the Measurement, Analysis and Improvement process
2. *Suppliers of higher risk products or processes*
3. Suppliers who provide products or services that directly impact the design outputs required for proper functioning of the device
4. Suppliers of processes that require validation or revalidation
5. Newly approved suppliers of products or services
6. Suppliers of products or services used in the manufacturing of multiple products
7. Suppliers of components or services not covered during previous audits

### ***Links***

None

## **Task 3 – Procedure for the control of purchased products and outsourced processes**

**Verify that procedures for ensuring purchased product conforms to purchasing requirements have been established and documented.**

### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 7.4.1

**TGA:** TG(MD)R Sch3 P1 CI1.4(5)(d)(ii)

**ANVISA:** RDC ANVISA 665/2022: Art. 21

**MHLW/PMDA:** MO169: 37

**FDA:** 21 CFR 820.50]

### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Procedures**

The medical device organization must define, document, and implement procedures to ensure that purchased product conforms to specified requirements. These procedures commonly contain information as to the mechanisms by which the medical device organization is going to categorize suppliers based on the risk the supplied product has on the ability of the finished device to meet specified requirements, the criteria the medical device organization intends to use to evaluate the suppliers, the means of determination that a

## **Chapter 7 - Purchasing**

Task 4 – Extent of controls applied to the supplier and the purchased product; criteria for selection, evaluation, and re-evaluation of the supplier

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supplier is acceptable, the methods for supplier monitoring, the requirements for re-evaluating suppliers, and the means by which a supplier might be determined to be unacceptable.

It is important to remember that the requirements for purchasing controls apply to all product received from a supplier by the medical device organization that have an impact on product realization, whether a payment occurs or not, and regardless of the corporate or financial affiliation between the supplier and the medical device organization.

### ***Links***

None

### **Task 4 – Extent of controls applied to the supplier and the purchased product; criteria for selection, evaluation, and re-evaluation of the supplier**

**Verify that the procedures assure the type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.**

**Verify that criteria for the selection, evaluation and re-evaluation of suppliers have been established and documented.**

### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 7.4.1

**ANVISA:** RDC ANVISA 665/2022: Art. 22, Art. 23

**MHLW/PMDA:** MO169: 37

**FDA:** 21 CFR 820.50]

### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Extent of control**

The type and extent of control applied to the supplier must take into consideration the affect the supplied product has on the finished device. Procedures commonly contain methods to categorize suppliers, based on the importance of the supplied product to the proper functioning of the finished device and the past history (if applicable) of the supplier.

## **Chapter 7 - Purchasing**

Task 5 – Selection of supplier based on ability of the supplier to satisfy the specified purchase requirements

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Be mindful of organizations that use a “one-size-fits-all” approach to managing their suppliers, as these systems may not provide the necessary amount of evaluation and oversight over suppliers of products essential for the proper functioning of the finished device.

### **Evaluation criteria**

The medical device organization must define, document, and implement procedures outlining the criteria for the selection, evaluation and re-evaluation of suppliers. The procedures for supplier evaluation and selection typically include such items as the methods by which suppliers will be evaluated and the means and frequency by which supplier performance will be monitored.

The evaluation of suppliers must provide a means to assess the capability of the supplier to supply products that meet specified requirements. The medical device organization can assess a supplier’s capability to supply quality product in a number of ways, including but not limited to performing supplier audits, first-article inspections, supplier surveys, and reviewing the supplier’s past history in supplying a similar product or service if applicable.

The medical device organization may also choose to consider the supplier’s conformity with quality management system requirements through third party certifications; however, third party certification should not be relied on exclusively in initially evaluating a supplier.

### **Controls over suppliers of sterilization processes**

For devices intended to be sterile, the medical device organization must determine the criteria the supplier must meet to be selected, with regards to the control of the sterility of the device and perform selection and monitoring of suppliers considering the identified criteria.

### **Links**

None

## **Task 5 – Selection of supplier based on ability of the supplier to satisfy the specified purchase requirements**

**Verify that suppliers are selected based on their ability to supply product or services in accordance with the medical device organization’s specified requirements.**

**Confirm that the degree of control applied to the supplier is commensurate with the significance of the supplied product or service on the quality of the finished device, based on risk.**

**Verify that records of supplier evaluations are maintained.**

## **Chapter 7 - Purchasing**

Task 5 – Selection of supplier based on ability of the supplier to satisfy the specified purchase requirements

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### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 4.2.1, 7.1, 7.4.1

**TGA:** TG(MD)R Sch1 P1 2

**ANVISA:** RDC ANVISA 665/2022: Art. 16, Art. 17, Art. Art. 18, Art. 23

**MHLW/PMDA:** MO169: 6, 26, 37; [Old: 6, 26, 37, 65]

**FDA:** 21 CFR 820.50(a)]

### ***Additional country-specific requirements***

#### ***Australia (TGA):***

The conformity assessment procedures require that a Manufacturer demonstrates compliance with the Essential Principles through application of a QMS. Hence a Manufacturer must show how risk management principles have been applied during design and construction, including purchasing, to mitigate risk. (EP 2 - TG(MD)R Sch1 P1 2).

The conditions of marketing authorization (ARTG inclusion) require that Australian Sponsors undertake some regulatory activities including; customer complaint handling (Act s 41FN, Reg 5.8), the management and communication of technical files /technical documentation (Act s 41FN(3)), adverse event reporting (Act s 41FN, Reg 5.7), conducting recalls (Part 4-9), ensuring that the name and address of the Sponsor is provided with the device (Reg 10.2), the storage of devices (Act s 41FN,Reg 5.9) and the keeping of complaint and distribution records (Act s 41FN,Reg 5.10). Some Sponsors also provide services for the installation and servicing of a device on behalf of the Manufacturer.

Where a regulatory requirement for a Sponsor intersects with a regulatory requirement or a requirement of ISO13485 for the Manufacturer, the activity is to be treated as an outsourced activity and documented in the Manufacturer's QMS. Verify that the Manufacturer has adequate supplier controls to mitigate risk and ensure the Sponsor fulfils the outsourced activities included in a written agreement [TG Act 41FN] for those activities.

Other activities that may be outsourced to the Sponsor include making applications on behalf of the Manufacturer to the TGA [TG Act s41EB], representing the Manufacturer in interactions with the TGA [TG Act s41FN(3)], as an intermediary in recalls of products [TG(MD)R Sch 3 - Part 1:1.4(3)], in the notification of substantial changes to a kind of medical device (TG Act s41BE) that may require a variation to an entry in the Australian Register of Therapeutic Goods (TG Act s9D), for the provision of records [TG(MD)R Schedule 3 - Part 1:1.5, 1.9 ], or other matters that may be required to allow the Sponsor to fulfill market authorization conditions [TG Act Part 4-5 Div 2].

## **Chapter 7 - Purchasing**

Task 5 – Selection of supplier based on ability of the supplier to satisfy the specified purchase requirements

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The requirement of Regulation 10.2 for “ensuring that the name and address of the Sponsor is provided with the device in such a way that the user of the device can readily identify the Sponsor” is only an obligation on the Sponsor. This activity does not need to be included in the Manufacturer’s QMS documentation however the arrangements for the provision of this information should be disclosed in the written agreement between the Manufacturer and the Sponsor. In cases where an activity performed by the Sponsor also includes the provision of information required by Essential Principle 13 (Labels and IFU) or 13A (implant cards and leaflets) the Manufacturer must treat the Sponsor as supplier for that activity.

The Sponsor does not need to be treated as a supplier if the scope of the Manufacturer’s quality management system includes the site and activities of the Sponsor. The oversight of the Sponsors activities should be clearly documented in the QMS and be included in plans for internal audit.

### ***Canada (HC):***

Verify that any regulatory correspondent used by the Manufacturer is treated as a supplier and is adequately qualified.

## **Assessing conformity**

### **Supplier selection**

The selection of suppliers must be based on defined criteria. An important concept to remember is that quality cannot be inspected or tested into products. Medical device organizations that choose to conduct product quality control solely in-house must still assess the capability of suppliers to provide acceptable product.

Some organizations require suppliers to maintain various types of certifications or registrations. While registrations and third-party certifications may be considered in supplier evaluations, the medical device organization should not exclusively rely on these methods to perform the initial evaluation of suppliers.

For the supplier(s) the audit team has chosen to review, confirm that the medical device organization’s selection of the supplier was based on defined criteria commensurate with the risk posed if the supplied product causes the finished device to not meet specified requirements.

### **Records of supplier evaluations**

The medical device organization must maintain records of the evaluation of the capability of the supplier to meet specified requirements. The records should include the mechanism by which the supplier was evaluated, the results of the evaluation, and the determination of whether the supplier was deemed to be acceptable.

For the supplier(s) the audit team has selected, review the medical device organization’s evaluation of the supplier(s). Confirm that the evaluation was made according to defined criteria and is commensurate with the effect the supplied product has on the essential design outputs.

## **Chapter 7 - Purchasing**

### Task 6 – Records of supplier evaluation

#### **Links**

##### **Design and Development, Production and Service Controls**

The establishment of the necessary purchasing controls and required acceptance activities is a design output. The degree of the purchasing controls necessary and extent of acceptance activities should be based on the risk posed by the product not meeting its specified requirements and essential design outputs.

Auditors may encounter situations where the medical device organization outsources processes that require validation.

During the review of the Purchasing process, review the controls the medical device organization has instituted over suppliers that perform validated processes. This typically includes confirming that the medical device organization has reviewed the process validation data generated by the supplier to ensure the process is effective, reproducible, and stable. This can be particularly important for higher risk validated processes performed by suppliers, since the medical device organization does not have immediate control over those processes.

The audit team should also consider reviewing the purchasing controls and requirements for suppliers of products that undergo minimal acceptance activities by the medical device organization.

## **Task 6 – Records of supplier evaluation**

**Verify that the medical device organization maintains effective controls over suppliers and product, so that specified requirements continue to be met.**

#### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 7.4.1

**ANVISA:** RDC ANVISA 665/2022: Art. 23

**MHLW/PMDA:** MO169: 37

**FDA:** 21 CFR 820.50(a)]

#### ***Additional country-specific requirements***

None

## **Chapter 7 - Purchasing**

### Task 6 – Records of supplier evaluation

## **Assessing conformity**

### **Monitoring supplier performance**

The medical device organization must define and implement processes to monitor the performance of suppliers. The monitoring of supplier performance should not be based solely on cost considerations or on-time deliveries. The monitoring of suppliers should take into consideration the actual performance of the supplier in terms of providing products that meet specified requirements. Examples of supplier monitoring activities may include, but are not limited to supplier re-audits, statistical analysis of incoming acceptance results, monitoring of complaints and nonconformities related to supplied product, independent confirmation of certificate of conformance data, and consideration of the supplier's responses to requests for corrective action.

In order for the supplier to maintain a status as an acceptable supplier, the supplier must be capable of supplying product that consistently meets the medical device organization's specified requirements. If supplier monitoring does not demonstrate that the supplier has the capability to provide acceptable products, the medical device organization must have a means to undertake appropriate action, including such activities as requesting corrective action from the supplier, and in some cases, removing the supplier from records of acceptable suppliers.

For the supplier(s) the audit team has chosen to review, confirm that the supplier monitoring is documented and reviewed by the appropriate individuals responsible for supplier selection. Be particularly mindful of instances where supplied product has caused complaints and/or product nonconformities. Verify that the medical device organization has performed the appropriate monitoring of the supplier and taken actions when necessary, such as requesting the supplier undertake a corrective action.

### **Links**

#### **Production and Service Controls, Measurement, Analysis and Improvement**

Organizations are expected to define, document, and implement systems and procedures for acceptance activities to verify that supplied products conform to specified requirements. Effective acceptance procedures and systems directly affect the ability of a medical device organization to demonstrate that supplied products meet specifications. During the audit of the Production and Service Controls process, confirm that the appropriate acceptance activities have been implemented and monitored to ensure the received product meets specified requirements.

Additionally, organizations are required to determine, collect, and analyze appropriate data to demonstrate the ability of suppliers to provide acceptable product. During the audit of the Measurement, Analysis and Improvement process, confirm that analysis of supplier performance data has been performed and considered for corrective or preventive action when necessary.

## **Chapter 7 - Purchasing**

Task 7 – Effective controls over supplier and products

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### **Task 7 – Effective controls over supplier and products**

**Confirm that the re-evaluation of the capability of suppliers to meet specified requirements is performed at intervals consistent with the significance of the product on the finished device.**

#### ***Clause and Regulation***

**ISO:** ISO: ISO 13485:2016: 7.4.1

**TGA:** TG(MD)R Sch1 P1 2

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 22

**MHLW/PMDA:** MO169: 37

**FDA:** 21 CFR820.50(a)]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Supplier re-evaluation intervals**

Organizations must implement the appropriate combination of supplier evaluation, supplier monitoring, and acceptance activities to provide the necessary confidence in the acceptability of supplied product. However, supplier evaluation is not a “one-time” assessment. The medical device organization must ensure the continued capability of the supplier to provide product that meets specified requirements. The frequency of re-evaluation must be performed according to the medical device organization’s procedures and at intervals consistent with the significance of the product or service on the finished device. The frequency of re-evaluation may change based on identified quality problems with the supplied product.

For the supplier(s) the audit team has chosen to review, confirm that the re-evaluation of the supplier was performed commensurate with the risk the supplied product poses to the ability of the finished device to meet specifications.

#### ***Links***

##### **Measurement, Analysis and Improvement**

The frequency and extent of supplier re-evaluation activities may be based, in part, on the performance of the supplier as demonstrated by such activities as statistical monitoring of the supplier, monitoring of complaints and nonconformities related to supplied product, and corrective or preventive actions related to the supplier.

## **Chapter 7 - Purchasing**

Task 8 – Verification of the adequacy of purchasing information, specified purchase requirements, and written agreement to notify changes, before their communication to the supplier

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### **Task 8 – Verification of the adequacy of purchasing information, specified purchase requirements, and written agreement to notify changes, before their communication to the supplier**

**Verify that the medical device organization assures the adequacy of purchasing requirements for products and services that suppliers are to provide, and defines risk management activities and any necessary risk control measures.**

**Confirm that the medical device organization ensures the adequacy of specified purchase requirements prior to their communication to the supplier and that a written agreement with the supplier is established in which suppliers has to notify the medical device organization about changes in the product.**

#### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 4.2.1, 7.4.2, TG(MD)R Sch1 P1 2

**ANVISA:** RDC ANVISA 665/2022: Art. 18, Art. 24, Art. 26

**MHLW/PMDA:** MO169: 6, 38

**FDA:** 21 CFR 820.50(b)

#### ***Additional country-specific requirements***

##### **Brazil (ANVISA):**

Confirm that purchase orders are approved by a designated person. This approval, including date and signature, shall be documented [RDC ANVISA 665/2022: Art. 27].

## **Assessing conformity**

### **Adequacy of purchasing information**

Purchasing information is commonly provided to suppliers in documents such as, but not limited to, specification sheets, drawings, contracts, purchase orders, and quality agreements. The amount of detail required in the purchasing information must be commensurate with the effect of the supplied product on the performance of the finished device.

### **Risk control measures**

The medical device organization is responsible for the quality and performance of the finished device. The specified requirements for the finished device cannot be met unless the individual parts of the finished device meet specifications. While the medical device manufacturer may require certain risk management activities to be adopted by the supplier to help ensure acceptability of incoming product, the ultimate responsibility for the MDSAP AU P0002.007

## **Chapter 7 - Purchasing**

Task 9 – Documented purchasing information and specified purchase requirements

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finished device is borne by the medical device organization. The medical device organization is responsible for identifying any risk control measures that are required for the supplied product. For suppliers that provide product and services related to the essential design outputs, the degree of necessary risk control measures is commensurate with the effect of the supplied product on the proper functioning of the finished device.

Some examples of risk control measures related to supplied product include, but are not limited to, requiring the supplier to use quality assurance procedures approved by the medical device organization, the establishment of inspections or testing of supplied product before shipment to the medical device organization, requiring each incoming shipment be accompanied by a certificate of conformance, periodic verification of the certificate of conformance by third-party laboratory analysis, implementation of acceptance activities at the medical device organization based on the risk the supplied product poses to the ability of the finished device to meet specifications, and the verification of validation data by the medical device organization for validated processes performed by a supplier.

For the supplier(s) files the audit team has selected for review, confirm that risk control measures have been identified when appropriate and the risk control measures have been implemented and are effective. If the auditor(s) observe that supplied product has been identified as an underlying cause of complaints and nonconformities, this can be an indication that the risk control measures are inadequate or ineffective.

### ***Links***

None

## **Task 9 – Documented purchasing information and specified purchase requirements**

**Verify that the medical device organization documents purchasing information, including where appropriate the requirements for approval of product, procedures, processes, equipment, qualification of personnel, sterilization services, and other quality management system requirements.**

**Confirm that documents and records for purchasing are consistent with traceability requirements where applicable.**

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 7.4.2, 7.5.9

**ANVISA:** RDC ANVISA 665/2022: Art. 24, Art. 25, Art. 113

**MHLW/PMDA:** MO169: 38, 48, 49

**FDA:** 21 CFR 820.50(b), 820.65, 820.160]

## **Chapter 7 - Purchasing**

Task 9 – Documented purchasing information and specified purchase requirements

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### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Documenting purchasing information**

Purchasing information must describe the product to be purchased, including (when appropriate) the requirements for approval of product, procedures, processes, and equipment, the requirements for qualification of personnel, and quality management system requirements related to the purchased product.

Where possible, the purchasing information must contain an agreement that the supplier agrees to notify the medical device organization of changes in products or services that may affect the quality of the finished device. The medical device organization should approve or reject these changes, based on the impact of the change on the essential design outputs of the finished device.

Purchasing information may be recorded in written or electronic format, but must be documented.

### **Traceability**

It is the responsibility of the medical device organization to establish procedures for traceability. For devices that are not implanted and are not life-supporting or life-sustaining, the medical device organization has the flexibility to determine which raw materials and components are required to be traceable, commensurate with the risk posed by the device in the event the component does not meet specified requirements.

Medical device organizations that produce finished devices whose failure could result in serious injury or harm to the user, or are implanted or life-supporting or life-sustaining must implement a traceability system. The traceability system must allow for each batch of finished devices to be traced by a control number or similar mechanism throughout the distribution chain. Organizations must provide for the control and traceability of components and materials used in the manufacture of the device when these could cause the finished device to not meet specified requirements.

The determination of which components and raw materials may be required to be traceable may be made by the medical device organization using risk management tools, such as risk analysis, or by the identification of the components and processes used to fulfill the essential design outputs.

### **Links**

None

## **Chapter 7 - Purchasing**

Task 10 – Verification of purchased products

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### **Task 10 – Verification of purchased products**

**Confirm that the verification (inspection or other activities) of purchased products is adequate to ensure specified requirements are met.**

***Confirm that the medical device organization has implemented an appropriate combination of controls applied to the supplier, the specification of purchase requirements, and acceptance verification activities that are commensurate with the risk of the supplied product upon the finished device.***

**Verify that records of verification activities are maintained.**

#### ***Clause and Regulation***

**ISO:** ISO: 13485:2016: 4.2.1, 7.1, 7.4.3

**TGA:** TG(MD)R Sch1 P1 2, Sch3 1.4(5)(e)

**ANVISA:** RDC ANVISA 665/2022: Art. 22, Art. 41, Art. 42, Art. 89

**MHLW/PMDA:** MO169: 6, 26, 39

**FDA:** 21 CFR 820.50, 820.80(b)]

#### ***Additional country-specific requirements***

##### ***Brazil (ANVISA):***

Verify that the manufacturer has established and maintains procedures to ensure the retention of components, raw materials, in-process products and returned products until inspections, tests or other specified verifications have been performed and documented [RDC ANVISA 665/2022: Art. 91].

## **Assessing conformity**

### **Establishment of acceptance activities**

The medical device organization must establish an appropriate combination of supplier assessment and receiving acceptance activities to ensure products and services, including sterilization services are acceptable for their intended use. After a supplier has been approved, the necessary acceptance activities for the supplied product must be implemented. The degree of acceptance activities may vary with the type and significance of the product or service on the quality of the finished device and the extent of measures performed by the supplier to ensure product acceptability.

Organizations are expected to define, document, and implement processes and procedures for acceptance activities to verify that supplied products conform to specified requirements. Recognized acceptance activities include, but are not limited to, inspections, tests, reviews of certificates of analysis, and supplier audits.

## **Chapter 7 - Purchasing**

### Task 10 – Verification of purchased products

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Effective acceptance procedures and systems directly affect the ability of a medical device organization to demonstrate the process and product meet specifications.

It is important to remember that acceptance activities apply to any incoming component, subassembly, or service, whether a payment occurs or not, and regardless of the medical device organization's financial or business arrangement with the supplier.

#### **Records of verification activities**

The records of verification activities must show the supplied product is in conformity with specified requirements. If nonconformities are found by the medical device organization, confirm the medical device organization has appropriately handled the nonconformity according to the medical device organization's established procedures.

The medical device organization can address nonconforming product by taking action to eliminate the detected nonconformity (e.g. sorting an incoming lot of components to remove components that do not meet specifications), authorizing its use, release, or acceptance under concession, or by taking action to prevent its original intended use (e.g. allowing the components to be used as training aids to show production personnel the difference between an acceptable and unacceptable component).

For the supplied product(s) the audit team has chosen to review, confirm the records of verification activities have been maintained. One way to perform this task is to request a sample of verification records for the chosen product and confirm the acceptance activities have been documented, including the documentation and appropriate disposition of nonconforming product.

#### **Links**

##### **Production and Service Controls**

The audit team may encounter instances where product has been deemed acceptable by the successful completion of acceptance activities but the product is later shown to not meet specified requirements (e.g. failure of the device due to nonconforming component leading to product complaint). This can be an indication that the acceptance activities are not sufficient to identify nonconformities; or were not appropriately conducted.

Confirm that the medical device organization has taken the appropriate action to determine the suitability of the acceptance activities. For example, the medical device organization may need to validate the test method used for incoming acceptance to ensure the test method is actually capable of identifying nonconforming product.

## **Chapter 7 - Purchasing**

Task 11 – Purchasing control activities as source of quality data for the measurement, analysis, and improvement process

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### **Task 11 – Purchasing control activities as source of quality data for the measurement, analysis, and improvement process**

**Verify that data from the evaluation of suppliers, verification activities, and purchasing are considered as a source of quality data for input into the Measurement, Analysis and Improvement process.**

#### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 8.4

**ANVISA:** RDC ANVISA 665/2022: Art. 120

**MHLW/PMDA:** MO169: 61

**FDA:** 21 CFR 820.100]

#### ***Additional country-specific requirements***

None

## **Assessing conformity**

### **Collection and analysis of data**

The medical device organization is responsible for assuring the supplied product meets specified requirements. In addition to supplier evaluation, the assurance that the supplied product meets specified requirements is accomplished with the implementation of appropriate acceptance activities and monitoring complaints and nonconformities associated with purchased product. The data regarding acceptance activities and nonconformities must be analyzed as appropriate to determine the need for corrective or preventive action.

## **Chapter 7 - Purchasing**

Task 12 – Top management commitment to the purchasing process

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### **Links**

#### **Measurement, Analysis and Improvement**

The medical device organization must determine the appropriate acceptance activities for supplied product, based on the essential design outputs of the device and the risk the device poses if specified requirements are not met. Confirm as necessary that supplied product was evaluated as to the effect on the essential design outputs. Additionally, verify that the appropriate acceptance activities were implemented based on the potential effect the supplied product poses to the essential design outputs.

Organizations are required to determine, collect, and analyze appropriate data to demonstrate the ability of suppliers to provide acceptable product. During the audit of the Measurement, Analysis and Improvement process, confirm that analysis of supplier performance data from evaluation and monitoring supplier process activities has been performed and considered for corrective or preventive action when necessary.

## **Task 12 – Top management commitment to the purchasing process**

**Determine, based on the assessment of the overall purchasing, whether management provides the necessary commitment to the purchasing process.**

### ***Clause and Regulation***

**ISO:** ISO 13485:2016: 4.1.3, 4.1.5, 5.2

**ANVISA:** RDC ANVISA 665/2022: Art. 8°, Art. 9°

**MHLW/PMDA:** MO169: 5-3, 5-5, 11, [Old: 5, 11]

### ***Additional country-specific requirements***

None

### **Links**

None

## **Annex 1 – Audit of Product/Process related Technologies and Technical Documentation**

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## **Annex 1 – Audit of Product/Process related Technologies and Technical Documentation**

**Purpose:** The requirements in IMDRF/MDSAP WG/N3FINAL:2016 (2<sup>nd</sup> Ed) for Auditing Organizations that audit medical device manufacturers, and may perform other related functions, include, to the extent possible during on-site audits and in accordance with the applicable regulatory system, aspects of evaluation including:

- product/process related technologies (e.g. injection molding, sterilization); and
- evidence of adequate product technical documentation in relation to relevant regulatory requirements.

It should be noted that:

- IMDRF/MDSAP WG/N3FINAL:2016 (2<sup>nd</sup> Ed) does not provide additional requirements for product certification (ISO/IEC 17065:2012) or the requirements of product testing (ISO/IEC 17025:2005)

The following is explicitly excluded from the scope of IMDRF/MDSAP WG/N3FINAL:2016 (2<sup>nd</sup> Ed) due to the lack of regulatory convergence:

- the premarket reviews (e.g. Design Dossier Examinations, Premarket Applications, Shounin Applications, Product Registration/Notifications) typically performed by product specialist(s)
- the final decisions of safety and performance/effectiveness of a medical device made by any Regulatory Authority.

### **Definitions:**

#### **Technical Documentation**

Documented evidence normally an output of the quality management system (QMS), which demonstrates compliance of a device to the regulatory requirements for products, and processes.

(Adapted from IMDRF/ MDSAP WG/ N3FINAL:2016 (2nd Ed) – Section 3.5)

#### **Technical Expert**

An individual who carries out the following functions at an Audit:

- evaluation of product/process related technologies
- evaluation of Technical Documentation
- evaluation of compliance with Regulations.

#### **IMDRF/ MDSAP WG/ N3FINAL:2016 (Edition 2)**

**Clause 7.1.2** - An Auditing Organization shall have access to the necessary administrative, technical, and scientific personnel with technical knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies.

## **Annex 1 – Audit of Product/Process related Technologies and Technical Documentation**

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**Clause 7.1.5** - An Auditing Organization shall be capable of carrying out all the tasks assigned to it with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the Auditing Organization itself or on its behalf and under its responsibility.

**Clause 9.2.4** - Stage 2 audit objectives shall specifically include evaluation of:

- the effectiveness of the Manufacturer's QMS incorporating the applicable regulatory requirements
- product/process related technologies (e.g. injection molding, sterilization)
- adequate product technical documentation in relation to relevant regulatory requirements
- the Manufacturer's ability to comply with these requirements.

**Clause 9.3.2** - Surveillance audit objectives during the audit cycle shall specifically include evaluation of the effectiveness of the Manufacturer's QMS incorporating the applicable regulatory requirements and the Manufacturer's ability to comply with these requirements. In addition:

- new or changed product/process related technologies (e.g. injection molding, sterilization)
- new or amended product technical documentation in relation to relevant regulatory requirements.

**Clause 9.4.1** - Recertification audit objectives shall specifically include evaluation of:

- the effectiveness of the Manufacturer's QMS incorporating the applicable regulatory requirements
- product/process related technologies (e.g. injection molding, sterilization)
- adequate product technical documentation in relation to relevant regulatory requirements
- the Manufacturer's continued fulfillment of these requirements.

## **ISO 13485:2016**

### **Clause 4.2.3 – Medical Device File**

For each medical device type or medical device family, the medical device organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.

The content of the file(s) shall include, but is not limited to:

- general description of the medical device, intended use/purpose, and labelling, including any instructions for use
- specifications for product
- specifications or procedures for manufacturing, packaging, storage, handling and distribution
- procedures for measuring and monitoring
- as appropriate, requirements for installation
- as appropriate, procedures for servicing.

## **Annex 1 – Audit of Product/Process related Technologies and Technical Documentation**

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### **Clause 7.3.10 - Design and development files**

The medical device organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

### **Auditing Technical Documentation:**

The Medical Device File (ISO 13485:2016 Cl 4.2.3) and the Design and Development Files (ISO 13485:2016 Cl 7.3.10) are to contain or reference documents to demonstrate compliance with requirements of the Standard and with applicable regulatory requirements. For compliance with the requirements of N3 (2<sup>nd</sup> Ed) these records should contain technical documentation that includes, but not limited to:

- Outputs from the design and development process, such as: design outputs, design verification data with acceptance criteria, design validation data with acceptance criteria, a risk management file, human factors analysis, software validation, clinical evaluation report, electrical safety and electromagnetic compatibility, etc.
- Specific design outputs, design verification data with acceptance criteria, design validation data with acceptance criteria for products where a regulatory authority has specific expectations for the type of evidence to demonstrate compliance with regulatory requirements.
- Inputs to the production and service controls process, such as: device production specifications including appropriate drawings, composition, formulation, component specifications, and software specifications.
- Specifications for a production processes including the appropriate equipment specifications, production methods, production procedures, and production environment specifications.
- Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used.
- Specifications for packaging and labeling, including methods and processes used for validation after transportation and environmental conditioning.
- Procedures and methods for installation, maintenance, and servicing.
- Jurisdiction-specific statements (such as a declaration of conformity, statement on the presence of specific substances, essential principles checklist, etc.).

The information may be a compilation of documented information or, if the documents constituting the technical documentation are maintained separately, may be a summary that includes an explicit reference to each of these documents.

## **Annex 1 – Audit of Product/Process related Technologies and Technical Documentation**

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Auditors are not expected to fully evaluate the data that substantiates the final decisions of safety and performance/effectiveness of a medical device made by any Regulatory Authority. However, the auditor is expected to apply the MDSAP Audit Approach for the review of Technical Documentation when auditing:

- the Design and Development Process (See Tasks #3-17 in Chapter 5)
- the Production and Service Controls Process (See Task #16 in Chapter 6)
- the Jurisdiction-specific statements identified in the Device Marketing Authorization and Facility Registration Process (See Task #2 in Chapter 2)

The Audit Approach requires the auditor to select design documentation and manufacturing process documentation for review. The selection is to be based on information collected earlier in the audit, and taking into account the risks (risk classification) associated with the device, the novelty of technology used in the device and the associated manufacturing processes or sterilization methods, along with any changes to the device or associated manufacturing processes that have been implemented by the Manufacturer since the last on-site audit, including non-reported changes controlled under the QMS. A minimum of one review of a design and development file and related medical device file should be undertaken per audit to verify that the Manufacturer has established evidence of conformity with regulatory requirements. Additional reviews may be undertaken if time permits or the auditor suspects that the technical documentation previously reviewed is not a representative sample. (See tasks #2 in chapters 5 and 6).

Surveillance audits should also confirm that the Manufacturer has arrangements in place to maintain the currency of the technical documentation for all devices. For example:

- a procedure for reviewing the currency of relevant standards and conducting gap analyses as required
- a requirement to assess design changes and the need for further technical testing
- a plan for post-market clinical trials, where necessary, or periodic literature reviews
- updating risk management documents (e.g. occurrence levels in risk analysis) based on post-market data.

The following table summarizes the tasks that an MDSAP auditor will use to review information that constitutes the Technical Documentation.

<b>Information</b>	<b>Audit Approach: Process, Task#</b>
Medical device general description, including variants and accessories	Design and Development, task #5, 7
Evidence of compliance with specified regulatory requirements for products or processes. <sup>5</sup>	Design and Development, task #5, 7

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<sup>5</sup> For example, Australia's - Essential Principles, Canada - Safety and Effectiveness Requirements

## Annex 1 – Audit of Product/Process related Technologies and Technical Documentation

Information	Audit Approach: Process, Task#
Evidence of inclusion of feedback into risk management for monitoring and maintaining the product requirements as well as product realization or improvement processes	
Information that confirms that design and development outputs for the product are traceable to, and satisfy, design input requirements	Design and Development, task #7
Intended use, and indication of use, of the medical device	Design and Development, task #5, 7, 10, 11
Labelling, (i.e. information that accompanies a medical device that is located on the device, its packaging, the instructions for use and in promotional material)	Design and Development, task #1, 7, 8, 16
Confirmation that the product is a medical device	Device Marketing Authorization and Facility Registration, task #1 Design and Development, task #5
Classification	Device Marketing Authorization and Facility Registration, task #1 Design and Development, task #5
Risk management file	Design and Development, task #8
Pre-clinical data (studies in animal models, testing to support compliance with relevant standards, technical performance tests etc.)	Design and Development, task #10
Clinical evidence	Design and Development, task #11
Manufacturing processes	Design and Development, task #7, 16 Production and Service Controls, task #3, 16
Process validation	Design and Development, task #16 Production and Service Controls, task #7, 8, 9
Evidence of compliance with specified regulatory requirements for marketing authorization.	Device Marketing Authorization and Facility Registration, task #1
Declaration of conformity	Device Marketing Authorization and Facility Registration, task #1

**Note:** this table may not exhaustively cover all information expected under all jurisdictions.

Auditors are expected to verify:

- the existence and the coherence of the information listed in this table
- the applicability of this information to the medical device subject to marketing authorization
- that the methods implemented throughout the Design and Development to generate this information are sound and commensurate to the risk associated with the medical device; and
- that conclusions are substantiated.

## **Annex 1 – Audit of Product/Process related Technologies and Technical Documentation**

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Although the auditors are not expected to make final device safety and effectiveness decisions based on a review of technical documentation, if an auditor suspects that device safety and effectiveness concerns exist, or that the evidence supporting compliance with safety and effectiveness requirements is lacking, the concerns should be explicitly described in the audit report. If an auditor suspects a public health threat, the Auditing Organisation must submit an early awareness communication notice ("MDSAP 5-day Notice") according to MDSAP AU P0027.001 Post-Audit Activities and Timeline Policy.

The depth and extent of this review should be commensurate with the classification of the medical device, the novelty of the intended use, the novelty of the technology or construction materials, and the complexity of the design and/or technology.

### **Expectations from participating Regulatory Authorities:**

Each participating regulator may have different requirements for the review of technical documentation and for the assessment of the adequacy of that technical documentation at audit.

If inadequacies are identified, nonconformities should be raised in the normal manner, using the most specific and relevant clause of ISO 13485, [see especially ISO 13485:2016 - §4.2.3 and §7.3.10] including those raised against technical documentation under country specific requirements [for example, see ISO 13485:2016 - §7.2.1.c, §7.3.3.b, §7.3.7, §4.1.1]. Refer to MDSAP AU P0037 for further guidance on the selection of appropriate clause and the grading of nonconformities. NCs from the review of technical documentation shall be included in the Nonconformity Grading and Exchange Form (MDSAP AU F0019.2).

Further guidance on the expectations for the evidence of compliance with regulatory requirements is provided in the following sections.

### ***Additional country-specific requirements***

#### **Australia – TGA**

##### **Auditing Technical Documentation:**

The assessment of product requirements for Australian Class I (supplied sterile), Class I (with a measuring function), Class IIa and Class IIb medical devices, and Class 1-3 IVDs, is performed by the TGA on a sampling basis prior to market authorization (aka "Application audit"). Technical documentation review is expected to be performed in the context of audit to increase the pool of sampled devices and strengthen the sampling based approach. Technical documentation review should take into consideration the provisions of IMDRF/MDSAP

## **Annex 1 – Audit of Product/Process related Technologies and Technical Documentation**

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WG/N3 – 9.3.1. This documentation shall contain sufficient detail to allow for an evaluation of the data and for the purpose of demonstrating:

- fulfillment of the requirement
- where an appropriate standard exists, fulfilment of the requirements of the relevant Standard that the Manufacturer has chosen as the means for demonstrating compliance with regulatory requirements for products and processes.

In the case of Class III, Active Implantable and Class 4 In Vitro Diagnostic medical devices that have been subject to a Design Examination separately from the QMS audit, the on-site audit should ensure that the technical documentation for these devices is maintained.

The technical documentation should contain, or reference, evidence of compliance with the Essential Principles and the following requirements. An Essential Principles checklist<sup>6</sup>, although not mandatory, is often used as an index to identify the applicable Essential Principles, any standard or validated method that has been used to demonstrate compliance, and a reference to the document that contains the evidence of compliance.

The assessment of each set of technical documentation selected for compliance with the Essential Principles, as a minimum, should consist of a review of:

- A detailed description of the product, including the intended use, intended user, risk classification and assigned Global Medical Device Nomenclature (GMDN) code. For IVD medical devices, the description should also include specimen types, a list of kit components, methodology and any instrumentation to be used
- the inclusion of information gathered in feedback processes (e.g. complaints, adverse event reporting or recalls for product correction) as a potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes
- an index of the compilation of documents, or if documentation is not collated, a reference to the relevant documentation
- a risk management file (e.g. select a particular risk and confirm that it has been managed in accordance with the requirements of ISO 14971)
- selected report(s) of pre-clinical data and/or bench testing (including studies in animal models, testing to support compliance with relevant standards, technical performance and safety tests for electrical safety,

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<sup>6</sup>For reference, manufacturers may choose to complete an Essential Principles Checklist as one way of indexing their evidence of conformity to requirements. The checklist is not mandatory; however, it provides a succinct way of identifying the relevant evidence. A sample template is available at <http://www.tga.gov.au> and by searching for "Essential Principles Checklist"

## **Annex 1 – Audit of Product/Process related Technologies and Technical Documentation**

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mechanical safety, radiation safety etc.) identified by the Manufacturer as evidence of compliance with relevant Essential Principles

- a selected clinical evaluation report to confirm that it is current and was prepared by an appropriately qualified expert (See TG(MD)Regs Sch 3 Part 8)
- any other documentation required for the type of device (e.g.- special requirements for devices incorporating medicinal substances or materials of animal origin);
- the information that accompanies a device (labelling, instructions for use, patient implant cards and leaflets)
- the declaration of conformity, for example, to comply with TG(MD)Reg Sch 3 Part 1 Clause 1.8 (this may be in a draft form for development devices that do not yet have marketing authorization).

### **Brazil – ANVISA**

Brazilian regulations require that product registration / market authorization is entirely performed by ANVISA for all medical device classes.

ANVISA expects that the Auditing Organization follows the Audit Approach for reviewing technical documentation, including the Brazilian specific requirements defined in the document MDSAP AU P0002 – Audit Approach. There are no additional requirements to be reviewed during an MDSAP audit.

### **Canada - Health Canada**

The Medical Devices Directorate, Health Canada, has assigned the responsibility for the review of technical documentation to the Bureau of Evaluation. For Health Canada, the objective of the audits conducted by MDSAP Auditing Organizations is to determine that Manufacturers who intend to license their devices in Canada have implemented a QMS in conformity with the requirements of the international standard ISO 13485 and Part 1 of the Canadian Medical Devices Regulations. Similarly, a holder of a medical device license is to maintain an effective QMS. Health Canada expects Auditing Organizations to confirm during their audits that the Manufacturer maintains evidence of safety and effectiveness and not to make a determination that the devices are safe and effective.

### **Japan – MHLW/PMDA**

The assessment of product requirements is performed prior to market authorization by the regulator or registered certification bodies, hence technical documentation review, as assessment of conformity to the Essential Principles of Safety and Performance of Medical Devices, is not performed in the context of MDSAP audit.

### **USA – FDA**

The US medical device regulations do not require a technical documentation as defined in the present document, although most data composing the technical documentation are direct output of the Design History File (820.30(j)) and the Device Master Record (820.181).

## **Annex 2 - Audit of Requirements for Sterile Medical Devices**

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### **Annex 2 - Audit of Requirements for Sterile Medical Devices**

**Overview:** The control of the sterility of a medical device is the result of a series of controlled processes including (but not limited to):

Design and Development:

- a) device cleanliness and sterility requirements
- b) compatibility of the device with the sterilization process
- c) transport, storage, and presentation of the device at point of use
- d) compatibility of the device packaging with the sterilization process
- e) ability of the device to be sterilized or re-sterilized
- f) shelf-life and device life user requirements
- g) rationale for adding the device to a product family covered by a validated sterilization process

Production and Process Controls, as applicable:

- a) process validation of the cleaning, sterile barrier packaging, and sterilization processes
- b) routine monitoring and measurement of the cleaning, packaging and sterilization processes
- c) routine acceptance criteria of the cleaning, packaging and sterilization processes
- d) (re-)qualification, (re-)verification, (re-)calibration and maintenance of the cleaning, packaging and sterilization equipment
- e) environmental control of production areas (cleanroom design and monitoring)
- f) storage of device parts, components, and packaging material
- g) storage of finished sterile product and management of shelf life
- h) handling process of non-sterile device for re-sterilization
- i) lot / batch release of terminally sterilized devices

Purchasing, depending on the purchased product or service:

- a) Determination of criteria the supplier must meet to be selected, with regards to the control of the sterility of the device
- b) Selection and monitoring of suppliers considering the identified criteria
- c) Purchasing information
- d) Verification of the purchased product/service (and associated documentation)

Therefore, the audit of the control of the sterility of a medical device requires a holistic approach.

#### **Competencies:**

It is up to the Auditing Organization to determine the competencies required to achieve the audit objectives and to assign a competent audit team. However, the AO should identify auditors and/or technical experts having the competencies identified below. The subsequent table identifies the competencies required to audit various aspects of sterilization.

## **Annex 2 - Audit of Requirements for Sterile Medical Devices**

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The auditing of activities and processes contributing to the sterility of a medical device may involve the following competencies:

Microbiology:

- a) Ability to assess the validation of sterilization processes and methods regardless of the availability of an established standard (or the lack of such a standard)
- b) Ability to assess the validation of environmental and microbial contamination controls
- c) Ability to assess the validation of packaging activities and sterile barrier systems
- d) A person deemed to have this competency would likely be educated as a medical microbiologist.

Packaging and Sterile Barrier Systems:

- a) Ability to assess the validation of activities and processes for packaging and sterile barrier systems.

Environmental and Contamination Control:

- a) Ability to evaluate the adequacy of environmental and microbial contamination control programs.

Routine Sterilization:

- a) Ability to assess the validation of sterilization processes and methods where an existing established standard on the method exists other than aseptic processes
- b) Ability to verify the implementation of non-standard sterilization activities and processes previously audited by someone having the microbiology competency
- c) Ability to assess the implementation of activities and processes for packaging and sterile barrier systems previously audited by someone having the packaging and sterile barrier systems or microbiology competency
- d) Ability to assess the implementation of environmental and microbial control activities previously assessed by someone having the microbiology or environmental and contamination control competency.

An auditor may possess several of these competencies.

## Annex 2 - Audit of Requirements for Sterile Medical Devices

The following table summarizes the competencies required to audit the requirements for sterile medical devices:

Topic being evaluated	Microbiology	Packaging and Sterile Barrier Systems	Environmental and contamination control	Routine Sterilization
Sterilization process (re-) validation according to well-established standards (excluding aseptic processes)	✓			✓
Sterilization process (re-) validation according to less common standards, or using less common sterilant, sterilization technologies, validation methods (including aseptic processes)	✓			
Packaging process validation and sterile barrier systems	✓	✓		
Environmental and microbial contamination controls	✓		✓	
Routine implementation of sterilization processes according to previously audited validated processes	✓			✓
Routine implementation of environmental controls and monitoring (including maintenance)	✓		✓	✓
Routine implementation of packaging activities according to previously validated processes	✓	✓		✓

## **Annex 2 - Audit of Requirements for Sterile Medical Devices**

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### **Audit of the Requirements for Sterility and Audit Cycle Considerations:**

All ISO 13485 and regulatory requirements for sterile medical devices must be audited at least once during the certification cycle. While Auditing Organizations have flexibility in deciding when these requirements are audited during the certification cycle, they should ensure that the requirements for sterility of a device have been audited before including this device in the scope of certification.

All sterilization methods used by a medical device organization should be covered throughout the certification cycle.

Objectives for the audit of requirements for sterile medical devices should include, but not be limited to, verification that:

- all processes that contribute to a device's sterility are controlled through the medical device organization's QMS and validation has been completed, where applicable (e.g. cleaning, disinfection, aseptic processing, sterile barrier systems, terminal sterilization, storage)
- criteria for re-validation are defined and are followed, (e.g. at defined periodicity, following significant changes and trends)
- processes are implemented and monitored to ensure compliance to their validated parameters
- routine environmental and product cleanliness controls are implemented and monitored
- results are consistent from batch to batch
- batch records(e.g. a device history file) are maintained for each sterilization batch per an approved device master record
- lot release is performed for each batch according to a procedure and by a designated person
- adequate control of suppliers is observed where sterilization is outsourced (process for selection of critical suppliers defined and followed, valid agreements, supplier audits, etc.)

In the absence of significant changes with potential impact on the validated status or new (re)validation activities since the previous audit, the audit should be focused on records review to determine that the validated processes are followed, monitoring is performed, batch records are maintained.

While some aspects may be audited remotely (e.g. review of sterilization process validation documentation), the audit of requirements for sterile medical devices must be conducted on-site.

The outcome of such remote review activities must serve as input to the on-site audit and be incorporated or attached to the MDSAP audit report. The off-site assessment of the controls of the product sterility should not prevent the on-site audit team from following audit trails, including audit trails necessitating the review of documents that had previously been assessed remotely.

The audit of processes for validation of sterilization and sterile barrier systems performed according to well-established standards (e.g. steam sterilization, 25 kGy gamma irradiation, Ethylene Oxide in chambers with

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traditional release) can be performed by someone having either the microbiology competency or the routine sterilization competency.

The audit of a validation performed according to less common standards, or using less common sterilant / sterilization technologies / validation methods (e.g. Ethylene oxide sterilization in a bag, ethylene oxide in chambers with parametric release, plasma sterilization, low dose gamma sterilization) should be performed by a person having the microbiology competency. This also applies to the evaluation of aseptic process validation or to the sterilization process validation of the microbiologic safety of devices incorporating substances, cells, tissues of animal or human origin.

Routine implementation of sterilization processes according to previously audited validation studies may be conducted by a person having the routine sterilization competency. This applies to all previously validated and audited sterilization processes including processes conducted according to less common standards, or using less common sterilant/sterilization technologies/validation methods.

If the requirements for sterile medical devices are audited separately by a competent auditor or technical expert, this shall cover all the applicable requirements and the results of this audit shall be part of the MDSAP audit report. This must not prevent the MDSAP audit team from following leads relative to requirements for sterile medical devices. Any nonconformities resulting from the audit of sterile medical devices and sterilization processes shall be graded in accordance with MDSAP policies regarding grading of nonconformities.

## **Annex 3 - Medical Device Adverse Events and Advisory Notices Reporting Process Quick Reference**

### **Annex 3 - Medical Device Adverse Events and Advisory Notices Reporting Process Quick Reference**

The following table is intended to be a quick reference guide for timeframes for submitting reports for individual adverse events and advisory notices. This table is not a substitute for knowledge and understanding regarding criteria required to be reported in the participating MDSAP jurisdictions, or a substitute for the information contained in MDSAP Audit Approach [Chapter 4 - Process: Medical Device Adverse Events and Advisory Notices Reporting](#).

<b>Jurisdiction</b>	<b>Individual Adverse Events</b>	<b>Advisory Notices</b>
Australia	<p>Manufacturer to report to the Sponsor or the TGA, as soon as practicable, if an event might have led to death or serious deterioration in health</p> <p>Sponsor must report within 48 hours if an event represents a public health threat</p> <p>Sponsor must report within 10 days if an event led to death or serious deterioration in health</p> <p>Sponsor must report within 30 days if an event might lead to death or serious deterioration in health if it were to recur</p>	Manufacturer to report to the Sponsor or the TGA, as soon as practicable, any technical or medical reason for a malfunction or deterioration that has led to recall
Brazil	<p>Must report within 72 hours in case of death, public health threat or counterfeiting</p> <p>Must report within 10 days in case of serious adverse events not involving death and non-serious adverse events, the re-occurrence of which has the potential to</p>	5 calendar days from the decision to start the field action

## Annex 3 - Medical Device Adverse Events and Advisory Notices Reporting Process Quick Reference

<b>Jurisdiction</b>	<b>Individual Adverse Events</b>	<b>Advisory Notices</b>
	<p>cause a serious adverse event to a patient, user, or other person</p> <p>Must report within 30 days in case of malfunction that could lead to a serious adverse event</p> <p>Must report within 10 days in case of death, public health threat or counterfeiting occurred in other countries and associated with health products registered in its name in Brazil</p>	
Canada	<p>For events that occur in Canada:</p> <p>10 days if the event led to the death or serious deterioration in health</p> <p>30 days if the event might lead to death or serious deterioration if the event were to recur.</p> <p>For occurrences that are captured under the Foreign Risk Notification requirements (61.2-61.3):</p> <p>72 hours after receiving or becoming aware of a notifiable action</p>	On or before undertaking the recall
Japan	Registered Manufacturing Sites must report any adverse event which meets the criteria specified by <a href="#"><u>the Ordinance for</u></a>	As soon as possible after the action

## Annex 3 - Medical Device Adverse Events and Advisory Notices Reporting Process Quick Reference

Jurisdiction	Individual Adverse Events	Advisory Notices
	<p><b><a href="#">Enforcement of PMD Act</a></b></p> <p><b><a href="#">Article 228-20</a></b> to the Marketing Authorization Holder <u>as soon as possible.</u></p> <p>MAHs must report any adverse event which meets the criteria specified by <b><a href="#">the Ordinance for Enforcement of PMD Act</a></b></p> <p><b><a href="#">Article 228-20</a></b> to the RA <u>within the timeframe specified by the ordinance.</u></p>	
United States	5 calendar days if FDA has issued a 5-day notice  30 calendar days reports of death or serious injury. Quarterly summary reporting is allowable for malfunction reports for most product codes.	10 working days of initiating the correction or removal

## **Annex 4 – Requirements for Written Agreements**

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### **Annex 4 – Requirements for Written Agreements**

There are a number of occasions when the interface between an organization (e.g. a manufacturer represented on the label of a product and responsible for the design, production, packaging, labelling and post-production monitoring activities), and a supplier (an external organization outside of the scope of the organization's QMS), needs to be defined in a written agreement. For example, from ISO 13485:2016;

**Clause 3.2** – an authorized representative is a natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on their behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.

**Clause 3.10** – Note 1 to entry: a manufacturer is responsible for ensuring compliance with all applicable regulatory requirements unless this responsibility is specifically imposed on another person by the regulatory authority within that jurisdiction. In many cases written agreements are necessary to establish the arrangements between a manufacturer and authorized representative to ensure the representative can fulfill their legal obligations.

**Clause 4.1.5** - requires manufacturers to retain responsibility for conformity to applicable regulatory requirements for outsourced processes. The controls for these processes shall include written quality agreements and be proportionate to the ability of the external party to meet the requirements identified in Clause 7.4.

**Clause 4.2.5** – requires manufacturers to define and implement methods for protecting confidential health information contained in records and for the retention and submission of any record in accordance with regulatory requirements. Arrangements defined in agreements with an Authorized Representative can ensure the confidentiality of information passed to a manufacturer via the representative in the receiving and recording of information for complaint handling and the retention of records held by the Authorized Representative.

**Clause 5.2, 5.4.1, 5.5.2, 5.6.2, 7.2.1, 7.3.3, 7.3.7, 7.3.9** – written agreements with Authorized Representatives can be a useful tool for ensuring that a manufacturer and its top management are informed of current regulatory requirements and changes in the jurisdictions to which product is supplied. This information may provide input to some of, and not limited to, the following areas; quality objectives, management review inputs, definition of customer requirements, and design and development controls.

**Clause 7.2.3** – requires a manufacturer to communicate with regulatory authorities in accordance with regulatory requirements. In some jurisdictions, the communication channel is through the authorized representative.

**Clause 7.4.1, 7.4.2** - requires the manufacturer to address the nonfulfillment of controls for outsourced processes, with the supplier, and in compliance with regulatory requirements. In some jurisdictions, the

## Annex 4 – Requirements for Written Agreements

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authorized representative is to fulfil relevant regulatory requirements with the cooperation of the manufacturer.

**Clause 7.5.9.1** - may require an authorized representative to play a part in ensuring the traceability of a product to the extent required by the manufacturer.

**Clause 8.2.1** – regulatory requirements may require a manufacturer to incorporate post-production information provided by an authorized representative to be included in a feedback process.

**Clause 8.2.2** – a written agreement with an Authorized Representative may be necessary to ensure the timely receiving and recording of information for complaint handling.

**Clause 8.2.3** - requires documented procedures for notification to regulatory authorities when complaints meet specified reporting criteria for adverse events or issuance of advisory notices. In some jurisdictions, an in-country authorized representative performs the notification of these events. A written agreement between the manufacturer and the representative is necessary to establish a clear communication channel between the manufacturer and the regulator and to ensure the maintenance of records of reporting.

**Clause 8.3.3** - requires procedures for issuing advisory notices in accordance with applicable regulatory requirements. In some jurisdictions, an in-country representative is required to coordinate the approval and issuing of advisory notices with the local regulatory authority, maintain distribution records that would facilitate recall in that jurisdiction and, if necessary, to coordinate a recall under the supervision of the local regulatory authority. A written agreement between the manufacturer and the representative is necessary to ensure that the local representative can fulfil their legal responsibilities and that the responsibilities are clear in the event of a recall.

### ***Additional country-specific requirements***

#### **Australia (TGA)**

Prior to being granted market authorization, Australian Sponsors (in-country authorized representative) are required to "certify matters" related to the device and its supply, including a commitment to enter into written agreements with an overseas Manufacturer for matters that are specified in Regulations [TG Act - 41FD (e) and (g)]. (Australian "legal" Manufacturers who are responsible for design, production and labelling, whether performed by their organization or on their behalf by another organization, are also, by definition, an Australian Sponsor).

Subsequent conditions for the market authorization include a requirement that the Sponsor continue to supply information related to quality, safety and performance of the device through procedures and a written agreement established with the overseas Manufacturer. This will include information that is only available from

## Annex 4 – Requirements for Written Agreements

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the overseas Manufacturer of the device who is accepting responsibility for the design, production, packaging and labelling etc. of the device (TG Act - s41BG).

Australian conformity assessment procedures also require overseas Manufacturers of medical devices supplied in Australia to make undertakings, to provide records (information, documents and records specified in the Conformity Assessment Procedures) and to notify the TGA or the Sponsor of specified events. These requirements of the Conformity Assessment Procedures, and conditions for marketing authorization, place a legal obligation on the Sponsor to participate in processes that are usually and wholly addressed by the manufacturer's quality management system. For example, some aspects of the ISO13485 requirements for advisory notices (e.g. recalls) are the responsibility of the Sponsor. Hence, the manufacturer must outsource these requirements to the Sponsor, and in doing so renders the Sponsor a supplier.

By entering into written agreements, the Sponsor and Manufacturer demonstrate their commitment to fulfil their obligations and clarify their roles and legal responsibilities within the Australian Regulatory framework for medical devices.

Manufacturers and Sponsors are to identify the regulatory requirements that are relevant to their responsibilities under the legislation (e.g. ISO 13485:2016 Cl 4.1.1). The following table provides some guidance and identifies many of the key requirements that could be identified in a written agreement between an overseas Manufacturer and the Australian Sponsor. The parties to an agreement should incorporate, as appropriate, the arrangements to fulfill these, or any other identified regulatory requirements, and may include any necessary commercial arrangements.

This table is a summary of requirements, intended to raise awareness of the roles and responsibilities that may need clarification in a written agreement. This is guidance and does not substitute for reference to ISO13485:2016 or the relevant legislation. Sponsors and Manufacturers should refer to the *Therapeutic Goods Act, 1989 (the Act)* and the Therapeutic Goods (Medical Devices) Regulations, 2002 (Regulations) to determine all applicable requirements.

Note that some requirements and conditions apply automatically by the Act and Regulations. The TGA may apply specified additional conditions on the manufacture and supply of a medical device at the time of market authorization, or later. Agreements may need amendment to account for any condition that may subsequently affect the relationship between the Sponsor and Manufacturer.

References to sections of *the Act*, are prefaced with "s" [e.g. s41FD]. References to a regulation of the Regulations are prefaced with "r" [e.g. r5.8]. References to Section, Part or a clause in a Schedule of the Regulations, are prefaced with "S", "P" and "Cl" e.g. [S3 Cl1.8].

## Annex 4 – Requirements for Written Agreements

Australian requirements that may require identification in a Written Agreement

Requirement	Ref(s)	Australian Sponsor Role	Manufacturer Role
Application for market authorization	s41FC, s41FD, s41FH, s41FI  r5.2	Certify the matters listed in TG Act s41FD including a procedure and written agreement with an overseas manufacturer to provide information from the overseas manufacturer about compliance with the Essential Principles and application of an appropriate Conformity Assessment Procedure, to the TGA, within 20 days of a request.	Provide information to the Sponsor that would allow the Sponsor to certify the matters identified in TG Act s41FD  Provide information requested by the TGA in a notice to the Sponsor if the application is selected for an Application Audit. (See also Reg 5.3)  If requested by the TGA, assist the Sponsor to provide a reasonable number of samples within the timeframe specified in the notice.
Conditions for market authorization	s41FN, s41FO, s41JA, s41MP2, s41MPA2 s42B s42BAA s42DD s42DJ s42DL(9)  r5.6 r5.7, r5.8, r5.9 r5.10 r5.11, r8.1A r8.1	Make arrangements that will permit an authorized person of the TGA to enter premises outside of Australia where a person deals with medical devices that have market authorization, for purposes of inspection, examination, measurement, testing, sampling, image recording etc. and obtaining documentary evidence. (Including the manufacturer's facilities or those of a supplier to the manufacturer)  Maintain procedures and agreements to ensure that information from the overseas manufacturer to substantiate compliance with the Essential Principles and application of an appropriate Conformity Assessment Procedure, or relevant changes to previously supplied information, can be	Assist the Sponsor with arrangements to permit the TGA to enter the Manufacturer's premises, or those of a supplier, for inspection activities.  If requested by the TGA, assist the Sponsor to provide a reasonable number of samples within the timeframe specified in the notice.  Ensure advertising material available for Australia is consistent with the intended purpose of the medical device and the Sponsor's obligation to comply with Australian advertising requirements.  Ensure continued provision of information within a timeframe that will permit a Sponsor to meet its regulatory obligations.  Ensure problem or complaint information, provided by the

## Annex 4 – Requirements for Written Agreements

	<p>supplied to the TGA, within 20 days of a request.</p> <p>Provide information to the TGA and the manufacturer that the sponsor is aware of in relation to a device about any malfunction or deterioration, inadequacy, or use, that might lead or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health (adverse events or near adverse events) within prescribed timeframes (r5.7);</p> <p>Provide information to the TGA (within prescribed timeframes - r5.7) and the manufacturer that the sponsor is aware of in relation to a device that relates to a technical or medical reason for a malfunction or deterioration that may require an advisory notice or recall of a device that has been distributed;</p> <p>Comply with the requirement to notify the TGA of information that indicates that a certification document issued to signify: compliance with the essential principles; or the application of relevant conformity assessment procedures has been restricted, suspended, revoked or is no longer in effect.</p> <p>Provide information to the TGA and the manufacturer that the sponsor is aware of in relation</p>	<p>Sponsor, is input for the manufacturer's feedback process.</p> <p>Assist the Sponsor to comply with conditions for records, manufacture, the essential principles etc. that may be imposed at the time of, or after, market authorization</p> <p>Provide the Sponsor with information related to their obligation to notify the TGA about adverse events, recalls/advisory notices, noncompliance with the essential principles or the validity of a certification document related to compliance with the Essential Principles or the application of conformity assessment procedures; including quality management system requirements.</p> <p>Ensure that the Sponsor is aware of the manufacturer's requirements for storage and transport of the device</p> <p>Assist the Sponsor with the provision of data for a report to the TGA as described in Reg 5.11; for Class AIMD, Class III, Class IIb medical devices that are implantable, or a Class 4 IVD.</p> <p>Assist the Sponsor with the provision of data for IVDs described in Reg 5.3(1)(j), for a report described in Reg 5.12.</p> <p>Inform the Sponsor of any poisons that may be present in the device as described in Reg 5.13</p>
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## Annex 4 – Requirements for Written Agreements

	<p>to a device, that a device does not comply with the Essential Principles</p> <p>Provide the Manufacturer of a medical device, information relevant to: the manufacturer's obligations under the conformity assessment procedures; and whether the manufacturer's medical devices comply with the essential principles.</p> <p>Ensure that devices comply with the applicable provisions of the Therapeutic Goods Advertising Code, and other relevant requirements (if any) in legislation and that the advertising material is consistent with the manufacturer's intended purpose.</p> <p>Ensure that an advertisement does not contain a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority), other than in those circumstances described in legislation.</p> <p>Provide information to the manufacturer about events that has led to any complaint or problem in relation to the</p>	<p>Inform the Sponsor of information that indicates that a certificate or other document (other than a TGA issued conformity assessment certificate or other document issued by the TGA) that the Sponsor used to certify matters under s41FD to signify:</p> <ul style="list-style-type: none"><li>(i) compliance with the essential principles; or</li><li>(ii) the application of relevant conformity assessment procedures to a device; has been restricted, suspended, revoked or is no longer in effect.</li></ul> <p>Ensure that manufacturing records are retained, and are available, for a period that is at least the lifetime of the device or for the minimum period defined in Australian conformity assessment procedures; 5 years.</p> <p>Ensure that the responsibility to retain, maintain and make available distribution records, and other records identified in r5.10, is in accordance with r5.10 and 8.1A, using arrangements that have been agreed and verified.</p>
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## Annex 4 – Requirements for Written Agreements

	<p>manufacturer's device, no matter how minor;</p> <p>Comply with the manufacturer's requirements for storage and transport of the device</p> <p>Create and maintain contemporaneous records of complaints, adverse events, recalls and product distribution and retain the records for the periods prescribed in Regulations (r5.10)</p> <p>Comply with additional conditions for records, manufacture, the essential principles, etc., specifically imposed by the TGA at the time of, or subsequent to, market authorization.</p> <p>For a Class AIMD medical device, a Class III medical device, a Class IIb medical device that is an implantable medical device, or a Class 4 IVD medical device, provide a report to the TGA as described in Reg 5.11.</p> <p>For IVDs described in Reg 5.3(1)(j), provide a report as described in Reg 5.12</p> <p>Ensure that a device is not supplied in Australia if the supply would contravene Part 2 of the current Poisons Standard.</p> <p>Ensure that manufacturing records and distribution records</p>	
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## Annex 4 – Requirements for Written Agreements

		are available for the periods defined in Reg 8.1.	
Public notification and recall of medical devices.	41KB	<p>Follow the guidance in the Uniform Recall Procedure for Therapeutic Goods (URPRG) to take the specified steps, in the specified manner and within such reasonable period as is specified, to recall medical devices of that kind that have been distributed, to publish specified information to inform the public and to notify the TGA of information relating to the persons to whom medical devices have been supplied.</p>	<p>Assist the Australian Sponsor to; meet the requirements outlined in the Uniform Recall Procedure for Therapeutic Goods (URPTG) for the recall of devices, effect a notification to the public of recalls and to inform the TGA of information relating to the persons to whom medical devices have been supplied.</p>
Application of the conformity assessment procedures and requests for information	s41DA, s41JA  rP3 Div 3.2, S3P1 CI1.9, S3P4 CI4.8, S3P5 CI5.8	<p>Assist the manufacturer of the device to determine the Class of the device in accordance with the Australian classification rules.</p> <p>Facilitate the provision of the manufacturer's records including, but not limited to; records to demonstrate compliance with the essential principles, conformity assessment procedures and any conditions imposed at the time of, or subsequent to, the granting of marketing authorization that is related to the manufacturer's activities, compliance with advertising requirements, the safety and efficacy of the devices for their intended purpose, the regulatory history of the devices in another country, etc. when such records are requested by the TGA.</p>	<p>Comply with the relevant conformity assessment procedures that are "obligations on the manufacturer".</p> <p>Classify a device.</p> <p>Apply an appropriate CA procedure to: implement a QMS appropriate for the class of the device.</p> <p>Demonstrate compliance with the relevant Essential Principles for use in the Australian market.</p> <p>Allow an authorized officer of the TGA to enter the premises of the manufacturer and whilst on those premises to inspect the premises and medical devices of any kind in accordance with the requirements of the legislation.</p> <p>On request, provide documentation to an authorized person relating to devices of a</p>

## Annex 4 – Requirements for Written Agreements

		<p>Ensure arrangements are in place to allow the TGA to monitor the operation of, and carry out inspections of, the manufacturer's quality management system.</p> <p>Obtain a Declaration of Conformity from the Manufacturer</p> <p>Where the TGA has performed a Design Examination, ensure that changes to the design are notified to the TGA</p> <p>Ensure that the manufacturer informs the Sponsor of adverse events and recalls that are to be reported to the TGA</p>	<p>kind covered by the TGA issued CA certificate, or to the manufacturer's QMS.</p> <p>Allow the authorized person to copy the documents.</p> <p>Make a Declaration of Conformity and provide to the Australian Sponsor for marketing authorization applications</p> <p>Make the records identified in the conformity assessment procedure applied by the manufacturer, available to TGA either directly or through the Australian Sponsor.</p> <p>Ensure that manufacturing records are retained, and are available, for a period that is at least the lifetime of the device or for the minimum period defined in Australian conformity assessment procedures; 5 years.</p> <p>Inform the relevant Auditing Organization (certification body) of changes to the design or QMS</p> <p>Undertake to inform the Sponsor or the TGA of adverse events or steps taken to recover / recall devices from the market.</p> <p>Ensure reporting to the relevant certification body of a substantial change to the system; or change to the kinds of medical devices to which the system is to be applied.</p>
Conditions on Conformity Assessment	s41EJ	Assist the manufacturer of the device in accordance with the Australian classification rules.	In addition to the roles above for "Application of the conformity assessment procedures "

## Annex 4 – Requirements for Written Agreements

Certificates issued by the TGA. (If a manufacturer chooses to participate in the MDSAP and is supplying product to Australia, the AO must include the requirements of the Australian jurisdiction within the scope of the audit. If the manufacturer is also required to hold a TGA issued CA Certificate, the conditions of that certificate must also be applied.)	Facilitate the provision of the manufacturer's records requested by the TGA.  Ensure arrangements are in place to allow the TGA to monitor the operation of, and carry out inspections of, the manufacturer's quality management system.  Obtain a Declaration of Conformity from the Manufacturer.  Where the TGA has performed a Design Examination ensure that changes to the design are notified to the TGA  Ensure that the manufacturer informs the Sponsor of adverse events and recalls that are to be reported to the TGA	Cooperate with the TGA in a review of whether the requirements of an appropriate CA procedure have been applied including; the application of a QMS and compliance with the essential principles in accordance with the requirements of the legislation.  Notify the TGA and the Auditing Organization of any substantial changes to the quality management system, the product range covered by the QMS or changes to the design of products covered by the certificate.  Comply with any additional and relevant condition applied to a conformity assessment certificate when issued or subsequently amended.
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### Clarification on the use of MDSAP in Australia

The TGA formally recognizes MDSAP certificates as a "conformity assessment document" if issued in accordance with MDSAP AU P0026 and references the regulatory requirements of the Australian jurisdiction. The TGA uses these documents as evidence of compliance with the QMS requirements of the Australian conformity assessment procedures. MDSAP certificates are often used when alternative EC Certification is not available.

Note that regardless of any pathway that may have been used, or is used, for marketing authorization in Australia, an MDSAP Auditing Organization must include the requirements of the Australian jurisdiction within the scope of the MDSAP audit if the manufacturer is supplying product to the Australian market

See the document "Use of market authorization evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs)"

Part 4A of the Therapeutic Goods Act 1989 makes provision for an Australian incorporated organization to be recognized as an Australian Conformity Assessment Bodies Body (CAB) if they satisfy assessment criteria that is

## **Annex 4 – Requirements for Written Agreements**

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based on the EU's MDR or IVDR Annex VII requirements. The legislation also makes provisions to recognize the product assessments and quality management system regulatory audits performed by Australian CABs.

Australian legislation separately recognizes MDSAP Audit Reports and Certificates as evidence from a comparable overseas regulator. See [\*\*Comparable overseas regulators for medical device applications | Therapeutic Goods Administration \(TGA\)\*\*](#) [s41FDA(c) and [\*\*related instruments\*\*](#)].

The assessment processes used to recognize an MDSAP Auditing Organization may be used to support an organization's application to be an Australian Conformity Assessment Body if the applicant is an Australian Corporation.

### **Brazil – ANVISA**

There are no additional expectations for the audit of written agreements during an MDSAP audit.

### **Canada - Health Canada**

There are no additional expectations for the audit of written agreements during an MDSAP audit.

### **Japan – MHLW/PMDA**

There are no additional expectations for the audit of written agreements during an MDSAP audit.

### **USA – FDA**

There are no additional expectations for the audit of written agreements during an MDSAP audit.

## Annex 5 – Japan’s QMS Ordinance Revision - Tables

### Annex 5 – Japan’s QMS Ordinance Revision - Tables

The following tables show the correspondence between MHLW MO 169 Chapter 2, as amended in 2020 (aligned with ISO 13485:2003) and amended in 2021 (aligned with ISO 13485:2016). Please see [footnote 3](#) in the Management process for information as to the MDSAP audit to the 2020 and 2021 versions.

Correspondence between ISO13485:2003 and MHLW MO 169 Chapter 2, as amended in 2020

<b>ISO 13485:2003</b>	<b>MHLW MO 169, Chapter 2</b>	<b>Note for understanding the requirements of MHLW MO 169 Chapter 2, as amended in 2020</b>
Clause 1.2 Application	Section 1 General Rules	
Clause 1.2, paragraph 2 and 3	Article 4	<p>Article 4 specifies the way of application of this chapter to the organization.</p> <p>Article 4.1 specifies that Class 1 medical devices are exempted from the requirements of design and development, Article 30 to Article 36.</p> <p>Article 4.2 and 4.3 specifies the rule of exclusion and non-application of the requirements. These articles are identical to the description of ISO 13485:2003 clause 1.2, paragraph 3.</p>
Clause 4 Quality management system	Section 2 Quality Management System	
Clause 4.1	Article 5	
Clause 4.2.1	Article 6	
Clause 4.2.2	Article 7	
Clause 4.2.3	Article 8	The retention period of obsolete documents required by the ordinance is specified by Article 67 of MHLW MO 169.

## Annex 5 – Japan's QMS Ordinance Revision - Tables

<b>ISO 13485:2003</b>	<b>MHLW MO 169, Chapter 2</b>	<b>Note for understanding the requirements of MHLW MO 169 Chapter 2, as amended in 2020</b>
Clause 4.2.4	Article 9	The record retention period required by the ordinance is specified by Article 68 of MHLW MO 169.
Clause 5 Management responsibility	Section 3 Management responsibility	
Clause 5.1	Article 10	
Clause 5.2	Article 11	
Clause 5.3	Article 12	
Clause 5.4.1	Article 13	
Clause 5.4.2	Article 14	
Clause 5.5.1	Article 15	
Clause 5.5.2	Article 16	
Clause 5.5.3	Article 17	
Clause 5.6.1	Article 18	
Clause 5.6.2	Article 19	
Clause 5.6.3	Article 20	
Clause 6 Resource Management	Section 4 Resource Management	
Clause 6.1	Article 21	
Clause 6.2.1	Article 22	
Clause 6.2.2	Article 23	
Clause 6.3	Article 24	
Clause 6.4	Article 25	

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<b>ISO 13485:2003</b>	<b>MHLW MO 169, Chapter 2</b>	<b>Note for understanding the requirements of MHLW MO 169 Chapter 2, as amended in 2020</b>
Clause 7 Product realization	Section 5 Product realization	
Clause 7.1	Article 26	
Clause 7.2.1	Article 27	
Clause 7.2.2	Article 28	
Clause 7.2.3	Article 29	
Clause 7.3.1	Article 30	
Clause 7.3.2	Article 31	
Clause 7.3.3	Article 32	
Clause 7.3.4	Article 33	
Clause 7.3.5	Article 34	
Clause 7.3.6	Article 35	Clinical evaluations and/or evaluation of results of usage of the medical device are required to be implemented as part of design and development validation, in the case that the medical device is designated by 23-2-5.3 or 23-2-9.4 of PMD Act.
Clause 7.3.7	Article 36	
Clause 7.4.1	Article 37	
Clause 7.4.2	Article 38	
Clause 7.4.3	Article 39	
Clause 7.5.1.1	Article 40	

## Annex 5 – Japan's QMS Ordinance Revision - Tables

<b>ISO 13485:2003</b>	<b>MHLW MO 169, Chapter 2</b>	<b>Note for understanding the requirements of MHLW MO 169 Chapter 2, as amended in 2020</b>
Clause 7.5.1.2.1	Article 41	
Clause 7.5.1.2.2	Article 42	The requirements of Article 42 are only applied to "installation controlled medical devices", which are specified in Article 114-55.1 of Regulation for Enforcement of PMD Act. The installation controlled medical devices are the devices that need assembling for installation and need control for the assembling to prevent occurrence of public health hazard.
Clause 7.5.1.2.3	Article 43	
Clause 7.5.1.3	Article 44	
Clause 7.5.2.1	Article 45	
Clause 7.5.2.2	Article 46	
Clause 7.5.3.1	Article 47	
Clause 7.5.3.2.1	Article 48	
Clause 7.5.3.2.2	Article 49	<p>The requirements of Article 49 are only applied to "designated medical devices" which are specified by the Article 68-5 of PMD Act.</p> <p>The devices are designated by the Minister of Health, Labour and Welfare as those whose location must be known in order to prevent the occurrence or spread of hazards in health and hygiene, such as medical devices which are used by implantation in the human body or other medical devices which might be used outside facilities providing medical treatment.</p> <p>The designated medical devices are included in the active implantable medical devices and</p>

## Annex 5 – Japan's QMS Ordinance Revision - Tables

<b>ISO 13485:2003</b>	<b>MHLW MO 169, Chapter 2</b>	<b>Note for understanding the requirements of MHLW MO 169 Chapter 2, as amended in 2020</b>
		<p>implantable medical devices which are required to be complied with the requirement in Clause 7.5.3.2.2 of ISO 13485:2003. The organization can be considered to comply with the requirement of Article 49 of the ordinance, when they comply with the requirement of Clause 7.5.3.2.2 of ISO 13485:2003.</p> <p>The requirements to maintain records of distribution specified in Clause 7.5.3.2.2 of ISO 13485:2003 are not applied to the organization, when the organization is the person operating the registered manufacturing site.</p>
Clause 7.5.3.3	Article 50	
Clause 7.5.4	Article 51	
Clause 7.5.5	Article 52	
Clause 7.6	Article 53	
Clause 8 Measurement, analysis and improvement	Section 6 Measurement, analysis and improvement	
Clause 8.1	Article 54	
Clause 8.2.1	Article 55	
Clause 8.2.2	Article 56	
Clause 8.2.3	Article 57	

## Annex 5 – Japan’s QMS Ordinance Revision - Tables

<b>ISO 13485:2003</b>	<b>MHLW MO 169, Chapter 2</b>	<b>Note for understanding the requirements of MHLW MO 169 Chapter 2, as amended in 2020</b>
Clause 8.2.4.1	Article 58	
Clause 8.2.4.2	Article 59	<p>The requirements of Article 59 are only applied to the designated medical devices (see the note for Article 49 above).</p> <p>The designated medical devices are included in the “active implantable medical devices and implantable medical devices” which are required to comply with the requirement in Clause 8.2.4.2 of ISO 13485:2003. The organization can be considered to comply with the requirement of Article 59 of the ordinance, when they comply with the requirement of Clause 8.2.4.2 of ISO 13485:2003.</p>
Clause 8.3	Article 60	
Clause 8.4	Article 61	
Clause 8.5.1	Article 62	<p>Article 62.6 specifies the requirements of establishment of procedures to notify adverse events for the Marketing Authorization Holder and the person operating the registered manufacturing site.</p> <p>The Marketing Authorization Holder shall establish documented procedures to report adverse events which meet reporting criteria specified by the Article 228-20.2 of Regulation for Enforcement of PMD Act to the Minister of Health, Labour and Welfare.</p> <p>When the organization is the person operating the registered manufacturing site, the organization shall establish documented</p>

## Annex 5 – Japan’s QMS Ordinance Revision - Tables

<b>ISO 13485:2003</b>	<b>MHLW MO 169, Chapter 2</b>	<b>Note for understanding the requirements of MHLW MO 169 Chapter 2, as amended in 2020</b>
		procedure to notify the information to the Marketing Authorization Holder.
Clause 8.5.2	Article 63	
Clause 8.5.3	Article 64	

### Correspondence between ISO13485:2016 and MHLW MO 169 Chapter 2, as amended in 2021

<b>ISO 13485:2016</b>	<b>MHLW MO 169, Chapter 2</b>	<b>Note for understanding the requirements of MHLW MO 169 Chapter 2, as amended in 2021</b>
Clause 1 Scope	Section 1 General Rules	
Clause 1, paragraph 4-5	Article 4	Article 4.1 specifies that Class 1 medical devices are exempted from the requirements of design and development, Article 30 to Article 36-2.  Article 4.2 and 4.3 specifies the rule of exclusion and non-application of the requirements. These articles are identical to the description of ISO 13485:2016 clause 1, paragraph 4 and 5.
Clause 4 Quality management system	Section 2 Quality management system	
Clause 4.1.1	Article 5-1	Roles undertaken by the organization are Marketing Authorization Holder provided by Article 23-2.1 of PMD Act, Registered Manufacturing Site provided by Article 23-2-3.1 and 23-2-4.1 of PMD Act, Seller of pharmaceutical products provided by Article 24.1 of PMD Act, Seller and Leaser of specially-controlled medical devices provided by Article 39.1 of PMD Act,

## Annex 5 – Japan's QMS Ordinance Revision - Tables

		Repairer of medical devices provided by Article 40-2.1 of PMD Act, or Seller and Leaser of controlled medical devices provided by Article 39-3.1 of PMD Act.
Clause 4.1.2	Article 5-2	
Clause 4.1.3	Article 5-3	
Clause 4.1.4	Article 5-4	
Clause 4.1.5	Article 5-5	
Clause 4.1.6	Article 5-6	
Clause 4.2.1	Article 6	
Clause 4.2.2	Article 7-1	
Clause 4.2.3	Article 7-2	
Clause 4.2.4	Article 8	The retention period of obsolete documents required by the ordinance is specified by Article 67 of MHLW MO 169.
Clause 4.2.5	Article 9	The record retention period required by the ordinance is specified by Article 68 of MHLW MO 169.
Clause 5 Management responsibility	Section 3 Management responsibility	
Clause 5.1	Article 10	
Clause 5.2	Article 11	
Clause 5.3	Article 12	
Clause 5.4.1	Article 13	
Clause 5.4.2	Article 14	
Clause 5.5.1	Article 15	
Clause 5.5.2	Article 16	

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Clause 5.5.3	Article 17	
Clause 5.6.1	Article 18	
Clause 5.6.2	Article 19	The organization is not required to input "reporting to regulatory authorities", the item specified in ISO 13485:2016 5.6.2 c), to management review, when the organization is the person operating the registered manufacturing site.
Clause 5.6.3	Article 20	
Clause 6 Resource Management	Section 4 Resource Management	
Clause 6.1	Article 21	
Clause 6.2, paragraph 1 and 2	Article 22	
Clause 6.2, paragraph 3	Article 23	
Clause 6.3	Article 24	
Clause 6.4.1	Article 25-1	
Clause 6.4.2	Article 25-2	
Clause 7 Product realization	Section 5 Product realization	
Clause 7.1	Article 26	
Clause 7.2.1	Article 27	
Clause 7.2.2	Article 28	
Clause 7.2.3	Article 29	
Clause 7.3.1 and 7.3.2	Article 30	

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Clause 7.3.3	Article 31	
Clause 7.3.4	Article 32	
Clause 7.3.5	Article 33	
Clause 7.3.6	Article 34	
Clause 7.3.7	Article 35-1	Clinical evaluations and/or evaluation of performance of the medical devices are required to be implemented as part of design and development validation, in the case that the medical device is designated by 23-2-5.3 or 23-2-9.4 of PMD Act.
Clause 7.3.8	Article 35-2	
Clause 7.3.9	Article 36-1	
Clause 7.3.10	Article 36-2	
Clause 7.4.1	Article 37	
Clause 7.4.2	Article 38	
Clause 7.4.3	Article 39	
Clause 7.5.1	Article 40	
Clause 7.5.2	Article 41	
Clause 7.5.3	Article 42	
Clause 7.5.4	Article 43	
Clause 7.5.5	Article 44	
Clause 7.5.6	Article 45	
Clause 7.5.7	Article 46	
Clause 7.5.8	Article 47	
Clause 7.5.9.1	Article 48	
Clause 7.5.9.2	Article 49	The requirements of Article 49.2 and Article 49.3, which are identical to the requirements of ISO 13485:2016

## Annex 5 – Japan's QMS Ordinance Revision - Tables

		7.5.9.2 paragraph 2 and 3, are not applied, when the organization is the person operating the registered manufacturing site.
Clause 7.5.10	Article 51	
Clause 7.5.11	Article 52	
Clause 7.6	Article 53	
Clause 8 Measurement, analysis and improvement	Section 6 Measurement, analysis and improvement	
Clause 8.1	Article 54	
Clause 8.2.1	Article 55-1	
Clause 8.2.2	Article 55-2	This article is identical to the requirement of ISO 13485:2016 8.2.2. However, it should be noted that the organization is required to determine the need to notify the information to the Marketing Authorization Holder instead of the regulatory authorities, when the organization is the person operating the registered manufacturing site.
Clause 8.2.3	Article 55-3	This article is identical to the requirement of ISO 13485:2016 8.2.3. However, it should be noted that the organization is required to notify the information to the Marketing Authorization Holder instead of the regulatory authorities, when the organization is the person operating the registered manufacturing site. Record of the notification shall also be maintained.
Clause 8.2.4	Article 56	
Clause 8.2.5	Article 57	
Clause 8.2.6, paragraph 1-3	Article 58	

## **Annex 5 – Japan's QMS Ordinance Revision - Tables**

Clause 8.2.6, paragraph 4	Article 59	
Clause 8.3.1	Article 60-1	
Clause 8.3.2	Article 60-2	
Clause 8.3.3	Article 60-3	
Clause 8.3.4	Article 60-4	
Clause 8.4	Article 61	
Clause 8.5.1	Article 62	
Clause 8.5.2	Article 63	
Clause 8.5.3	Article 64	

## **Annex 6 – Acceptable exclusions from an organization’s scope of certification**

### **Annex 6 – Acceptable exclusions from an organization’s scope of certification**

GHTF document N3 clause 8.2.2 requires that "the Auditing Organization shall not exclude any processes, products, or services from the audit scope or the scope of the certificate, unless the regulations administered by the recognizing Regulatory Authority(s) permit the exclusion". This requirement is used to justify that an organization participating in MDSAP must be audited for a scope of certification that includes all the jurisdictions where the medical devices are distributed, and all medical devices being distributed in these jurisdictions. See item 88 in the [Question and Answers document](#). The activities/processes, products or facilities that are eligible for exclusion from an MDSAP Program are outlined in the following table. A device may be excluded from the scope of the MDSAP audit only if it meets the corresponding exclusion criteria from all the jurisdictions applicable to the audit. A jurisdiction may be excluded only if none of the medical devices are distributed in this jurisdiction, or all medical devices distributed in this jurisdiction can be excluded.

Jurisdiction	Consideration	Comments
Australia	Class I medical devices (non-sterile, no measuring function) are not required to have a certified quality management system.	TG(MD)R Schedule 3 Part 6 establishes obligations / requirements for manufacturers of Class I medical devices (non-sterile, no measuring function) that includes process definition, adverse event and recall reporting. By default, a certified QMS is not required by legislation for Class I medical devices (non-sterile, no measuring function). However, a manufacturer may: <ul style="list-style-type: none"><li>- voluntarily choose to apply a more onerous conformity assessment procedure (e.g., Schedule 3 Part 1 or Part 4); OR</li><li>- request an Auditing Organization to include Class I medical devices (non-sterile, no measuring function) within the scope of an MDSAP ISO13458 certification.</li></ul> In these circumstances, the Auditing Organization should treat the requirements of the relevant Conformity Assessment Procedure (Part 1, 4 or 6) as regulatory requirements when establishing audit criteria.

## Annex 6 – Acceptable exclusions from an organization's scope of certification

<b>Brazil</b>	<p>Class I and Class II medical devices are not subject to GMP Certification*.</p> <p>* However, ANVISA Resolution RDC 15/2014 still require that the manufacturer of the finished device have an effective QMS in place.</p>	If all devices in the scope of certification are class I or II, or if the audited facility's contribution to the scope of certification only applies to class I or class II medical devices, the audit at that facility may disregard the requirements of the Brazilian regulation for registration purposes.
<b>Canada</b>	Class I medical devices are not required to have a certified quality management system.	If all devices in the scope of certification are class I or if the audited facility's contribution to the scope of certification only applies to class I medical devices, the audit at that facility may disregard the requirements of the Canadian regulation.
<b>Japan</b>	Class I medical devices are not required to have a certified quality management system.	If all devices in the scope of certification are class I or if the audited facility's contribution to the scope of certification only applies to class I medical devices, the audit at that facility may disregard the requirements of the Japanese regulation.
<b>United States</b>	Some Class 1 medical devices are "GMP-exempt", i.e. not subject to the US quality system regulation.	If all devices in the scope of certification are GMP-exempt or if the audited facility's contribution to the scope of certification only applies to GMP-exempt medical devices, the audit at that facility may disregard the requirements of the US Quality System regulation (21 CFR 820), with the exception of the requirements for maintaining complaint files and recordkeeping. Additionally, requirements still apply for compliance to Medical Device Reporting (21 CFR 803), Medical Devices; Reports of Corrections and Removals (21 CFR 806), and Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices (21 CFR 807).

## **Summary of Changes from Prior Revisions**

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### **Summary of Changes from Prior Revisions**

#### **Changes from version 006 to 007**

##### **Overview**

- Added reference to MDSAP AU P0037 - Guidelines on the use of GHTF/SG3/N19:2012 for MDSAP purposes on page 10
- Added reference to new Annex 6 on page 13

##### **Chapter 1 to Chapter 7**

- Update Australian regulatory clause references following updates to the *Therapeutic Goods Act 1989* and *Therapeutic Goods (Medical Devices) Regulations 2002*.
- Update Brazilian regulatory clause references
- Update Japanese regulatory clauses references

##### **Device Marketing Authorization and Facility Registration**

###### **Task 3**

- Clarify FDA premarket notification requirements for changes

##### **Measurement, Analysis and Improvement**

###### **Task 12**

- Update requirements for Health Canada

###### **Task 15**

- Update regulation reference for Brazil

##### **Medical Device Adverse Events and Advisory Notices Reporting**

###### **Task 1**

- Update requirements for Health Canada

###### **Task 2**

- Clarify Australian recall reporting requirements.
- Update regulation references for Brazil
- Update requirements for Health Canada

# **Summary of Changes from Prior Revisions**

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## **Production and Service Controls**

### Task 9

- Amendment to the Australian country specific requirements and legislative links

## **Annex 1**

- Change GHTF SG3 N19 reference to MDSAP AU P0037.
- Amendment to the Australian country specific requirements to include updated regulatory references.

## **Annex 4**

- Update to Australian regulatory references relating to the maintenance of distribution records.
- Update to the Clarification on the use of MDSAP in Australia section to remove requirements related to Regulation 4.1 (which has been repealed) and to reference TGA guidance on use of comparable overseas evidence and related legislative instruments.

## **Annex 6**

- Explains acceptable exclusions of medical devices or regulations from the scope of certification.

## **Changes from version 005 to 006**

### **Chapter 1 to Chapter 7**

- Added clause number(s) of the new MHLW MO169 in the case that the number(s) is/are different from those for the old ordinance.

### **Management Process**

### Task 1

- Added footnote to explain the meaning of the word, "Old", in the sections of Clause and Regulation references for Japanese requirements – page 21

# **Summary of Changes from Prior Revisions**

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## **Purchasing**

### Task 5

- Deleted a task related to a Japanese country specific requirement, as the requirement is deleted in the new ordinance – page 168

## **Annex 5**

- Added new Annex that has tables showing Japan's new and old QMS ordinance and the relationship between ISO 13485 – page 211

## **Changes from version 004 to 005**

### **Foreword/Use of this document**

- Added statement regarding the combination of the MDSAP Audit Approach and Companion Document, formerly separate documents, into this single document – page 5
- Added statement regarding special access programs – page 7

### **Audit Sequence**

- Clarified that order in which processes are to be audited is fixed, however the sequence of audit tasks within a process may be arranged to allow for an efficient audit; clarified that reasonable exceptions are allowed for following the audit sequence – pages 8-9

### **Conducting the Audit**

- Added clarifying language as to the assessment of the medical device organization's application of risk management principles – page 10

### **Navigating the Audit Sequence**

- Clarified use of clause 4.2.1(e) in conjunction with regulatory requirements – page 10

### **Terminology**

- Added language for "medical device organization", "outsourced" process, product or service, "suppliers", "critical suppliers" – throughout the document as appropriate.

### **Annexes**

- Reference to Annex 1 changed – page 13
- Introduction of two new annexes to summarize country specific requirements for:
  - reporting timeframes for adverse events and advisory notices – page 13

## **Summary of Changes from Prior Revisions**

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- written agreements – page 13

### **MDSAP Audit Cycle**

- Added statement regarding Stage 1 audits for re-certification audits in certain circumstances– page 17
- Added paragraph regarding sampling during audits – page 18

### **Surveillance Audits**

- Added reference to Appendix 1 of MDSAP AU P0008 – page 16

### **Management Process**

#### Task 1 – Assessing conformity

- added text under Quality System Procedures and Instructions heading regarding expectations for the term “documented” - page 22;
- added text under Quality Management System Planning heading regarding evidence of quality management system planning – page 23

#### Task 5 – Added text for Australia country-specific requirement:

- Reference to EP13A for patient implant cards – page 28
- Clarification of the inclusion of Sponsors activities in the medical device organization’s internal audit. – page 28

### **Device Marketing Authorization and Facility Registration Process**

#### Task 1

- Move the matters that relate to Australian requirements for the written agreement to Annex 4 – page 41;
- “Note” to “Assessing conformity”; added text regarding special attention should be paid to instances where devices are being marketed to jurisdictions where marketing authorization has not been granted – page 40;
- corrected expiry dates for Brazil for Registration and Notification – page 42

#### Task 2

- Clarifying text for Australia country-specific requirements – page 46;
- Corrected expiry dates for Brazil for Registration and Notification – page 46

#### Task 3

## **Summary of Changes from Prior Revisions**

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- Added text within the task to emphasize the link between design changes and the need to assess for market authorization – page 48;
- added text to the Australia country-specific requirement regarding notifying TGA of changes in cases where the Manufacturer also holds a TGA Conformity Assessment Certificate – page 48;
- corrected a reference for Japan to PMD Act 23-2-5.12 – page 50

## **Device Marketing Authorization and Facility Registration**

### Task 2

- Changed “manufacturer should” to “manufactures must” maintain a list of Australian Sponsors and the products ... – page 46
- Additional reminder that Sponsors are required to have a written agreement with manufacturers – page 46

## **Measurement, Analysis and Improvement Process**

### Task 2

- Added statement that information from the organization’s analysis of quality data should be used to inform the audit team’s decision as to specific products and processes to audit during Design and Development, Production and Service Controls, and Purchasing processes – page 57

### Task 7

- Corrected text for country-specific requirements for Australia, added text to the Australia country-specific requirement regarding notifying TGA of changes in cases where the Manufacturer also holds a TGA Conformity Assessment Certificate – page 65

### Task 12

- Added criteria for selection of complaints for review – page 71
- Added post-marketing systems as experience to be gained from the post-production experience – page 71;
- added “postmarket surveillance activities” under the “Selecting records” page 75
- added “Risk management” headings to “Assessing conformity” for this task – page 75;
- added text that information from reviewing post-production sources, including complaints and postmarket surveillance reports, should guide the audit team in selecting designs to review and production processes to audit – page 76

## **Summary of Changes from Prior Revisions**

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### Task 14

- Task was rewritten to focus on the audit of the organization's process for evaluating complaints for potential individual adverse event reports – pages 75-76

### Task 15

- Task was rewritten to focus on audit of the organization's processes for evaluating quality issues for potential advisory actions – page 77

## **Medical Device Adverse Events and Advisory Notices Process**

### Task 1

- Added Note for Canada that requirement to report incidents meeting the requirements of section 59.(1) that occur outside of Canada does not apply unless the Manufacturer has indicated, to a regulatory agency of the country in which the incident occurred, the Manufacturer's intention to take corrective action, or unless the regulatory agency has required the Manufacturer to take corrective action - page **Error! Bookmark not defined.**;
- for United States, added allowance for quarterly summary reporting for malfunction MDRs – page 88

## **Design and Development Process**

### Task 5

- Post-production feedback is to be used for maintaining product requirements and improving product realization processes - page 101
- Under "Assessing conformity", "Design inputs" heading, added text relating design inputs to manufacturing processes – page 102

### Task 7

- Under "Assessing conformity", "Design outputs" heading, added text that design outputs can include documents such as diagrams, drawings, specifications, and procedures for both products and processes – page 105

### Task 13

- Added 8.2.1 as a relevant clause for design changes – page 114
- Added text to the Australia country-specific requirement regarding notifying TGA of changes in cases where the Manufacturer also holds a TGA Conformity Assessment Certificate – page 115

# **Summary of Changes from Prior Revisions**

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## **Production and Service Controls Process**

### Task 1

- Under "Assessing conformity", "Unique Device Identifier" heading, removed the phase-in dates for device classes – page 123

## **Purchasing**

### Task 5

- added text for EP13A for patient implant cards for Australia – pages 168

## **ANNEXES**

### **Annex 1**

- Change of Title to reflect the general content of this section.
- General requirements for Assessing Technical Documentation - Added some clarifying text for the expected output from design control for technical documentation – page 181; and the monitoring of the update of risk management documents – page 182.
- Australian minimum requirement for assessing technical documentation – Added the inclusion of information gathered in feedback processes – page 185; and patient implant cards – page 186

### **Annex 2**

- Clarified requirements for grading nonconformities found during audit of sterilization processes – page 195

### **Annex 3**

- Quick reference guide for reporting timeframes for adverse events and advisory notices – page 192

### **Annex 4**

- Clarification of when Written Agreements may be required to support regulatory requirements and the topics that may need to be included – page 195

# **Medical Device Single Audit Program**

## **Frequently Asked Questions**

### **Table of Content**

- A. General Questions about MDSAP**
- B. Questions related to Assessments**
- C. Questions related to Audits**

### **A. General Questions about MDSAP**

#### **1. What is the Medical Device Single Audit Program?**

The Medical Device Single Audit Program (MDSAP) is a program that allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system that satisfies the requirements of multiple regulatory jurisdictions. Audits are conducted by Auditing Organizations authorized by the participating Regulatory Authorities to audit under MDSAP requirements.

The MDSAP is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. The program's main mission is to "...jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers."

#### **2. Why was the MDSAP developed?**

The MDSAP was developed to:

- The MDSAP was implemented-based on requirements that are defined in the IMDRF MDSAP Model;
- Enable appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on industry;
- Promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the sovereignty of each authority;
- Promote globally, in the longer term, a greater alignment of regulatory approaches and technical requirements based on international standards and best practices;
- Promote consistency, predictability and transparency of regulatory programs by standardizing;
  - the practices and procedures of participating regulators for the oversight of third party auditing organizations, and
  - the practices and procedures of participating third party auditing organizations; and
  - Leverage, where appropriate, existing requirements and procedures for conformity assessment.

**3. Which Regulatory Authorities are part of the MDSAP and what is the plan for expansion of the program?**

The MDSAP was developed by representatives of the Australian Therapeutic Goods Administration (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, MHLW/PMDA, and the U.S. Food and Drug Administration (FDA). All regulatory authorities participating in the MDSAP are equal partners in the program.

Others Regulatory Authorities may eventually decide to participate in the MDSAP and to become active participants in the Program. For example, the World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union (EU) are Official Observer to the MDSAP Regulatory Authority Council (RAC) and Subject Matter Expert (SME) Work Group.

**4. What is the difference between a Regulatory Authority being a participant in MDSAP Subject Matter Expert (SME) Working Group (WG) versus being an observer to this working group?**

The Regulatory Authority participants provide the resources to support the development, implementation, maintenance and expansion of MDSAP and participate actively in the process of recognizing, monitoring, and re-recognizing Auditing Organizations under the framework of the IMDRF MDSAP. The

participating Regulatory Authorities have committed to use the MDSAP deliverables in order to assess program success. Each Regulatory Authority participant is also represented on the MDSAP Regulatory Authority Council (RAC); the MDSAP's governing board, by two senior level managers.

A Regulatory Authority who is an "observer" may attend MDSAP SME WG meetings, assessments, and other activities, but does not utilize MDSAP program deliverables to replace or supplement its regulatory scheme deliverables or portions of these deliverables. The observers are represented on the MDSAP RAC by one senior level manager.

**5. Is the list of medical device manufacturers participating in the MDSAP made publicly available?**

No, actually this information is not made publicly available by the Regulatory Authorities.

**6. Can industry provide input into MDSAP documents or the program in general?**

Yes. There are two venues for the industry to contribute.

Following each MDSAP audit, Medical Device Firms participating in the MDSAP are invited to provide feedback through a survey that is [available in MDSAP FDA webpage](#).

Besides it, the Regulatory Authorities that are participating in the MDSAP have established and are implementing an MDSAP Quality Management System [MDSAP Documentation](#). Feedback on MDSAP can be submitted to any of the participating Regulatory Authorities in written format, electronically, by telephone, or in person. Electronic feedback is preferred and may be submitted to one of the four email addresses listed below. MDSAP participating regulators will address the feedback in accordance with the procedure [MDSAP QMS P0011](#) Complaints and/or Customer Feedback Procedure. Manufacturers are encouraged to provide feedback.

Contact emails:

[MDSAP@tga.gov.au](mailto:MDSAP@tga.gov.au)  
[MDSAP.ATENDIMENTO@anvisa.gov.br](mailto:MDSAP.ATENDIMENTO@anvisa.gov.br)  
[QS\\_MDB\\_HC@hc-sc.gc.ca](mailto:QS_MDB_HC@hc-sc.gc.ca)  
[MDSAP@pmda.go.jp](mailto:MDSAP@pmda.go.jp)  
[MDSAP@fda.hhs.gov](mailto:MDSAP@fda.hhs.gov)

**7. What is the criterion that must be achieved for the MDSAP to be considered successful?**

The MDSAP Subject Matter Experts Working Group has developed a plan to gather evidence for a “proof of concept” of the MDSAP. The plan includes eight performance indicators for the measurement of the success of this program. - The criteria are related to audit reports and non-conformities, the audit model, duration of audits, Auditing Organizations and manufacturers. A method for data collection, sampling, method of analysis and targets were defined for each indicator. [MDSAP P0007 Proof of concept for MDSAP Program.](#)

**8. Have there been discussions with WHO regarding the pre-clearance process for IVDs and taking account the results of an MDSAP audit? Will medical devices assessed by the WHO be included in the program at a later stage?**

WHO is participating as an observer to the MDSAP. WHO has indicated a willingness to adapt and integrate MDSAP processes as much as possible in their *Prequalification Program*. WHO intends to utilize MDSAP reports where possible if they are available for devices that are subject to their *Prequalification Program*.

**9. If an RA decides to change its GMP/QMS or Regulatory requirements, how will the changes be incorporated into MDSAP?**

MDSAP Audit Model and the MDSAP Audit Model Companion document can be periodically revised to reflect any changes in regulatory requirements. Accordingly, the impacted MDSAP training will be updated. The IMDRF MDSAP WG N3 document requires “The Auditing Organizations to participate in any regulatory coordination group established for the purpose of keeping the Auditing Organization’s personnel current on medical device legislation, guidance documents, standards, and best practice documents adopted in the applicable regulatory systems.” (N3 – Clause 6.1.3)

**10. How do I find out more specific information on the documents, policies, and procedures used in the MDSAP?**

The MDSAP participating Regulatory Authorities and the candidate Auditing Organizations primarily utilize the IMDRF MDSAP WG documents that can be found at: [IMDRF Documentation](#).

In addition, there are many other MDSAP Regulatory Authority Council approved documents in order to implement program, for example: an audit strategy for

auditing medical device manufacturers, requirements for the audit reports, a method for audit time calculation, and the MDSAP Quality Management System procedures. For further information on the MDSAP and associated documents, please refer to the [MDSAP Home Page](#) or contact one of the participating Regulatory Authorities at:

[MDSAP@tga.gov.au](mailto:MDSAP@tga.gov.au)  
[MDSAP.ATENDIMENTO@anvisa.gov.br](mailto:MDSAP.ATENDIMENTO@anvisa.gov.br)  
[QS\\_MDB\\_HC@hc-sc.gc.ca](mailto:QS_MDB_HC@hc-sc.gc.ca)  
[MDSAP@pmda.go.jp](mailto:MDSAP@pmda.go.jp)  
[MDSAP@fda.hhs.gov](mailto:MDSAP@fda.hhs.gov)

## B. Questions related to Assessments

### 11. Which Auditing Organizations can apply to the MDSAP?

During the MDSAP Pilot, only the Auditing Organizations recognised under CMDCAS program were invited to apply to participate in the MDSAP Pilot. From January 1st, 2017 the program was opened for applications from others candidate Auditing Organizations. More information can be found on the [announcement](#) available on MDSAP web page.

### 12. Can Contract Research Organizations participate in MDSAP? What about Certified Quality Auditors?

The MDSAP includes the use of Auditing Organizations, also known as Certification Bodies or Registrars in other schemes. If an Auditing Organization also acts as a Contract Research Organization, the organization's management system must ensure the impartiality of the Auditing Organization.

An independent Certified Quality Auditor may not individually apply for recognition under the MDSAP. Should an auditor become permanently employed or work on a contract basis for an Auditing Organization, and meet the competency and other criteria for auditors as required under MDSAP, e.g. absence of conflict of interest, that auditor may be qualified to perform MDSAP audits as long as the AO is recognized under MDSAP.

### 13. How will an Auditing Organization pay regulators for the application and training?

Actually there are no application fees or costs associated with the MDSAP Training. Training on the MDSAP Audit Model and the requirements of the participating Regulatory Authorities is available on-line to Auditing Organizations candidate applicants ([MDSAP Training Material](#)).

**14. How are assessments of Auditing Organizations being conducted by RAs under the MDSAP?**

The assessment program is defined in key documents for the planning and conduct of assessments by Regulatory Authority assessment teams; and, the follow-up and monitoring of assessment activities of Auditing Organizations. The sequence of all assessment activities follows a 4-year cycle. The cycle begins with an initial authorization, followed by annual surveillance assessments for three consecutive years. Assessments are performed per document [IMDRF MDSAP WG N5](#), *Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations* and associated MDSAP documents [MDSAP Documentation](#).

**15. Must Auditing Organizations have all documentation in English to be assessed by the Regulatory Authorities?**

Auditing Organizations must have at least the documents requested for the application submission and for Stage 1 Assessment in English. During the Stage 2 Assessment, the Auditing Organizations must have personnel with fluency in English to translate documents and records that are not in English. Additionally, records that are specific to the MDSAP program (including but not limited to the documents included in the audit report package) should be in English as well.

**16. What is the best way to determine what is expected of the Auditing Organizations with regard to multiple jurisdictions?**

Medical device manufacturers will have to be audited according to the scope declared in their application for certification services. Based on the countries where the manufacturer sells (or intends to sell) or has devices registered, the AO will determine the regulatory requirements applicable to that manufacturer.

The AOs will have to refer to the [Audit Model MDSAP AU P0002](#) and [Audit Model Companion MDSAP AU G0002.1](#) to make that determination. The two documents incorporate or reference the regulatory requirements of each of the participating Regulatory Authorities.

## **17. What oversight do Regulatory Authorities have over the Auditing Organizations?**

In accordance with best practices, the MDSAP incorporates a transparent assessment program by Regulatory Authorities who will oversee the compliance of the Auditing Organizations with MDSAP requirements. This program includes a robust plan and schedule for assessing the competence and compliance of MDSAP Auditing Organizations and includes assessments of their head office and critical locations, as well as witnessing the performance of Auditing Organization's audits ("witnessed" audits), as part of an ongoing four year recognition cycle.

The Regulatory Authorities involved MDSAP will base their recognition and assessment process on the IMDRF MDSAP WG and MDSAP documents in addition to other documents approved by the Regulatory Authority Council. [IMDRF Documentation](#) and [MDSAP Documentation](#).

In particular, Regulatory Authorities will evaluate or "assess" an Auditing Organizations' compliance to the requirements of IMDRF MDSAP WG documents N3 and N4.

- [IMDRF MDSAP WG N3 Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition](#)
- [IMDRF MDSAP WG N4 Competence and Training Requirements for Auditing Organizations](#)

## **18. What is a witnessed audit?**

A witnessed audit is performed to permit Regulatory Authorities to verify that an Auditing Organization adequately conducts their audits using the MDSAP Audit Model and reports appropriately on the outcomes of audits. It is an essential assessment activity for building and maintaining confidence in the reliability of the third party Auditing Organization. During a witnessed audit, the Auditing Organization's audit team conducts the audit of the medical device manufacturer and the Regulatory Authorities' assessment team observes the AO without interfering in the audit process. The RA Assessment team does not assist or coach the AO auditors, nor does it provide additional information to the AO audit team or collect information on their behalf.

After the Auditing Organization has issued the audit report, the assessment team finalizes and shares their conclusions with the Auditing Organization.

The RA conclusions are not in relation to the compliance of the manufacturer to ISO 13485 and the relevant regulatory requirements. The RA's conclusions only relate

to the ability of the Auditing Organization to audit against the requirements of the MDSAP.

**19. Who performs witnessed audits and how are the assessors selected?**

The witnessing of an audit being conducted by an Auditing Organization will be performed by qualified MDSAP Regulatory Authority Assessors. These assessors are experienced Regulatory Authority Assessors who will have knowledge of the MDSAP requirements, the requirements of the participating Regulatory Authorities and the device and manufacturing technologies used by the medical device manufacturer that is being audited.

Regulatory Authority Assessors are qualified against the competency requirements as defined in the document IMDRF MDSAP WG N6 FINAL:2013, *Regulatory Authority Assessor Competence and Training Requirements*.

**20. Can an Auditing Organization contest an unfavorable recognition decision or a nonconformity and its grading?**

If an Auditing Organization disagrees with an unfavorable recognition decision or a nonconformity issued by the Regulatory Authorities, it may formally file for an appeal to the participating Regulatory Authorities. The process is defined in [MDSAP AS P0021.002: Appeals Procedure](#).

**21. If a current Notified Body applies for authorization to perform audits under the MDSAP, but does not pass the MDSAP assessment, could they also be de-notified to the EU Directive?**

No. European Competent Authorities and Designating Authorities are not participants in the MDSAP. It is therefore unlikely that European Authorities would de-notify a Notified Body based on the outcome of an MDSAP Assessment. Nevertheless, European Authorities are likely to be informed if the reason for refusing the authorization was due to concerns that arose from a concurrent assessment by an Auditing Organization of the relevant European regulations. In such cases, the European Authorities may follow-up with the Auditing Organization and make their own assessment of the situation.

**22. Who from the Auditing Organization or the Regulatory Authorities makes the final decision on the compliance of the medical device manufacturer?**

The Auditing Organizations are fully responsible for making the decision on compliance to issue MDSAP certification documents under the program.

Independently, each MDSAP participant Regulatory Authority may use the report for different purposes, to support the regulatory decisions in their jurisdiction. If, based on the Auditing Organization's audit report, a Regulatory Authority concludes that the manufacturer is not in compliance with the regulations, the Regulatory Authority may engage in enforcement activities according to their policies, taking into account, if possible, the follow-up activities conducted by the Auditing Organization.

### **23. How does a regulatory authority inspectorate become an Auditing Organization?**

Regulatory Authorities who are seeking recognition under MDSAP need to comply with the same requirements as a commercial Auditing Organization. The other participating Regulatory Authorities will conduct an assessment according to the international standard ISO/IEC 17021-1 and the additional requirements defined in IMDRF MDSAP WG N3 and IMDRF MDSAP WG N4, per the assessment methodology documented in IMDRF MDSAP WG N5.

### **24. How will MDSAP ensure that every RA has the same evaluation standards for the Auditing Organization?**

Auditing Organizations are assessed for compliance with the requirements of ISO/IEC 17021-1 and the additional requirements of N3 and N4. An assessment program and assessment methodology for Auditing Organizations is defined in N5 and guidance for RA Assessors is to be provided in N8. Regulatory Authority assessors execute assessment tasks for each process defined in the documents above and identify objective evidence of definition, implementation and effectiveness of each of the requirements. If nonconformities are identified, a grading system is used to assist in determining the timeline for any corrections or corrective actions and to support a predefined Auditing Organization recognition or Auditing Organization de-recognition process.

Regulatory Authority assessors are qualified against the requirements of [IMDRF MDSAP WG N6, Regulatory Authority Assessor Competence and Training Requirements](#) to perform the assessment of an Auditing Organization. Regulatory Authority assessors will participate in both face to face and distance training activities. The MDSAP Regulatory Authorities are committed to operating under a joint MDSAP Quality Management System to establish controls over the program and to facilitate continuous improvement. Applicable procedures and forms are publically available at [MDSAP Assessment Procedures and Forms](#).

**25. Would an Auditing Organization receive independent recognition by each participating Regulatory Authority?**

No. Recognition is a joint exercise and hence recognition of an AO by the MDSAP Regulatory Authority Council (RAC) means recognition by each participating Regulatory Authority. It may be possible that some jurisdictions have to internalize MDSAP Recognition in your national regulatory framework. For example, Anvisa is publishing a Resolution in “*The Brazilian National Gazette*” for each AO that is recognized in the MDSAP. It has the same effective and expiration date of the MDSAP recognition letter.

**26. Will Auditing Organizations be informed when there is a complaint against them so that improvements can be made?**

Yes. MDSAP QMS P0011 Complaints and/or Customer Feedback Procedure include in its scope complaints related to the Auditing Organizations and to Medical Device Manufacturer participating in MDSAP.

## C. Questions related to Audits

**27. Which manufacturers are eligible to undergo an MDSAP audit?**

As currently planned, any manufacturer of medical devices is eligible to undergo an audit under the MDSAP. However, each regulatory authority may establish exclusion criteria for manufacturers meeting certain conditions if deemed necessary or when limited by legislation. It is important to note that manufacturers that participate in the MDSAP program are responsible for securing and maintaining a contract with an MDSAP recognized AO. AOs operate as fee-for-service organizations. In other words, medical device manufacturers are responsible to paying for MDSAP audits conducted by an AO. The Regulatory Authorities participating in MDSAP are not involved in contractual arrangements / the contract negotiation process between manufacturers and AOs.

**28. How can a medical device manufacturer participate in the MDSAP?**

All medical device manufacturers interested in participate to MDSAP can contact any of the Auditing Organizations authorized or recognized to perform MDSAP

audits. The [List of Auditing Organization Availability to Conduct MDSAP Audits](#) is available online.

Medical device manufacturers do not apply to a Regulatory Authority for an audit under MDSAP.

## **29. Does the MDSAP add requirements for the manufacturer?**

No. The MDSAP audit model was developed to cover existing requirements from the Regulatory Authorities participating in the MDSAP. The program does not add any new requirements to existing requirements from ISO 13485 or other country-specific requirements of the participating Regulatory Authorities.

## **30. What are the potential benefits of a manufacturer participating in the MDSAP?**

The MDSAP offers many benefits to medical device manufacturers including the following:

- A single audit is used in lieu of multiple separate audits or inspections by participating regulatory authorities or their representatives. Therefore, for many medical device manufacturers, the MDSAP reduces the overall number of audits or inspections and optimizes the time and resources expended on audit activities.
- Additionally, as a longer term goal, it is expected that the program will enhance confidence in the reliability of third party audits, that more Regulatory Authorities will join the program, and that other Regulatory Authorities will use information made available through the program to limit the need for additional audits.
- Some participating regulatory authorities will use MDSAP audit outcomes as an alternative to their own inspections to process applications for medical device marketing authorization.
- Like in any third party auditing program, the medical device manufacturer is free to choose among all authorized auditing organizations to perform the audits. Routine audits are announced and planned with the manufacturer.
- The MDSAP is expected to improve the predictability of audit outcomes through:
  - enhanced auditing organization recognition criteria,
  - monitoring of auditing organizations by the participating Regulatory Authorities,
  - the use of a standard MDSAP audit model,
  - the grading of any nonconformity using objective criteria to characterize the significance of the finding,

- the reporting of the audit outcomes using a standard report template.
- Enrolling in the MDSAP may be seen as evidence of a medical device manufacturer's commitment to quality management systems for product quality and regulatory compliance.

**31. What are the potential benefits to the manufacturer participating, specific to each jurisdiction?**

**Australia:** The Therapeutic Goods Administration – TGA

*Where regulations do not require a manufacturer or product to hold a TGA Conformity Assessment Certificate;*

- The TGA will take into account MDSAP- audit reports when considering whether a manufacturer has demonstrated compliance with an Australian Conformity Assessment procedure; or

*Where regulations require a manufacturer or product to hold a TGA Conformity Assessment Certificate;*

- The TGA will take into account MDSAP audit reports when considering whether to issue or maintain a TGA Conformity Assessment Certificate<sup>1</sup>. Under some circumstances a manufacturer may avoid routine TGA inspections.

Following a successful evaluation of the MDSAP, the following may apply:

*Where regulations do not require a manufacturer or product to hold a TGA Conformity Assessment Certificate;*

- The TGA will accept MDSAP certificates as evidence of compliance with ISO13485:2003 where the Standard has been used to demonstrate partial compliance with the requirements of an Australian Conformity Assessment Procedure. It is expected that Australian Sponsors may be required to submit to the TGA, additional technical documentation to demonstrate compliance with the requirements of the Essential Principles of Safety and Performance and the manufacturer's chosen Conformity Assessment Procedure.

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<sup>1</sup> TGA issued CA certificates are required for; manufacturers of medical devices that incorporate a medicinal substance, or a material of animal origin that has been rendered non-viable, or that contains tissues, cells or substances of microbial or recombinant origin, or that incorporate stable derivatives of human blood or human plasma.

*Where regulations require a manufacturer or product to hold a TGA Conformity Assessment Certificate;*

- The TGA will continue to take into account MDSAP audit reports when deciding whether to issue or maintain a TGA Conformity Assessment Certificate. Under some circumstances a manufacturer may avoid routine TGA inspections.

**Brazil:** The Brazilian National Health Surveillance Agency – ANVISA utilizes the outcomes of the program, including the reports, to constitute an important input on ANVISA's pre-market and post-market assessment procedures, providing, when applicable, key information that are expected to support regulatory technical evaluation on these issues.

As defined in RDC 15/2014 and RE 2.347/2015, ANVISA may use MDSAP audits in lieu of a premarket inspection by ANVISA to grant ANVISA's GMP Certificate to manufacturers intending to put medical devices of class III or IV on the Brazilian market. Undergoing an MDSAP audit may accelerate ANVISA's GMP certification process, which is a pre-requisite to the marketing authorization.

ANVISA can also use MDSAP audits to renew ANVISA's GMP Certificate bi-annually, as an alternative to an ANVISA comprehensive inspection.

Note: ANVISA do not use MDSAP audit reports from manufacturers where the result of ANVISA's previous inspection was considered unsatisfactory and therefore the manufacturer had the certification submission denied. In such cases ANVISA will start using the MDSAP reports only after a new ANVISA inspection with a satisfactory result.

**Canada:** Health Canada will operate the current Canadian Medical Device Conformity Assessment System (CMDCAS) program and the MDSAP in parallel - - Health Canada will accept either an MDSAP certificate or a CMDCAS certificate for the purpose of obtaining a new (or maintaining an existing) Class II, III or IV medical device license, pursuant to section 32 of the Regulations.

Additionally, Health Canada's intent is to implement the Medical Device Single Audit Program as the mechanism to assess regulatory compliance for quality management system requirements in Canada.

**Japan:** When an MDSAP audit report is submitted at the timing of premarket or periodical post-market QMS inspection application, Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) will use the report as a trial:

- 1) To exempt a manufacturing site etc.\* from on-site inspection, and/or

- 2) To allow a Marketing Authorization Holder (MAH) to substitute considerable part of documents required for the inspection with the report.

**Note:** PMDA may perform on-site inspection or request additional QMS documents, when it is determined necessary after a review of the MDSAP audit report package.

\*Exceptions:

- a) A Registered Manufacturing Site (RMS) which manufactures medical devices made of human/animal tissues,
- b) A RMS which manufactures radioactive IVDs, and
- c) An establishment of a MAH.

**United States:** U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health, will accept the MDSAP audit reports as a substitute for FDA routine inspections (biennial by policy). Additional benefits include:

- MDSAP routine audits are announced, scheduled by the Auditing Organization with the manufacturer, with a pre-established duration;
- The FDA will review MDSAP audit reports with a level of scrutiny commensurate to the significance of audit findings, taking into account the review and follow-up performed by the Auditing Organization;
- Firms have one month to provide their full response to critical nonconformities (grade 4 and 5) to the Auditing Organization (as opposed to 15 working days following a FDA inspection);
- Certification documents issued by the Auditing Organization state compliance with applicable US regulations, which may provide a marketing advantage.

**Note:** Inspections conducted "For Cause" or "Compliance Follow-up" by FDA will not be affected by this program. Moreover, this MDSAP program would **not** apply to any necessary pre-approval or post approval inspections for Premarket Approval (PMA) applications or to decisions under section 513(f)(5) of the Act (21 U.S.C. 360c(f)(5)) concerning the classification of a device.

Firms with activities related to the Electronic Product Radiation Control (EPRC) provisions of the Act will continue to be subject to FDA inspections for the EPRC activities.

**World Health Organization (WHO):** In the framework of the *Prequalification Program* for diagnostic devices, the WHO may recognize successful MDSAP - audits as acceptable evidence of QMS compliance with international regulations. This may result in either abbreviated or waived WHO inspection depending on the scope of audit.

### **32. What are the costs associated with MDSAP audits**

The cost of conducting an MDSAP audit is dictated by the commercial arrangement between the medical device manufacturer and the authorized MDSAP Auditing Organization.

### **33. Where can industry find out which jurisdictions an AO is recognized for?**

An Auditing Organization authorized or recognized to perform MDSAP audits must have demonstrated competence in each jurisdiction's regulations. Therefore, the recognition is not restricted in terms of a Regulatory Authority's jurisdiction and covers all jurisdictions participating in MDSAP. The letter of recognition to conduct medical device regulatory audits under MDSAP is standardized. .

### **34. How does the MDSAP ensure that medical devices are being manufactured in accordance with the regulations of multiple jurisdictions?**

The MDSAP relies on:

- Annual audits of manufacturers according to an audit model specific to the program. This audit model was developed to review the compliance of a manufacturer's quality management system to the international standard ISO 13485 and additional regulatory requirements applicable to the countries where the devices are sold; and
- Annual assessments of the Auditing Organizations' management system compliance to the international standard ISO/IEC 17021-1 and MDSAP specific requirements as defined in IMDRF MDSAP WG documents.

### **35. How do Auditing Organizations ensure that duplicate efforts are not performed during an audit of a manufacturer that sells in multiple jurisdictions?**

The MDSAP audit process was designed and developed not only to prevent duplication, but also to ensure that the program provides efficient and thorough coverage of the requirements of; Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:-) and any corresponding section(s) of the Australian Therapeutic Goods (Medical Devices) Regulations (SR 236, 2002), the Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), the Canadian Medical Device Regulations (CMDR, Part 1), the Japanese QMS ordinance (MHLW MO 169), the Quality System Regulation (21CFR 820), and other country-specific requirements.

The MDSAP audit sequence follows a process approach and was designed and developed to allow the audit to be conducted in a logical, focused, and efficient manner.

Additionally, [MDSAP AU P0029 Initial Manufacturer Audit and MDSAP Manufacturer Withdrawal Notification Procedure](#) was created to ensure that Auditing Organizations properly notify the MDSAP Team, describing the MDSAP notification process and timeframes that AO must follow when an initial MDSAP audit has been scheduled, rescheduled or transferred. The document also instructs how to properly notify the MDSAP Team when a Medical Device Manufacturer withdraws from MDSAP participation.

Timely notification of MDSAP initial audit schedules by AOs will prevent the duplication of inspection/audit of Medical Device Manufacturers participating in MDSAP. Additionally, adequate notification of situations where a Medical Device Manufacturer no longer elects to participate in MDSAP will ensure that continued regulatory oversight is maintained by all participating RA's.

### **36. How are regional regulatory differences addressed in the program?**

The regulatory requirements of the participating Regulatory Authorities have been incorporated into the MDSAP Audit Model and further discussed in the MDSAP Audit Model Companion Document. An auditing organization will perform audits using this model and record findings in relation to the regulations of the participating Regulatory Authorities.

Each Regulatory Authority independently utilizes the MDSAP audit deliverables (audit reports, certification documents) according to their regulations and policies.

### **37. How will audits of medical device manufacturers be conducted under the MDSAP?**

Authorized Auditing Organizations will perform MDSAP audits according to documents developed by the participating Regulatory Authorities. Some relevant policies and procedures introduced by the program to ensure consistency across Auditing Organizations and/or auditor teams include:

- The sequence of tasks specified in the Audit Model [MDSAP AU P0002](#) will have to be followed; the audit duration will be based on planned audit tasks [MDSAP AU P0008 Audit Time Determination - Procedure](#), ensuring consistency across Auditing Organizations. In general, the duration of MDSAP audits will not exceed the accumulated time of audits and inspections

performed currently by each participating Regulatory Authority according to their governing regulatory frameworks.

- An audit report will be issued at the end of each audit, using a standard fillable template specifically designed for medical device regulatory audits.
- Nonconformities identified during an audit will be graded on a scale from 1 (least critical) to 5 (most critical), and will be managed according to criteria defined in the document [GHTF/SG3/N19:2012, Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange](#).
- Audited manufacturer will be responsible for timely development and implementation of action plans to address non-conformities identified during audits [MDSAP AU P0027 Post Audit Activities and Timeline Policy](#).
- Auditing Organizations will share the audit outcomes with the participating Regulatory Authorities to support their pre-market or post-market programs. Upon successful certification or recertification audits, Auditing Organizations will issue MDSAP-specific certification documents stating compliance to ISO 13485:- and applicable regulatory requirements. [MDSAP AU P0026 Certificate Document Requirements](#).

### **38. What is the difference between a Stage 1 and a Stage 2 Audit? (Initial Audit?)**

The “Initial” audit also known as an “Initial Certification” audit consists of a Stage 1 and a Stage 2 audit.

- Stage 1 – A first Stage 1 audit consists of a documentation review and the evaluation of the readiness of the manufacturer to undergo a Stage 2 audit.
- Stage 2 – The purpose of a Stage 2 audit is to determine if all applicable QMS requirements of ISO 13485 and all other applicable regulatory requirements from participating regulatory authorities have been effectively implemented.

### **39. How did the revision of ISO 13485 impact MDSAP?**

The audit model was revised to consider the new version of ISO 13485. Both versions (based on ISO 13485:2003 and the one based on ISO13485:2016) are available on the website. During the transition period of the ISO 13485, the AO can use the old or the new version, depending on the manufacturer transition plan.

### **40. Can an “upgrade audit” be performed to update the MDSAP certificate to ISO 13485 version instead of a full MDSAP re-certification audit?**

An “upgrade audit” could be performed as part of a surveillance audit, but this would require the audit to include ALL the new/modified requirements of the revised standard. Since it can become a more comprehensive audit requiring additional

time, a stage 1 or document review may be necessary prior to the onsite audit to maximize audit efficiency.

Please be aware that:

- The manufacturers are required to comply with ISO13485:2016 and the relevant regulatory requirements of the participating RAs within the timeframes set by the ISO whitepaper and Health Canada's announcement for the transition from CMDCAS to MDSAP.
- AO's are required to apply the MDSAP audit model and an MDSAP audit program to determine compliance with these requirements. MDSAP does not introduce additional requirements for manufacturers.
- MDSAP Certificates represent the application of an audit methodology to determine compliance with the requirements of ISO13485:2016 and relevant regulatory requirements for QMS through a single audit for multiple regulators. Hence a certificate cannot reference ISO13485:2016 until the methodology has been applied.
- The prospect of a change to the Standard has been known for many years. To minimize unexpected costs the manufacturer could align their transition to the newer standard with the recertification audit that would naturally occur during the transition period.

#### **41. How is the audit duration determined?**

The method and the criteria to be used by the Auditing Organizations to calculate the time necessary to conduct an MDSAP audit of a medical device manufacturer is defined in the procedure [MDSAP AU P0008](#) entitled *Audit Time Determination*.

The MDSAP audit model defines the activities and tasks that are to be performed in an MDSAP Audit Cycle including; the activities and tasks for an Initial (Stage 1 and 2) Audit (a.k.a. Certification Audit), Surveillance, Re-audit (a.k.a. Recertification Audit), and for Special Audits. The appropriate audit tasks defined within the MDSAP Audit Cycle must be used when calculating audit times. When applicable, the appropriateness of the audit duration for subsequent activities should be confirmed during the Stage 1 audit.

There are varying numbers of audit tasks depending on the process being audited. Audit time is calculated based on the number of applicable audit tasks associated with the type of audit to be conducted (as defined in the MDSAP Audit Cycle) and the specific activities of the organization to be audited.

#### **42. At what frequency do MDSAP audits occur?**

The medical device manufacturers that will volunteer to participate in the-MDSAP will be audited annually, according to a three-year certification cycle. The Initial

Audit, also referred to as the “*Initial Certification Audit*” is a complete audit of a medical device manufacturer’s quality management system (QMS). The initial Audit is followed by partial Surveillance Audits conducted once per year for two consecutive years. The cycle re-commences with a complete Re-audit, also referred to as a “*Recertification Audit*” in the third (3rd) year.

Special Audits, Audits Conducted by Regulatory Authorities, and Unannounced Audits are potential extraordinary audits that may occur at any time within the audit cycle.

#### **43. Can the scope of an MDSAP audit include combination products?**

The implementation of the MDSAP is intended to allow for a single audit to satisfy the regulatory requirements of the participants.

Medical Devices that include; drugs (medicinal substances) or biologics (e.g. materials of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin, human blood or extracts of human blood or blood products, etc.) (a.k.a. “combination products”) may be included in the scope of an MDSAP audit.

The Regulatory Authorities that take into account MDSAP audit reports for combination products expect that the Auditing Organization, when conducting an audit for these products, will:

- undertake, to the extent possible during on-site audits, an assessment of the product / process related technologies in accordance with the requirements of N3 Clauses 9.2.4, 9.3.2 and 9.4.1, and the requirements of the MDSAP audit model for compliance with the country specific requirements;
- assign relevant technical competence to the audit team that is assessing the product / process related technologies and relevant controls for the handling, testing and manufacture of these types of devices; and
- record their findings in accordance with the requirements of [MDSAP AU P0019](#) MDSAP Medical Device Regulatory Audit Reports.

However, due to differences in the way that these products are regulated in the jurisdictions of the participating Regulatory Authorities, MDSAP audit reports and certification documents will not be considered an alternative to the inspection and assessment requirements in some jurisdictions, as described below:

**Australia:** These products are subject to an off-site examination of the design by the TGA under the Australian Conformity Assessment Procedures. A Design

Examination Certificate will be issued upon the successful completion of the examination.

The TGA is also required to issue a Conformity Assessment Certificate for the Full Quality Assurance procedure applied by the manufacturer for these products. When considering whether to issue or maintain this certificate the TGA may take into account MDSAP audit reports. An effective MDSAP audit report may reduce the frequency of TGA inspections for these devices.

**Brazil:** According to Brazilian regulations there are no specific requirements for combination products regarding the Quality Management System, and for that, all the requirements already disposed on the MDSAP companion documents promote adequate coverage for the needs established on the Brazilian legislation and regulation for those products. Therefore, combination products that are considered medical devices in Brazil are included in MDSAP –

**Canada:** The MDSAP Audit model covers the requirements for combination products that are regulated as medical devices.

**Japan:** There are no Japanese characteristic requirements for combination products which are categorized as devices. Therefore, MDSAP Audit results will be considered as alternatives to confirm the compliance of Quality Management System (QMS) requirements for such products.

**United States:** The MDSAP audit model only covers the requirements of the US medical device regulations. As additional requirements of the US regulations apply to devices incorporating drugs or biologics, the FDA cannot consider MDSAP - audits of combination product manufacturers as an alternative to FDA inspections. Consequently, such products are still subject to FDA inspections regardless of the participation of the manufacturer in the program. Nevertheless, the FDA may take into account the outcome of an MDSAP - audit covering combination products to optimize the scope of the FDA inspection to be performed.

**NOTE:** When a combination product manufacturer also manufactures non-combination products, it is expected that during the initial certification audit and at least once during the subsequent certification cycle the audit team includes the technical competence to audit combination products; and, when applicable, the audit plan includes the quality management system processes and activities associated with the combination product. MDSAP audit plans and reports of combination product manufacturers must consider, where applicable:

- 1) Supplier Controls and acceptance activities (including testing) associated with the starting material that is to be used in the manufacture of the drug or biologic component (in particular Active Pharmaceutical Ingredients);
- 2) Controls of the manufacturing processes for the drug or biologic

- component;
- 3) Final acceptance and testing activities, including those associated with the drug or biologic component in the finished product; and
- 4) Stability programs that consider the drug or biologic component in the finished product.

**44. Is there a checklist available for industry that compares the ISO 13485 requirements with each participating country's regulations?**

The *Audit Model* [MDSAP AU P0002](#) contains specific instructions on the MDSAP audit process. It incorporates an audit sequence and instructions for auditing each specific process. The audit process tasks incorporate references to the applicable ISO 13485:- clause(s) and any corresponding section(s) of the Australian Therapeutic Goods (Medical Devices) Regulations (SR 236, 2002), the Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), the Canadian Medical Device Regulations (CMDR, Part 1), the Japanese QMS ordinance (MHLW MO 169), and the Quality System Regulation (21CFR 820).

**45. Is MDSAP a top down inspection, as with the Quality System Inspection Technique employed by FDA?**

The MDSAP Audit Model, which was inspired by the FDA's Quality System Inspection Technique document, is based on a “top-down” auditing approach.

**46. Does the audit process include a daily review of areas of concern?**

Yes. Auditing Organizations must be in compliance with the requirements of IMDRF MDSAP WG N3, and N4, including the requirements of ISO/IEC 17021-1 and all other related MDSAP documents. ISO/IEC 17021-1, Sub-Clause 9.4.3.1- *Conducting the opening meeting*, requires that “during the audit, the client will be kept informed of the audit progress and any concerns.”

**47. Are MDSAP audits conducted by single or multiple auditors?**

Procedure [MDSAP AU P0008](#) Audit Time Determination specifies how to determine the on-site audit duration in man-days. Auditing Organizations decide how many auditors will compose the audit team. For instance, a 6 man-day audit could be completed in 3 days by a 2-auditors team. Auditing Organisations are also required to take into account the competency of the audit team for the type of audit and the scope of products that are produced under the control of the manufacturer's QMS.

**48. Who assigns a particular auditor? The Auditing Organization or Regulatory Authority?**

It is the AOs' responsibility to assign auditors for individual audits of medical device manufacturers, taking into account their competence, impartiality and availability.

Unlike other certification programs, a manufacturer may not oppose the choice of the auditor under the MDSAP ([IMDRF MDSAP WG N3 Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition](#) exception to ISO /IEC 17021-1, section 9.2).

**49. If MDSAP becomes mandatory for one or more participating countries will manufacturers be expected to be compliant with regulations in a jurisdiction that it does not market?**

The manufacturers are expected to be compliant only with the regulations for the jurisdictions where their products are marketed.

**50. Can RA's discredit/void any audits that were conducted by an AO due to inadequate audit method/technique? If so, will manufacturers have to go through re-audits for audits they believed to have passed?**

The MDSAP does not include mechanisms for requiring an audit to be re-done. Nevertheless, if an audit report appears to be unreliable, a participating Regulatory Authority may not be able to utilize the report as part of their process to grant a marketing authorization. A misleading audit report may also present a risk to public health and could lead the Regulatory Authorities to conduct its own follow-up inspection. Alternatively, an RA may request that an AO conduct a special audit to follow up on an issue. ([IMDRF MDSAP WG N3 – clause 9.6.6.](#))

Manufacturers may forward a complaint with the participating Regulatory Authorities in relation to an audit performed by an Auditing Organization. The complaint will be processed using the procedure described in [MDSAP QMS P0011](#).

**51. If an AO issues a negative final report, does this mean the manufacturer can no longer supply to/sell in all of the regulatory jurisdictions that are participating in the Program?**

MDSAP audit reports records the recommendation of the audit team for initial, continuing certification or re-certification of the audited medical device manufacturer. When the AO determines that the audited manufacturer does not meet QMS or other

regulatory requirements, each of the Regulatory Authorities concerned would determine appropriate actions relative to the identified nonconformities. The nonconformities may or may not be associated with regulatory requirements of all participating regulatory authorities.

**52. What happens if significant non-conformities are identified by an Auditing Organization and subsequently shared with the Regulatory Authorities?**

Non-conformities identified by an Auditing Organization are to be graded in accordance with the document [GHTF/SG3/N19:2012](#) – Quality management system – Medical devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange. Nonconformities are to be recorded and graded by the Auditing Organization using [MDSAP AU F0019.2 NC Grading and Exchange Form](#).

[IMDRF MDSAP WG N3](#) defines that the Auditing Organization shall provide information to the recognizing Regulatory Authority(s) about the audits and decision on conformity to quality management system requirements. The procedure [MDSAP AU P0027 Post-Audit Activities and Timeline Policy](#) defined that if the audit identified one or more grade 5 nonconformities, or more than two grade 4 nonconformities, or a public health threat, or any fraudulent activity or counterfeit product, the Auditing Organization shall inform the Regulatory Authorities within 5 working days. For Grade 4 or 5 nonconformities, manufacturers are expected to provide evidence to the Auditing Organization of implementation of the remediation actions addressing any grade 4 or 5 nonconformity within 30 days of the audit end date. Auditing Organizations are subsequently expected to provide the audit package, which includes the NC Grading and Exchange form, to a recognizing Regulatory Authority within 45 days of the end of audit. Post-audit actions timelines for a manufacturer and an Auditing Organization are further described in [MDSAP AU P0027 Post-Audit Activities and Timeline Policy](#).

On receipt of the 5 days' notice the participating Regulatory Authorities will undertake actions that are appropriate for their jurisdictions and notify with the other participating Regulatory Authorities on the actions that should be taken in relation to the manufacturer.

**53. How are nonconformities that are identified during an MDSAP audit managed? What is the timeline for a manufacturer to respond to nonconformities?**

The document [MDSAP AU P0027 Post-Audit Activities and Timeline Policy](#) defines the activities to be completed and timeline that a medical device manufacturer must follow to address the nonconformities identified during an MDSAP audit.

The manufacturer must provide a remediation plan for each nonconformity within 15 calendar days from the date the non-conformity report was issued. The plan must include:

- the outcome of the investigation of the nonconformity and its cause(s),
- the planned correction(s), and
- the planned corrective action(s) to prevent recurrence.

The evidence of implementation of the remediation actions addressing any grade 4 or 5 nonconformity must be provided within 30 calendar days after the audit end date. (Page 1-section 2 Timeline)

#### **54. Who would conduct follow-up visits to close the non-conformities?**

An Auditing Organization would normally conduct close-out activities for all non-conformities in accordance with their procedures.

A participating Regulatory Authority may request that an Auditing Organization carry out a Special Audit to further investigate, follow-up or to closeout an audit under the direction of the requesting Regulatory Authority.

A recognizing Regulatory Authority may conduct its own Special Audit at any time it deems necessary and within the purview of its jurisdiction. ([IMDRF MDSAP WG N3 – clause 9.6.6.](#))

#### **55. Do Auditing Organizations collect evidence of nonconformities, or other evidence usually collected during Regulatory Authorities' inspections?**

Under the MDSAP, Auditing Organizations are not required to collect any evidence, but the audit report must substantiate any audit finding by reference to audit evidence. Due to this restriction, the US FDA will limit enforcement actions based on MDSAP audit reports to advisory actions only.

This waiver also applies to other evidence usually collected during Regulatory Authorities' inspections, such as evidence of interstate commerce by the FDA.

For example, what does the FD&C Act mean by "Interstate Commerce". *Section 201(b) of the FD&C Act [21 U.S.C. 321(b)] tells what circumstances place a product in interstate commerce:*

- (1) *Commerce between any State or Territory and any place outside thereof, and*
- (2) Commerce within the District of Columbia or within any other Territory not organized with a legislative body.*

*"Interstate commerce" applies to all steps in a product's manufacture, packaging, and distribution. It is very rare that a cosmetic product on the market is not in "interstate commerce" under the law. For example, at least some of your ingredients or packaging most likely originates from out of state, or even out of the country. Likewise, it is foreseeable that your products will leave the state. Although there are certain exemptions [21 CFR 701.9], factors such as these generally cause the requirements of the FD&C Act to apply to your products."*

**56. During witnessed audits, will Regulatory Authorities prompt AO's in identifying nonconformities? (There is concern that the potential negative influence by RA on an AO)**

The RAs will not interfere in the way an AO conducts its audit. The MDSAP is intended to allow competent auditors from MDSAP recognized AOs to conduct a single audit of a medical device manufacturer's quality management system in compliance with the requirements of the RAs participating in the MDSAP program. For this purpose, the RA's will ensure, by periodical assessment, including the witnessing of audits of manufacturers conducted by AOs, that AOs are applying the MDSAP audit model and assigning adequate competence to the task.

**57. As a manufacturer, how do I show that I was successfully audited under the MDSAP?**

Upon successful completion of an initial audit or re-audit, an Auditing Organization will issue certification documents including a reference to the MDSAP that will state compliance to ISO 13485: and the applicable Medical Device Regulations from each jurisdiction that were used as audit criteria.

**58. If a manufacturing site is already under regulatory action with a participating Regulatory Authority, can they participate in the MDSAP?**

If a manufacturer is currently subject to regulatory action from one of the participating Regulatory Authorities, then the manufacturer should consult with the RA about their eligibility for an MDSAP audit prior to resolution of the action. There are no exclusion criteria regardless of the past audit/inspection history, and regardless of the type of medical devices manufactured by the organization. Nevertheless, if a manufacturer had a previously unfavorable inspection by a participating Regulatory Authority, this Regulatory Authority may still choose to conduct a follow-up inspection. For example, this is the case with inspections conducted by the U.S. FDA. ANVISA will not use MDSAP audit reports from

manufacturers where the result of ANVISA's previous inspection was considered unsatisfactory and therefore the manufacturer had the certification submission denied. In such cases ANVISA will start using the MDSAP reports only after a new ANVISA inspection with a satisfactory result.

**59. What happens to a Manufacturer when the AO recognition is revoked?**

The impact of a cessation of recognition or the revocation of the authorization to audit, under the MDSAP may affect a large number of manufacturers. The event should not directly affect any existing marketing authorization. Nevertheless, Regulatory Authorities may need to consider individual or collective transitional arrangements to assure existing or potential public health risks are mitigated.

To stay in the program, a manufacturer would need to contract another Auditing Organization to resume the audit cycle at the point of departure of the de-recognized Auditing Organization.

**60. Will industry auditors have access (for a fee) to the AO auditor training? [Will training be available for manufacturers to ensure that its QMS will meet the MDSAP criteria?]**

Computer-based on-line training modules have been created describing the MDSAP Audit Model that is to be used by Auditing Organizations to conduct audits of Medical Device manufacturers. This training is a requirement for each Auditing Organization auditor who will be conducting MDSAP audits. Due to limited availability of licenses agreement the training is not being made available to non-Auditing Organization certification bodies or to medical device manufacturers. However some of the MDSAP training modules are available on the MDSAP webpage - [CDRH Learn \(Postmarket Activities Section/ Inspections – Global Harmonization\)](#); scroll down to “Postmarket Activities - (New module 2/9/17)”.

**61. For manufacturers already holding ISO 13485 certification under the CMDCAS program how would they transition to the MDSAP program? Will a full initial audit be required?**

In order to minimize the impact on ongoing certifications under CMDCAS, the MDSAP audit cycle may be synchronized with the CMDCAS audit cycle. Medical device manufacturers can participate in the MDSAP Program at their convenience and therefore their first MDSAP audit may be a surveillance audit. To be noted that in this case:

1. The manufacturer would not obtain an MDSAP certificate until a recertification audit is conducted;
2. A regulatory authority may not be able to use a surveillance audit report in their process to issue a marketing authorization.

The medical device manufacturer should therefore make the decision whether to synchronize the MDSAP audit cycle with the CMDCAS audit cycle or not based on their regulatory and business interests.

**62. Why aren't MDSAP audit reports used by the FDA as substitutes for inspections for Premarket Approval (PMA) applications?**

The FDA explicitly excludes PMA pre-approval and post-approval inspections for Premarket Approval (PMA) due to the lack of regulatory convergence in the following:

1. the premarket device assessment processes performed under the various regulations (e.g. US Premarket Application, Australian Design Dossier or Design Examination, Canadian Device License Application); and,
2. where the responsibilities for final decisions of safety and performance/effectiveness of a medical device are placed (regulatory authority vs. third party organization).

**63. Which country specific regulatory requirements are included in the MDSAP audit criteria?**

The Medical Device Single Audit Program (MDSAP) audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the relevant requirements of; Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485-), the Australian Therapeutic Goods (Medical Devices) Regulations (SR 236, 2002), the Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), the Japanese QMS ordinance (MHLW MO 169), the Quality System Regulation (21 CFR Part 820), and other specific requirements of medical device regulatory authorities participating in the MDSAP program including 21 CFR Part 803 and 21 CFR Part 806.

**64. How will the determination be made on whether an audit report supports an FDA advisory action without the supporting evidence?**

The determination will be made following existing FDA criteria for situation 1 as described in the applicable Compliance Program, Part V. The evidence will be

described in the narrative descriptions of nonconformities contained in the audit report. The auditor competency (including ability to identify existing nonconformities) is something the regulatory authorities review extensively during Auditing Organization assessment activities. An independent inspection by the FDA would be necessary to support judicial actions.

**65. How will Nationally Recognized Testing Laboratory (NRTL) Program audits be accepted?**

NRTL tests and MDSAP audit are completely separate programs, evaluating compliance to distinct criteria. NRTL tests are required by the US Occupational Safety and Health Administration.

**66. Can Regulatory Authorities not participating in MDSAP have access to audit reports? If so, what amount of information will be made available and at what cost?**

Regulatory Authorities not participating in the MDSAP will not have full access to audit reports. Nevertheless, if a Regulatory Authority has a confidentiality agreement with a participating Regulatory Authority, a request may be made to obtain a copy of a particular report.

However, non-participating Regulatory Authorities may request audit reports and certificates from the medical device manufacturer.

**67. Do the IMDRF or the Regulatory Authorities participating to the MDSAP plan to influence/revise the International Accreditation Forum (IAF) mandatory document MD9 on the audit of medical device manufacturers to ISO 13485?**

No. The document [IMDRF MDSAP WG N3](#) states that “IMDRF Regulatory Authorities have no official status within groups such as the IAF, or any voice in IAF governance or IAF mutual recognition agreements, that would allow the Regulatory Authorities to revise IAF documents to meet the needs of the regulators. It was also determined that the standard most commonly utilized is the ISO (the International Organization for Standardization) and IEC (the International Electro-Technical Commission) standard ISO/IEC 17021-1 entitled, “Conformity assessment – Requirements for bodies providing audit and certification of management systems.” Medical device Regulatory Authorities also have little influence in the standards organization that produces this standard and cannot simply change the standard for medical device regulatory purposes.”

**68. Is the CE certification included in the outcome of a successful MDSAP audit?**

The MDSAP Audit Model [MDSAP AU P0002](#) does not incorporate the requirements from the European regulations. Nevertheless, the medical device regulatory Audit Report form [MDSAP AU F0019.1](#) may be used for multipurpose audits and an Auditing Organization may incorporate the European requirements into the MDSAP audit criteria to eliminate duplicate reporting.

**69. Can the RAs consider if one report can represent a multi-audit site?**

After reconsideration during the 2016 MDSAP Forum, the Regulatory Authorities agreed that a separate report is necessary for each audited site.

**70. Do audit tasks have to be repeated during a multi-site audit?**

- The implementation of applicable QMS process elements should be audited at each site.
- Content of common procedures does not have to be audited again. However, the implementation of applicable QMS process elements should be audited at all applicable sites.
- The non-implementation of applicable QMS process elements may lead to nonconformities relating to document control (current, approved procedure not available at all sites); or failure to effectively train users of the procedure; or failure to effectively implement the procedure, among others.

**71. What additional guidance can RAs provide AOs on the application of the MDSAP audit model to multi-site audits and for suppliers?**

- The AO should determine the applicable QMS activities and corresponding audit tasks at each site included in the audit program.
- Content of common procedures does not have to be audited again. However, the implementation of applicable QMS process elements should be audited at all applicable sites.
- The audit team should pay attention to the interaction and coordination of activities between sites.
- MDSAP audit could be extended to a supplier facility if the manufacturer cannot demonstrate effective controls.

**72. How should an AO handle companies that have a legal address with no association to the company's daily operations?**

- Per IMDRF MDSAP WG N3, the AO shall audit all sites that will be recorded on the certificate.
- AOs can initially visit the site to confirm its activities and relationship to the QMS.
- Describe relationships/activities and site omissions in the audit report.
- Auditors should confirm if changes result in additions of sites to audit program.
- Non-operations/functional sites should not be audited/certified.

**73. Should a remote-audited facility be included on the certificate?**

According to [MDSAP AU P0026](#), section 7, “The certification document shall record all sites of the manufacturer’s quality management system that have been audited on-site. ”

**74. How should AOs handle “virtual” manufacturers?**

Virtual Manufacturers shall be treated as manufacturers and shall be audited accordingly for all activities applicable to the devices designed or manufactured.

**75. Manufacturers indicated that the grading system was too complex to understand. Is there any plan to review it?**

- The grading system is based off of GHTF/SG3/N19:2012 and there are no plans to change the document at this time.
- RAs will develop a CDRH Learn training module on GHTF/SG3/N19:2012.

**76. Can RA provide additional guidance on how to distribute the audit activities among the audit team, using the audit model?**

- Audits require effective pre-audit planning.
- While one auditor is reviewing a primary process of the audit model (e.g., Management), another auditor can cover a supporting process. (e.g., Facility Registration)
- Auditors covering the same process can cover different audit tasks.
- Maintaining audit team communication is essential.

- Additional guidance is discussed in the Articulate Online Module; “Introduction to MDSAP” slides 37 and 38.

**77. How should an AO apply the audit model when sites are not responsible for all QMS activities?**

- AO should determine the applicable QMS activities and corresponding audit tasks at each site included in the audit program. This can be done in Stage 1 of the audit.
- The audit time calculation procedure, MDSAP AU P0008, and associated spreadsheets, MDSAP AU F0008.1 (Audit Model 2013) and MDSAP AU F0008.2 (Audit Model 2017) can assist in identifying/planning audit tasks.

**78. When should an AO employ a Technical Expert during an MDSAP audit?**

ISO/IEC 17021-1 states: “The criteria for the selection of technical experts are determined on a case-by-case basis by the needs of the audit team and the scope of the audit.”

**79. Can audit tasks be accomplished during pre-on-site audit activities?**

Yes. RAs encourage AOs to use pre-audit planning, communications and other activities as a mechanism to complete or assist in the completion of audit tasks when appropriate.

**80. Under what circumstances the AO audit may be considered not sufficient and RAs may perceive that an RA inspection is still required?**

A RA inspection may be required if:

- An MDSAP audit report failed to provide evidence required to support market authorization decisions.
- An audit reveals public health safety concerns or fraudulent activity.
- Combination product device manufacturers may still require RA audits/inspections. See question #44 of the MDSAP Q&A document for additional guidance on combination products.
- Some situations when the manufacturer is currently subject to regulatory action (see question #57)

**81. When should multi-site audit reports be submitted?**

Audit reports must be submitted following the audit of each site, as stated in MDSAP AU P0027, Post-Audit Activities and Timeline Policy.

**82. How should AOs handle sharing of audit reports with RAs that are not participating in MDSAP?**

This should be worked out between the AO and its clients and spelled out in contracts when necessary.

**83. Have the RAs defined the term “Public Health Threat”?**

Public Health Threat is synonymous to the GHTF/SG2/N54R8:2006 term, Serious Public Health Threat – *Any event type, which results in imminent risk of death, serious injury, or serious illness that requires prompt remedial action.*

**84. How should AO auditors structure nonconformity statements?**

Nonconformities should be written in accordance with GHTF/SG3/N19:2012, section 4.1; and section 5.0 Appendix A.

**85. Why have the RAs imposed an initial response period of fifteen (15) calendar days?**

RAs operate under time constraints that require an awareness of audit outcomes within a specified number of days. In order to make informed decisions about audit outcomes, the RAs must assess the manufacturer's response.

**86. For a consistent interpretation, could the RAs define the term "implementation" in MDSAP AU P0027 and AS F0015.1?**

- NCs cited by AOs after an MDSAP audit of a manufacturer: In the context of a manufacturer replying to nonconformities identified during an MDSAP audit, the term “implement” relates to the implementation of the actions specified in the manufacturer’s correction and corrective action plan.
- Please refer to [MDSAP AU P0027](#), sections 2 and 3.
- NCs cited by RAs following and assessment of an AO: In the context of an auditing organization replying to nonconformities identified during an RA assessment, the term “implementation” relates to the implementation, and

confirmation of the effectiveness of corrections and corrective actions, subsequent to the review and acceptance by the RAs of the AO's correction and corrective action plan.

- Please refer to MDSAP AS F0015.1 AO Nonconformity Process Flowchart.

#### **87. What does the MDSAP certificate represent?**

- The MDSAP certificate is an attestation by the AO that the facilities listed in the certificate have been audited against the listed criteria for the listed scope and found to conform to those requirements, including the regulatory requirements for the specified jurisdictions of the RAs.
- It does not represent a marketing authorization nor does it oblige participating Regulatory Authorities to issue any such marketing authorization or endorsement of the manufacturer or its devices.

#### **88. Can suppliers be MDSAP certified?**

Yes, if the supplier meets the participation criteria for any participating Regulatory Authority.

#### **89. Can the RAs provide additional guidance on what should be recorded if the minimum N4 requirements cannot be fulfilled by an initial start-up AO?**

- The RAs recognize that not all AOs will have the initial client participation to fulfill prerequisite annual experience requirements.
- AOs should document the circumstances and justify why requirements were not met in accordance with the principles for pre-requisite experience described in N4 Clause 6.2.
- RAs will consider each justification on a case-by-case basis.

#### **90. Can MDSAP Survey results be periodically posted?**

Yes. We plan to post them at six month intervals. However, if there is limited survey participation, the updates may not occur at this frequency.

#### **91. Can the RAs clarify the requirements for the transfer of certification for participating manufacturers?**

Transfer guidelines are currently being discussed by the RAs.

**92. Can the RAs develop a single dispute resolution to minimize inconsistency if a manufacturer uses multiple AOs?**

[MDSAP P0031](#) – Documenting Differing Professional Opinion and Dispute Resolution Policy sets out a single mechanism for resolving disputes within the MDSAP program.

**93. How long will RAs allow an MDSAP certificate to reference a jurisdiction where no product is distributed?**

- MDSAP AOs can issue certificates referencing jurisdictions where the manufacturer does not yet have market authorization.
- Recognizing that market entry can take time, such certifications can be extended for a full three years.
- If at the end of three years, the manufacturer has not obtained or applied for market authorization, the requirements for the affected jurisdiction should be removed from the certificate until such time as the manufacturer can demonstrate implementation and effectiveness.

**94. What is the process requesting a D-U-N-S number?**

To meet the requirements described in the MDSAP AU P0029 Initial Manufacturer Audit and MDSAP Manufacturer Withdrawal Notification Procedure, medical device manufacturers will have to submit a D-U-N-S number(s) which may take time to obtain. For this reason, we encourage any facility, site, or organization that does not have their D-U-N-S number readily available to begin as soon as possible the process of obtaining that information.

A D-U-N-S number is required to uniquely identify each physical location of the business's facility or site (e.g., branches, divisions, and headquarters). A D-U-N-S number is a unique nine-digit sequence provided by Dun & Bradstreet. The D-U-N-S number is specific for each site. Each distinct physical location of an entity (e.g., branch, division, and headquarter) would be assigned a different D-U-N-S number.

The site-specific D-U-N-S number is a widely recognized business identification tool and serves as a useful resource for MDSAP in identifying and verifying certain business information submitted by a user.

If no D-U-N-S number has been assigned, a business entity may obtain one at no cost directly from Dun & Bradstreet. A new number may be obtained, or an existing number verified, by phone or online.

Note: It takes Dun & Bradstreet approximately 30 business days to process a new D-U-N-S number and communicate it via email. A business entity may receive a D-U-N-S number in approximately 10 business days for an expedited service fee. Please note that a business entity may not request or apply for a new D-U-N-S number on behalf of another business entity due to the verification procedures used by Dun & Bradstreet.

More information is available at the [Dun & Bradstreet](#) web page. See also the [step-by-step instructions](#) for obtaining a D-U-N-S number for businesses based either in the United States or abroad.

#### **95. Can the manufacturer exclude a jurisdiction from the scope of an MDSAP audit?**

A manufacturer may exclude the requirements of a jurisdiction where the organization does not intend to supply medical devices. In other words, audit criteria under the MDSAP include at a minimum ISO 13485 and the medical device regulations that are applicable in any of the participating regulatory authority's jurisdiction where the organization supplies medical devices.

#### **96. What constitutes a counterfeit medical device or a fraudulent activity requiring to inform the Regulatory Authorities?**

For all practical purpose:

- A counterfeit medical device is a medical device that is represented as, and likely to be mistaken for, an authentic medical device with a valid marketing authorization, or whose identity, nature and/or source are fraudulently misrepresented, or that is otherwise intended to defraud.
- A fraudulent activity is an intentional, reckless, dishonest and recurrent, or systematic, activity resulting, for example, in the production of a counterfeit product, or in the creation of fake records, false representations, or the alteration of genuine records to imply compliance. The unintentional failure to comply with requirements, despite due diligence, does not qualify as fraudulent activity.

# **Medical Device Single Audit Program**

## **Frequently Asked Questions**

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- B. [Questions related to Assessments](#)**
- C. [Questions related to Audits](#)**

### **A. General Questions about MDSAP**

#### **1. What is the Medical Device Single Audit Program?**

The Medical Device Single Audit Program (MDSAP) is a program that allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system that satisfies the requirements of multiple regulatory jurisdictions. Audits are conducted by Auditing Organizations authorized and recognized by the participating Regulatory Authorities to audit under MDSAP requirements.

The MDSAP is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. The program's main mission is to "...jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers."

#### **2. Why was the MDSAP developed?**

The MDSAP was developed to:

- Implement requirements that are defined in the IMDRF MDSAP Model;
- Enable appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on industry;
- Promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the sovereignty of each authority;
- Promote globally, in the longer term, a greater alignment of regulatory approaches and technical requirements based on international standards and best practices;
- Promote consistency, predictability and transparency of regulatory programs by standardizing:
  - the practices and procedures of participating regulators for the oversight of third party auditing organizations,
  - the practices and procedures of participating third-party auditing organizations; and
  - Leverage, where appropriate, existing requirements and procedures for conformity assessment.

**3. Which Regulatory Authorities are part of the MDSAP and what is the plan for expansion of the program?**

The MDSAP was developed by representatives of the Australian Therapeutic Goods Administration (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, Japan's MHLW/PMDA, and the U.S. Food and Drug Administration (FDA). All regulatory authorities participating in the MDSAP are equal partners in the program.

Other Regulatory Authorities may eventually decide to participate in the MDSAP and to become active participants in the Program. For example, the World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme, the European Union (EU) and United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) are Official Observer to the MDSAP Regulatory Authority Council (RAC) and Subject Matter Expert (SME) Work Group.

**4. What is the difference between a Regulatory Authority being a participant in MDSAP Subject Matter Expert (SME) Working Group (WG) versus being an observer to this working group?**

The Regulatory Authority participants provide the resources to support the development, implementation, maintenance and expansion of MDSAP and participate actively in the process of recognizing, monitoring, and re-recognizing

Auditing Organizations under the framework of the IMDRF MDSAP. The participating Regulatory Authorities have committed to use the MDSAP deliverables. Each Regulatory Authority participant is also represented on the MDSAP Regulatory Authority Council (RAC); the MDSAP's governing board, by senior-level manager(s).

A Regulatory Authority who is an “observer” may attend MDSAP SME WG meetings, assessments, and other activities, but does not utilize MDSAP program deliverables to replace or supplement its regulatory scheme deliverables or portions of these deliverables. The observers are represented on the MDSAP RAC by one senior-level manager.

**5. Is the list of medical device manufacturers participating in the MDSAP made publicly available?**

No, this information is not made publicly available by the Regulatory Authorities.

**6. Can industry provide input into MDSAP documents or the program in general?**

Yes. There are two venues for the industry to contribute.

Following each MDSAP audit, Medical Device Firms participating in the MDSAP are invited to provide feedback through a survey that is [available on the MDSAP FDA webpage](#).

Additionally, the MDSAP participating Regulatory have established and implemented an MDSAP Quality Management System. Feedback on MDSAP can be submitted to any of the participating Regulatory Authorities in written format, electronically, by telephone, or in person. Electronic feedback is preferred and may be submitted to one of the five email addresses listed below. MDSAP participating regulators will address the feedback in accordance with the procedure [MDSAP QMS P0011](#) (Complaints and/or Customer Feedback Procedure.) Manufacturers are encouraged to provide feedback.

Contact emails:

[MDSAP@tga.gov.au](mailto:MDSAP@tga.gov.au)

[MDSAP.ATENDIMENTO@anvisa.gov.br](mailto:MDSAP.ATENDIMENTO@anvisa.gov.br)

[gs.mdb@hs-sc.gc.ca](mailto:gs.mdb@hs-sc.gc.ca)

[MDSAP@pmda.go.jp](mailto:MDSAP@pmda.go.jp)

[MDSAP@fda.hhs.gov](mailto:MDSAP@fda.hhs.gov)

**7. Have there been discussions with WHO regarding the use of MDSAP audits in the pre-clearance process for? Will medical devices assessed by the WHO be included in the program at a later stage?**

WHO is participating as an observer to the MDSAP. WHO has indicated a willingness to adapt and integrate MDSAP processes as much as possible in their *Prequalification Program*. WHO intends to utilize MDSAP reports where possible if they are available for devices that are subject to their *Prequalification Program*.

**8. If an RA decides to change its GMP/QMS or Regulatory requirements, how will the changes be incorporated into MDSAP?**

MDSAP Audit Approach documents can be periodically revised to reflect any changes in regulatory requirements. Accordingly, the impacted MDSAP training will be updated. The IMDRF MDSAP WG N3 document requires “The Auditing Organizations to participate in any regulatory coordination group established for the purpose of keeping the Auditing Organization’s personnel current on medical device legislation, guidance documents, standards, and best practice documents adopted in the applicable regulatory systems.” (N3 – Clause 6.1.3)

**9. How do I find out more specific information on the documents, policies, and procedures used in the MDSAP?**

The MDSAP participating Regulatory Authorities and the candidate Auditing Organizations primarily utilize the IMDRF MDSAP WG documents that can be found at: [IMDRF Documentation](#).

In addition, there are many other MDSAP Regulatory Authority Council approved documents in order to implement the program, for example: an audit strategy for auditing medical device manufacturers, requirements for the audit reports, a method for audit time calculation, and the MDSAP Quality Management System procedures. For further information on the MDSAP and associated documents, please refer to the [MDSAP Home Page](#) or contact one of the participating Regulatory Authorities at:

[MDSAP@tga.gov.au](mailto:MDSAP@tga.gov.au)  
[MDSAP.ATENDIMENTO@anvisa.gov.br](mailto:MDSAP.ATENDIMENTO@anvisa.gov.br)  
[gs.mbd@hc-sc.gc.ca](mailto:gs.mbd@hc-sc.gc.ca)[MDSAP@pmda.go.jp](mailto:MDSAP@pmda.go.jp)  
[MDSAP@fda.hhs.gov](mailto:MDSAP@fda.hhs.gov)

## B. Questions related to Assessments

### 10. Can Contract Research Organizations participate in MDSAP? What about Certified Quality Auditors?

The MDSAP includes the use of Auditing Organizations, also known as Certification Bodies or Registrars in other schemes. If an Auditing Organization also acts as a Contract Research Organization, the organization's management system must ensure the impartiality of the Auditing Organization.

An independent Certified Quality Auditor may not individually apply for recognition under the MDSAP. Should an auditor become permanently employed or work on a contract basis for an Auditing Organization, and meet the competency and other criteria for auditors as required under MDSAP, e.g. absence of conflict of interest, that auditor may be qualified to perform MDSAP audits as long as the AO is authorized or recognized under MDSAP.

### 11. How will an Auditing Organization pay regulators for the application and training?

There are currently no application fees or costs associated with the MDSAP Training. Training on the MDSAP Audit Approach and the requirements of the participating Regulatory Authorities is available on-line to Auditing Organizations candidate applicants ([MDSAP Training Material](#)).

The MDSAP Consortium is developing a cost-recovery scheme to ensure the ongoing and stable financing of the program and its electronic platform REPs (Regulatory Exchange Platform – secure)

### 12. How are assessments of Auditing Organizations being conducted by RAs under the MDSAP?

The assessment program is defined in key documents for the planning and conduct of assessments by Regulatory Authority assessment teams; and, the follow-up and monitoring of assessment activities of Auditing Organizations. The sequence of all assessment activities follows a 4-year cycle. The cycle begins with an initial authorization, followed by annual surveillance assessments for three consecutive years. Assessments are performed per document MDSAP AS P0034: *Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations* and associated [MDSAP Documentation](#).

**13. Must Auditing Organizations have all documentation in English to be assessed by the Regulatory Authorities?**

Auditing Organizations must have at least the documents requested for the application submission and for Stage 1 Assessment in English. During the Stage 2 Assessment, the Auditing Organizations must have personnel with fluency in English to translate documents and records that are not in English. Additionally, records that are specific to the MDSAP program (including but not limited to the documents included in the audit report package) should be in English as well.

**14. What is the best way to determine what is expected of the Auditing Organizations with regard to multiple jurisdictions during audits of manufacturers?**

Medical device manufacturers will have to be audited according to the scope declared in their application for certification services. Based on the countries where the manufacturer sells (or intends to sell) or has devices registered, the AO will determine the regulatory requirements applicable to that manufacturer.

The AOs will have to refer to the MDSAP AU P0002 Audit Approach to make that determination. This document incorporates or references the regulatory requirements of each of the participating Regulatory Authorities.

**15. What oversight do Regulatory Authorities have over the Auditing Organizations?**

In accordance with best practices, the MDSAP incorporates a transparent assessment program by Regulatory Authorities who will oversee the compliance of the Auditing Organizations with MDSAP requirements. This program includes a robust plan and schedule for assessing the competence and compliance of MDSAP Auditing Organizations and includes assessments of their head office and critical locations, as well as witnessing the performance of Auditing Organization's audits ("witnessed" audits), as part of an ongoing four year recognition cycle.

The Regulatory Authorities participating in MDSAP will base their recognition and assessment process on the IMDRF MDSAP WG and MDSAP documents in addition to other documents approved by the Regulatory Authority Council. [IMDRF Documentation](#) and [MDSAP Documentation](#).

In particular, Regulatory Authorities will evaluate or "assess" an Auditing Organizations' compliance to the requirements of IMDRF MDSAP WG documents N3 and N4.

- [IMDRF MDSAP WG N3 Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition](#)
- [IMDRF MDSAP WG N4 Competence and Training Requirements for Auditing Organizations](#)

## **16. What is a witnessed audit?**

A witnessed audit is performed to permit Regulatory Authorities to verify that an Auditing Organization adequately conducts their audits using the MDSAP Audit Approach and reports appropriately on the outcomes of audits. It is an essential assessment activity for building and maintaining confidence in the reliability of the third party Auditing Organization. During a witnessed audit, the Auditing Organization's audit team conducts the audit of the medical device manufacturer and the Regulatory Authorities' assessment team observes the AO without interfering in the audit process. The RA Assessment team does not assist or coach the AO auditors, nor does it provide additional information to the AO audit team or collect information on their behalf.

After the Auditing Organization has issued the audit report, the assessment team finalizes and shares their conclusions with the Auditing Organization.

The RA conclusions are not in relation to the compliance of the manufacturer to ISO 13485 and the relevant regulatory requirements. The RA's conclusions only relate to the ability of the Auditing Organization to audit against the requirements of the MDSAP.

## **17. Who performs witnessed audits and how are the assessors selected?**

The witnessing of an audit being conducted by an Auditing Organization will be performed by qualified MDSAP Regulatory Authority Assessors. These assessors are experienced Regulatory Authority Assessors who have knowledge of the MDSAP requirements, the requirements of the participating Regulatory Authorities and the device and manufacturing technologies used by the medical device manufacturer that is being audited.

Regulatory Authority Assessors are qualified against the competency requirements as defined in the document IMDRF MDSAP WG N6 FINAL:2013, *Regulatory Authority Assessor Competence and Training Requirements*.

## **18. Can an Auditing Organization contest an unfavorable recognition decision or a nonconformity and its grading?**

If an Auditing Organization disagrees with an unfavorable recognition decision or a nonconformity issued by the Regulatory Authorities, it may formally file for an appeal to the participating Regulatory Authorities. The process is defined in [MDSAP AS P0021: Appeals Procedure.](#)

**19. If a current Notified Body applies for recognition to perform audits under the MDSAP, but does not pass the MDSAP assessment, could they also be de-notified to the EU Directive?**

No. European Competent Authorities and Designating Authorities are not participants in the MDSAP. It is therefore unlikely that European Authorities would de-designate a Notified Body based on the outcome of an MDSAP Assessment. Nevertheless, European Authorities are likely to be informed if the reason for refusing the authorization was due to concerns that arose from a concurrent assessment of an Auditing Organization of the relevant European regulations. In such cases, the European Authorities may follow-up with the Auditing Organization and make their own assessment of the situation.

**20. Who from the Auditing Organization or the Regulatory Authorities makes the final decision on the compliance of the medical device manufacturer?**

The Auditing Organizations are fully responsible for making the decision on compliance to issue MDSAP certification documents under the program.

Independently, each MDSAP participant Regulatory Authority may use the report for different purposes, to support the regulatory decisions in their jurisdiction. If, based on the Auditing Organization's audit report, a Regulatory Authority concludes that the manufacturer is not in compliance with the regulations, the Regulatory Authority may engage in enforcement activities according to their policies, taking into account, if possible, the follow-up activities conducted by the Auditing Organization.

**21. How does a regulatory authority inspectorate become an Auditing Organization?**

Regulatory Authorities who are seeking recognition under MDSAP need to comply with the same requirements as a commercial Auditing Organization. The other participating Regulatory Authorities will conduct an assessment according to the international standard ISO/IEC 17021-1 and the additional requirements defined in IMDRF MDSAP WG N3 and IMDRF MDSAP WG N4, per the assessment methodology documented in MDSAP AS P0034.

**22. How will MDSAP ensure that every RA has the same evaluation standards for the Auditing Organization?**

Auditing Organizations are assessed for compliance with the requirements of ISO/IEC 17021-1 and the additional requirements of N3 and N4. An assessment program, assessment methodology for Auditing Organizations and guidance for RA Assessors is defined in MDSAP AS P0034. Regulatory Authority assessors execute assessment tasks for each process defined in the documents above and identify objective evidence of definition, implementation and effectiveness of each of the requirements. If nonconformities are identified, a grading system is used to assist in determining the timeline for any corrections or corrective actions and to support a predefined recognition and de-recognition process.

Regulatory Authority assessors are qualified against the requirements of [IMDRF MDSAP WG N6, Regulatory Authority Assessor Competence and Training Requirements](#) to perform the assessment of an Auditing Organization. Regulatory Authority assessors will participate in both face to face and distance training activities. The MDSAP Regulatory Authorities are committed to operating under a joint MDSAP Quality Management System to establish controls over the program and to facilitate continuous improvement. Applicable [MDSAP Assessment Procedures and Forms](#) are publicly available.

**23. Would an Auditing Organization receive independent recognition by each participating Regulatory Authority?**

No. Recognition is a joint exercise and hence recognition of an AO by the MDSAP Regulatory Authority Council (RAC) means recognition by each participating Regulatory Authority. It may be possible that some jurisdictions have to internalize MDSAP Recognition in their national regulatory framework. For example, Anvisa publishes a Resolution in "*The Brazilian National Gazette*" for each AO that is authorized or recognized in the MDSAP. It has the same effective and expiration date as the MDSAP recognition letter.

**24. Will Auditing Organizations be informed when there is a complaint against them so that improvements can be made?**

Yes. MDSAP QMS P0011 Complaints and/or Customer Feedback Procedure include in its scope complaints related to the Auditing Organizations and to Medical Device Manufacturer participating in MDSAP.

## C. Questions related to Audits

### **25. Which manufacturers are eligible to undergo an MDSAP audit?**

All manufacturers of medical devices are eligible to undergo an audit under the MDSAP. However, each regulatory authority may establish exclusion criteria for manufacturers meeting certain conditions if deemed necessary or when limited by legislation. It is important to note that manufacturers that participate in the MDSAP program are responsible for securing and maintaining a contract with an MDSAP recognized AO. AOs operate as fee-for-service organizations. In other words, medical device manufacturers are responsible for paying for MDSAP audits conducted by an AO. The Regulatory Authorities participating in MDSAP are not involved in contractual arrangements / the contract negotiation process between manufacturers and AOs.

### **26. How can a medical device manufacturer participate in the MDSAP?**

All medical device manufacturers interested in participating in MDSAP can contact any of the Auditing Organizations authorized or recognized to perform MDSAP audits. The [List of Auditing Organization Availability to Conduct MDSAP Audits](#) is available online.

Medical device manufacturers do not apply to a Regulatory Authority for an audit under MDSAP.

### **27. Does the MDSAP add requirements for the manufacturer?**

No. The MDSAP Audit Approach was developed to cover existing requirements from the Regulatory Authorities participating in the MDSAP. The program does not add any new requirements to existing requirements from ISO 13485 or other country-specific requirements of the participating Regulatory Authorities.

### **28. What are the potential benefits of a manufacturer participating in the MDSAP?**

The MDSAP offers many benefits to medical device manufacturers including the following:

- A single audit is used in lieu of multiple separate audits or inspections by participating regulatory authorities or their representatives. Therefore, for

many medical device manufacturers, the MDSAP reduces the overall number of audits or inspections and optimizes the time and resources expended on audit activities.

- Additionally, as a longer term goal, it is expected that the program will enhance confidence in the reliability of third-party audits, that more Regulatory Authorities will join the program, and that other Regulatory Authorities will use information made available through the program to limit the need for additional audits.
- Some participating regulatory authorities will use MDSAP audit outcomes as an alternative to their own inspections to process applications for medical device marketing authorization.
- Like in any third party auditing program, the medical device manufacturer is free to choose among all authorized auditing organizations to perform the audits. Routine audits are announced and planned with the manufacturer.
- The MDSAP is expected to improve the predictability of audit outcomes through:
  - enhanced auditing organization recognition criteria,
  - monitoring of auditing organizations by the participating Regulatory Authorities,
  - the use of a standard MDSAP audit approach,
  - the grading of any nonconformity using objective criteria to characterize the significance of the finding,
  - the reporting of the audit outcomes using a standard report template.
- Enrolling in the MDSAP may be seen as evidence of a medical device manufacturer's commitment to quality management systems for product quality and regulatory compliance.

**29. What are the potential benefits to the manufacturer participating, specific to each jurisdiction?**

**Australia:** The Therapeutic Goods Administration – TGA

- The TGA currently uses MDSAP audit reports and certificates as part of the evidence that is assessed for compliance with medical device conformity assessment procedures and market authorization requirements, unless the medical device is otherwise excluded or exempt from these requirements or if current policies restrict the use of MDSAP audit reports. Further details are provided in the '*Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs)*' guidance.
- For MDSAP certificates and audit reports to be considered by the TGA, the Australian regulatory requirements must have been covered in the audit(s), and certificates must show that the manufacturer has been assessed and found to comply with the relevant aspects of the Therapeutic Goods (Medical Devices) Regulations 2002.

**Brazil:** The Brazilian National Health Surveillance Agency – ANVISA utilizes the outcomes of the program, including the reports, to constitute an important input on ANVISA's pre-market and post-market assessment procedures, providing, when applicable, key information that are expected to support regulatory technical evaluation on these issues.

As defined in RDC 15/2014 and RE 2.347/2015, ANVISA may use MDSAP audits in lieu of a premarket inspection by ANVISA to grant ANVISA's GMP Certificate to manufacturers intending to put medical devices of class III or IV on the Brazilian market. Undergoing an MDSAP audit may accelerate ANVISA's GMP certification process, which is a pre-requisite to the marketing authorization.

ANVISA can also use MDSAP audits to renew ANVISA's GMP Certificate bi-annually, as an alternative to an ANVISA comprehensive inspection.

Note: ANVISA do not use MDSAP audit reports from manufacturers where the result of ANVISA's previous inspection was considered unsatisfactory and therefore the manufacturer had the certification submission denied. In such cases ANVISA will start using the MDSAP reports only after a new ANVISA inspection with a satisfactory result.

**Canada:** MDSAP certification is required to obtain a new (or maintaining or amend an existing) Class II, III or IV medical device license, pursuant to section 32 of the Regulations.

**Japan:** When an MDSAP audit report is submitted at the timing of premarket or periodical post-market QMS inspection application, Japan's Ministry of Health,

Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) will use the report:

- 1) To exempt a manufacturing site etc.\* from on-site inspection, and/or
- 2) To allow a Marketing Authorization Holder (MAH) to substitute considerable part of documents required for the inspection with the report.

Note: PMDA may perform on-site inspection or request additional QMS documents, when it is determined necessary after a review of the MDSAP audit report package.

\*Exceptions:

- a) A Registered Manufacturing Site (RMS) which manufactures medical devices made of human/animal tissues,
- b) A RMS which manufactures radioactive IVDs, and
- c) An establishment of a MAH.

**United States:** U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health, will accept the MDSAP audit reports as a substitute for FDA routine inspections. Additional benefits include:

- MDSAP routine audits are announced, scheduled by the Auditing Organization with the manufacturer, with a pre-established duration;
- The FDA will review MDSAP audit reports with a level of scrutiny commensurate to the significance of audit findings, taking into account the review and follow-up performed by the Auditing Organization;
- Firms have one month to provide their full response to critical nonconformities (grade 4 and 5) to the Auditing Organization (as opposed to 15 working days following an FDA inspection);
- Certification documents issued by the Auditing Organization state compliance with applicable US regulations, which may provide a marketing advantage.

Note: Inspections conducted "For Cause" or "Compliance Follow-up" by FDA will not be affected by this program. Special inspections, such as the annual Risk Based Workplan inspection program may also not be affected by MDSAP. Moreover, this MDSAP program would **not** apply to any necessary pre-approval or post approval inspections for Premarket Approval (PMA) applications or to decisions under section 513(f)(5) of the Act (21 U.S.C. 360c(f)(5)) concerning the classification of a device.

Firms with activities related to the Electronic Product Radiation Control (EPRC) provisions of the Act will continue to be subject to FDA inspections for the EPRC activities. Manufacturers of products that are not subject to device inspections, i.e. drugs, biologics, etc., may also require an FDA inspection (see question #39).

**World Health Organization (WHO):** In the framework of the *Prequalification Program* for diagnostic devices, the WHO may recognize successful MDSAP -

audits as acceptable evidence of QMS compliance with international regulations. This may result in either abbreviated or waived WHO inspection depending on the scope of audit.

### **30. What are the costs associated with MDSAP audits?**

The cost of conducting an MDSAP audit is dictated by the commercial arrangement between the medical device manufacturer and the authorized or recognized MDSAP Auditing Organization.

### **31. Where can industry find out which jurisdictions an AO is recognized for?**

An Auditing Organization authorized or recognized to perform MDSAP audits must have demonstrated competence in each jurisdiction's regulations. Therefore, the recognition is not restricted in terms of a Regulatory Authority's jurisdiction and covers all jurisdictions participating in MDSAP. The letter of recognition to conduct medical device regulatory audits under MDSAP is standardized.

### **32. How does the MDSAP ensure that medical devices are being manufactured in accordance with the regulations of multiple jurisdictions?**

The MDSAP relies on:

- Annual audits of manufacturers according to an audit approach specific to the program. This audit approach was developed to review the compliance of a manufacturer's quality management system to the international standard ISO 13485 and additional regulatory requirements applicable to the countries where the devices are sold; and
- Annual assessments of the Auditing Organizations' management system compliance to the international standard ISO/IEC 17021-1 and MDSAP specific requirements as defined in IMDRF MDSAP WG documents.

### **33. How do Auditing Organizations ensure that duplicate efforts are not performed during an audit of a manufacturer that sells in multiple jurisdictions?**

The MDSAP audit process was designed and developed not only to prevent duplication, but also to ensure that the program provides efficient and thorough coverage of the requirements of; Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485: 2016) and any corresponding section(s) of the Australian Therapeutic Goods (Medical Devices) Regulations (SR

236, 2002), the Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), the Canadian Medical Device Regulations (CMDR, Part 1), the Japanese QMS ordinance (MHLW MO 169), the Quality System Regulation (21CFR 820), and other country-specific requirements.

The MDSAP audit sequence follows a process approach and was designed and developed to allow the audit to be conducted in a logical, focused, and efficient manner.

MDSAP AOs are required to create a facility profile in the online portal (REPs) for each facility audited. The profile is kept updated by the AOs. This allows for timely notification to RAs of a manufacturer's participation or withdrawal from MDSAP.

Timely notification of MDSAP initial audit schedules by AOs will prevent the duplication of inspection/audit of Medical Device Manufacturers participating in MDSAP. Additionally, adequate notification of situations where a Medical Device Manufacturer no longer elects to participate in MDSAP will ensure that continued regulatory oversight is maintained by all participating RA's.

#### **34. How are regional regulatory differences addressed in the program?**

The regulatory requirements of the participating Regulatory Authorities have been incorporated into the MDSAP Audit Approach. An auditing organization will perform audits using this approach and record findings in relation to the regulations of the participating Regulatory Authorities.

Each Regulatory Authority independently utilizes the MDSAP audit deliverables (audit reports, certification documents) according to their regulations and policies.

#### **35. How are audits of medical device manufacturers conducted under the MDSAP?**

Authorized and recognized Auditing Organizations perform MDSAP audits according to documents developed by the participating Regulatory Authorities. Some relevant policies and procedures introduced by the program to ensure consistency across Auditing Organizations and/or auditor teams include:

- The sequence of processes specified in the Audit Approach [MDSAP AU P0002](#) must be followed; the audit duration is based on planned audit tasks [MDSAP AU P0008 Audit Time Determination - Procedure](#), ensuring consistency across Auditing Organizations. In general, the duration of MDSAP audits will not exceed the accumulated time of audits and inspections

performed currently by each participating Regulatory Authority according to their governing regulatory frameworks.

- An audit report is issued with each audit, using a standard fillable template specifically designed for medical device regulatory audits.
- Nonconformities identified during an audit are graded on a scale from 1 (least critical) to 5 (most critical), and are managed according to criteria defined in the document [GHTF/SG3/N19:2012, Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange](#).
- Audited manufacturer are responsible for the timely development and implementation of action plans to address non-conformities identified during audits [MDSAP AU P0027 Post Audit Activities and Timeline Policy](#).
- Auditing Organizations share the audit outcomes with the participating Regulatory Authorities to support their pre-market or post-market programs. Upon successful certification or recertification audits, Auditing Organizations issue MDSAP-specific certification documents stating compliance to ISO 13485:- and applicable regulatory requirements. [MDSAP AU P0026 Certificate Document Requirements](#).

## **36. What is the difference between a Stage 1 and a Stage 2 Audit? (Initial Audit?)**

The “Initial” audit also known as an “Initial Certification” audit consists of a Stage 1 and a Stage 2 audit.

- Stage 1 – A first Stage 1 audit consists of a documentation review and the evaluation of the readiness of the manufacturer to undergo a Stage 2 audit.
- Stage 2 – The purpose of a Stage 2 audit is to determine if all applicable QMS requirements of ISO 13485 and all other applicable regulatory requirements from participating regulatory authorities have been effectively implemented.

## **37. How is the audit duration determined?**

The method and the criteria to be used by the Auditing Organizations to calculate the time necessary to conduct an MDSAP audit of a medical device manufacturer is defined in the procedure [MDSAP AU P0008](#) entitled *Audit Time Determination*.

The MDSAP audit approach defines the activities and tasks that are to be performed in an MDSAP Audit Cycle including; the activities and tasks for an Initial (Stage 1 and 2) Audit (a.k.a. Certification Audit), Surveillance, Re-audit (a.k.a. Recertification Audit), and for Special Audits. The appropriate audit tasks defined within the MDSAP Audit Cycle must be used when calculating audit times. When applicable,

the appropriateness of the audit duration for subsequent activities should be confirmed during the Stage 1 audit.

There are varying numbers of audit tasks depending on the process being audited. Audit time is calculated based on the number of applicable audit tasks associated with the type of audit to be conducted (as defined in the MDSAP Audit Cycle) and the specific activities of the organization to be audited.

### **38. At what frequency do MDSAP audits occur?**

Medical device manufacturers that participate in the MDSAP are audited annually, according to a three-year certification cycle. The Initial Audit, also referred to as the “*Initial Certification Audit*” is a complete audit of a medical device manufacturer’s quality management system (QMS). The initial Audit is followed by partial Surveillance Audits conducted once per year for two consecutive years. The cycle re-commences with a complete Re-audit, also referred to as a “*Recertification Audit*” in the third (3rd) year.

Special Audits, Audits Conducted by Regulatory Authorities, and Unannounced Audits are potential extraordinary audits that may occur at any time within the audit cycle.

### **39. Can the scope of an MDSAP audit include combination products?**

The implementation of the MDSAP is intended to allow for a single audit to satisfy the regulatory requirements of the participants.

Medical Devices that include; drugs (medicinal substances) or biologics (e.g. materials of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin, human blood or extracts of human blood or blood products, etc.) (a.k.a. “combination products”) may be included in the scope of an MDSAP audit.

The Regulatory Authorities that take into account MDSAP audit reports for combination products expect that the Auditing Organization, when conducting an audit for these products, will:

- undertake, to the extent possible during on-site audits, an assessment of the product / process related technologies in accordance with the requirements of N3 Clauses 9.2.4, 9.3.2 and 9.4.1, and the requirements of the MDSAP audit approach for compliance with the country specific requirements;

- assign relevant technical competence to the audit team that is assessing the product / process related technologies and relevant controls for the handling, testing and manufacture of these types of devices; and
- record their findings in accordance with the requirements of [MDSAP AU P0019 MDSAP Medical Device Regulatory Audit Reports.](#)

However, due to differences in the way that these products are regulated in the jurisdictions of the participating Regulatory Authorities, MDSAP audit reports and certification documents will not be considered an alternative to the inspection and assessment requirements in some jurisdictions, as described below:

**Australia:** Manufacturers of some medical devices, other than IVD medical devices, that contain tissues of animal origin or microbial origin, or incorporating stable derivatives of human blood or human plasma, or incorporate, or are intended to incorporate a substance that, if used separately, might be considered to be a medicine, are ‘specified medical devices’ defined under s.4 Definitions of the Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018. MDSAP Audit Reports can be used to support a TGA application for Conformity Assessment for ‘specified medical devices’.

**Brazil:** According to Brazilian regulations there are no specific requirements for combination products regarding the Quality Management System, and for that, all the requirements already disposed on the MDSAP Audit Approach promotes adequate coverage for the needs established in the Brazilian legislation and regulation for those products. Therefore, combination products that are considered medical devices in Brazil are included in MDSAP –

**Canada:** The MDSAP Audit Approach covers the requirements for combination products that are regulated as medical devices.

**Japan:** There are no Japanese characteristic requirements for combination products which are categorized as devices. Therefore, MDSAP Audit results will be considered as alternatives to confirm the compliance of Quality Management System (QMS) requirements for such products.

**United States:** The MDSAP Audit Approach only covers the requirements of the US medical device regulations. As additional requirements of the US regulations apply to devices incorporating drugs or biologics, the FDA cannot consider MDSAP - audits of combination product manufacturers as an alternative to FDA inspections. Consequently, such products are still subject to FDA inspections regardless of the participation of the manufacturer in the program. Nevertheless, the FDA may take into account the outcome of an MDSAP audit covering combination products to optimize the scope of the FDA inspection to be performed.

**NOTE:** When a combination product manufacturer also manufactures non-combination products, it is expected that during the initial certification audit and at least once during the subsequent certification cycle the audit team includes the technical competence to audit combination products; and, when applicable, the audit plan includes the quality management system processes and activities associated with the combination product. MDSAP audit plans and reports of combination product manufacturers must consider, where applicable:

- 1) Supplier Controls and acceptance activities (including testing) associated with the starting material that is to be used in the manufacture of the drug or biologic component (in particular Active Pharmaceutical Ingredients);
- 2) Controls of the manufacturing processes for the drug or biologic component;
- 3) Final acceptance and testing activities, including those associated with the drug or biologic component in the finished product; and
- 4) Stability programs that consider the drug or biologic component in the finished product.

**40. Is there a checklist available for industry that compares the ISO 13485 requirements with each participating country's regulations?**

The *Audit Approach* [MDSAP AU P0002](#) contains specific instructions on the MDSAP audit process. It incorporates an audit sequence and instructions for auditing each specific process. The audit process tasks incorporate references to the applicable ISO 13485: 2016 clause(s) and any corresponding section(s) of the Australian Therapeutic Goods (Medical Devices) Regulations (SR 236, 2002), the Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), the Canadian Medical Device Regulations (CMDR, Part 1), the Japanese QMS ordinance (MHLW MO 169), and the Quality System Regulation (21CFR 820).

**41. Is MDSAP a top down inspection, as with the Quality System Inspection Technique employed by FDA?**

The MDSAP Audit Approach, which was inspired by the FDA's Quality System Inspection Technique document, is based on a "top-down" auditing approach.

**42. Does the audit process include a daily review of areas of concern?**

Yes. Auditing Organizations must be in compliance with the requirements of IMDRF MDSAP WG N3, and N4, including the requirements of ISO/IEC 17021-1 and all other related MDSAP documents. ISO/IEC 17021-1, Sub-Clause 9.4.3.1-

*Conducting the opening meeting*, requires that “during the audit, the client will be kept informed of the audit progress and any concerns.”

**43. Are MDSAP audits conducted by single or multiple auditors?**

Procedure [MDSAP AU P0008](#) Audit Time Determination specifies how to determine the on-site audit duration in man-days. Auditing Organizations decide how many auditors will compose the audit team. For instance, a 6 man-day audit could be completed in 3 days by a 2-auditor team. Auditing Organisations are also required to take into account the competency of the audit team for the type of audit and the scope of products that are produced under the control of the manufacturer's QMS.

**44. Who assigns a particular auditor? The Auditing Organization or Regulatory Authority?**

It is the AOs' responsibility to assign auditors for individual audits of medical device manufacturers, taking into account their competence, impartiality and availability.

Unlike other certification programs, a manufacturer may not oppose the choice of the auditor under the MDSAP ([IMDRF MDSAP WG N3 Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition](#) exception to ISO /IEC 17021-1, section 9.2).

**45. If MDSAP becomes mandatory for one or more participating countries will manufacturers be expected to be compliant with regulations in a jurisdiction that it does not market?**

The manufacturers are expected to be compliant only with the regulations for the jurisdictions where their products are marketed or manufactured for distribution.

**46. Can RA's discredit/void any audits that were conducted by an AO due to inadequate audit method/technique? If so, will manufacturers have to go through re-audits for audits they believed to have passed?**

The MDSAP does not include mechanisms for requiring an audit to be re-done. Nevertheless, if an audit report appears to be unreliable, does not include a participating MDSAP jurisdiction in which the products are distributed, or does not include all the appropriate devices in the audit scope a participating Regulatory Authority may not be able to utilize the certificate or report as part of their process to grant a marketing authorization. A misleading audit report may also present a risk to

public health and could lead the Regulatory Authorities to conduct its own follow-up inspection. Alternatively, an RA may request that an AO conduct a special audit to follow up on an issue. ([IMDRF MDSAP WG N3](#) – clause 9.6.6.)

Manufacturers may forward a complaint with the participating Regulatory Authorities in relation to an audit performed by an Auditing Organization. The complaint will be processed using the procedure described in [MDSAP QMS P0011](#).

**47. If an AO issues a negative final report, does this mean the manufacturer can no longer supply to/sell in all of the regulatory jurisdictions that are participating in the Program?**

MDSAP audit reports records the recommendation of the audit team for initial, continuing certification, or re-certification of the audited medical device manufacturer. When the AO determines that the audited manufacturer does not meet QMS or other regulatory requirements, each of the Regulatory Authorities concerned would determine appropriate actions relative to the identified nonconformities. The nonconformities may or may not be associated with regulatory requirements of all participating regulatory authorities.

**48. What happens if significant non-conformities are identified by an Auditing Organization and subsequently shared with the Regulatory Authorities?**

Non-conformities identified by an Auditing Organization are to be graded in accordance with the document [GHTF/SG3/N19:2012](#) – Quality management system – Medical devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange. Nonconformities are to be recorded and graded by the Auditing Organization using [MDSAP AU F0019.2 NC Grading and Exchange Form](#).

[IMDRF MDSAP WG N3](#) defines that the Auditing Organization shall provide information to the recognizing Regulatory Authority(s) about the audits and decision on conformity to quality management system requirements. The procedure [MDSAP AU P0027 Post-Audit Activities and Timeline Policy](#) defined that if the audit identified one or more grade 5 nonconformities, or more than two grade 4 nonconformities, or a public health threat, or any fraudulent activity or counterfeit product, the Auditing Organization shall inform the Regulatory Authorities within 5 working days. For Grade 4 or 5 nonconformities, manufacturers are expected to provide evidence to the Auditing Organization of implementation of the remediation actions addressing any grade 4 or 5 nonconformity within 30 days of the audit end date. Auditing Organizations are subsequently expected to provide the audit package, which includes the NC Grading and Exchange form, to a recognizing Regulatory Authority within 45 days of the end of audit. Post-audit actions timelines for a manufacturer and an Auditing Organization are further described in [MDSAP AU P0027 Post-Audit Activities and Timeline Policy](#).

On receipt of the 5 days' notice the participating Regulatory Authorities will undertake actions that are appropriate for their jurisdictions and will notify the other participating Regulatory Authorities of the actions that should be taken in relation to the manufacturer.

**49. How are nonconformities that are identified during an MDSAP audit managed? What is the timeline for a manufacturer to respond to nonconformities?**

The document [MDSAP AU P0027 Post-Audit Activities and Timeline Policy](#) defines the activities to be completed and timeline that a medical device manufacturer must follow to address the nonconformities identified during an MDSAP audit.

The manufacturer must provide a remediation plan for each nonconformity within 15 calendar days from the date the non-conformity report was issued. The plan must include:

- the outcome of the investigation of the nonconformity and its cause(s),
- the planned correction(s), and
- the planned corrective action(s) to prevent recurrence.

The evidence of implementation of the remediation actions addressing any grade 4 or 5 nonconformity must be provided within 30 calendar days after the audit end date. (Page 1-section 2 Timeline)

**50. Who would conduct follow-up visits to close the non-conformities?**

An Auditing Organization would normally conduct close-out activities for all non-conformities in accordance with their procedures.

A participating Regulatory Authority may request that an Auditing Organization carry out a Special Audit to further investigate, follow-up or to close an audit under the direction of the requesting Regulatory Authority.

A recognizing Regulatory Authority may conduct its own Special Audit at any time it deems necessary and within the purview of its jurisdiction. ([IMDRF MDSAP WG N3](#) – clause 9.6.6.)

**51. Do Auditing Organizations collect evidence of nonconformities, or other evidence usually collected during Regulatory Authorities' inspections?**

Under the MDSAP, Auditing Organizations are not required to collect any evidence, but the audit report must substantiate any audit finding by reference to audit evidence. Due to this restriction, the US FDA will limit enforcement actions based on MDSAP audit reports to advisory actions only.

This waiver also applies to other evidence usually collected during Regulatory Authorities' inspections, such as evidence of interstate commerce by the FDA.

For example, what does the FD&C Act mean by "Interstate Commerce". *Section 201(b) of the FD&C Act [21 U.S.C. 321(b)] tells what circumstances place a product in interstate commerce:*

- (1) *Commerce between any State or Territory and any place outside thereof, and*
- (2) *Commerce within the District of Columbia or within any other Territory not organized with a legislative body.*

*"Interstate commerce" applies to all steps in a product's manufacture, packaging, and distribution. It is very rare that a cosmetic product on the market is not in "interstate commerce" under the law. For example, at least some of your ingredients or packaging most likely originates from out of state, or even out of the country. Likewise, it is foreseeable that your products will leave the state. Although there are certain exemptions [21 CFR 701.9], factors such as these generally cause the requirements of the FD&C Act to apply to your products."*

**52. During witnessed audits, will Regulatory Authorities prompt AO's in identifying nonconformities?**

The RAs will not interfere in the way an AO conducts its audit. The MDSAP is intended to allow competent auditors from MDSAP recognized AOs to conduct a single audit of a medical device manufacturer's quality management system in compliance with the requirements of the RAs participating in the MDSAP program. For this purpose, the RA's will ensure, by periodical assessment, including the witnessing of audits of manufacturers conducted by AOs, that AOs are applying the MDSAP audit approach and assigning adequate competence to the task.

**53. As a manufacturer, how do I show that I was successfully audited under the MDSAP?**

Upon successful completion of an initial audit or re-audit, an Auditing Organization will issue certification documents including a reference to the MDSAP that will state compliance to ISO 13485 and the applicable Medical Device Regulations from each jurisdiction that were used as audit criteria.

**54. If a manufacturing site is already under regulatory action with a participating Regulatory Authority, can they participate in the MDSAP?**

If a manufacturer is currently subject to regulatory action from one of the participating Regulatory Authorities, then the manufacturer should consult with the RA about their eligibility for an MDSAP audit prior to resolution of the action. There are no exclusion criteria regardless of the past audit/inspection history, and regardless of the type of medical devices manufactured by the organization. Nevertheless, if a manufacturer had a previously unfavorable inspection by a participating Regulatory Authority, this Regulatory Authority may still choose to conduct a follow-up inspection. For example, this is the case with inspections conducted by the U.S. FDA. ANVISA will not use MDSAP audit reports from manufacturers where the result of ANVISA's previous inspection was considered unsatisfactory and therefore the manufacturer had the certification submission denied. In such cases ANVISA will start using the MDSAP reports only after a new ANVISA inspection with a satisfactory result.

**55. What happens to a Manufacturer when the AO recognition is revoked?**

The impact of a cessation of recognition or the revocation of the authorization to audit, under the MDSAP may affect a large number of manufacturers. The event should not directly affect any existing marketing authorization. Nevertheless, Regulatory Authorities may need to consider individual or collective transitional arrangements to assure existing or potential public health risks are mitigated.

To stay in the program, a manufacturer would need to contract another Auditing Organization to resume the audit cycle at the point of departure of the de-recognized Auditing Organization.

**56. Will industry auditors have access (for a fee) to the AO auditor training? [Will training be available for manufacturers to ensure that its QMS will meet the MDSAP criteria?]**

Computer-based on-line training modules have been created describing the MDSAP Audit Approach that is to be used by Auditing Organizations to conduct audits of Medical Device manufacturers. This training is a requirement for each Auditing Organization auditor who will be conducting MDSAP audits. Due to limited availability of licenses agreement the training is not being made available to non-Auditing Organization certification bodies or to medical device manufacturers. However some of the MDSAP training modules are available on the MDSAP webpage - [CDRH Learn \(Postmarket Activities Section/ Inspections – Global Harmonization\)](#); scroll down to "Postmarket Activities".

**57. Why aren't MDSAP audit reports used by the FDA as substitutes for inspections for Premarket Approval (PMA) applications?**

The FDA explicitly excludes PMA pre-approval and post-approval inspections for Premarket Approval (PMA) due to the lack of regulatory convergence in the following:

1. the premarket device assessment processes performed under the various regulations (e.g. US Premarket Application, Australian Design Dossier or Design Examination, Canadian Device License Application); and,
2. where the responsibilities for final decisions of safety and performance/effectiveness of a medical device are placed (regulatory authority vs. third party organization).

**58. Which country specific regulatory requirements are included in the MDSAP audit criteria?**

The Medical Device Single Audit Program (MDSAP) audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the relevant requirements of; Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485: 2016), the Australian Therapeutic Goods (Medical Devices) Regulations (SR 236, 2002), the Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), the Canadian Medical Devices Regulations (Part 1), the Japanese QMS ordinance (MHLW MO 169), the Quality System Regulation (21 CFR Part 820), and other specific requirements of medical device regulatory authorities participating in the MDSAP program including 21 CFR Part 803 and 21 CFR Part 806.

**59. How will the determination be made on whether an audit report supports an FDA advisory action without the supporting evidence?**

The determination will be made following existing FDA criteria for situation 1 as described in the applicable Compliance Program, Part V. The evidence will be described in the narrative descriptions of nonconformities contained in the audit report. The auditor competency (including ability to identify existing nonconformities) is something the regulatory authorities review extensively during Auditing

Organization assessment activities. An independent inspection by the FDA would be necessary to support judicial actions.

**60. How will Nationally Recognized Testing Laboratory (NRTL) Program audits be accepted?**

NRTL tests and MDSAP audit are completely separate programs, evaluating compliance to distinct criteria. NRTL tests are required by the US Occupational Safety and Health Administration.

**61. Can Regulatory Authorities not participating in MDSAP have access to audit reports? If so, what amount of information will be made available and at what cost?**

Regulatory Authorities not participating in the MDSAP will not have full access to audit reports. Nevertheless, if a Regulatory Authority has a confidentiality agreement with a participating Regulatory Authority, a request may be made to obtain a copy of a particular report.

However, non-participating Regulatory Authorities may request audit reports and certificates from the medical device manufacturer.

Regulatory Authorities participating in the MDSAP Affiliate Program may request the MDSAP Audit Report from the medical device manufacturer. A list of MDSAP Affiliates and information regarding the MDSAP Affiliate Program is listed on the [MDSAP webpage](#).

**62. Do the IMDRF or the Regulatory Authorities participating in the MDSAP plan to influence/revise the International Accreditation Forum (IAF) mandatory document MD9 on the audit of medical device manufacturers to ISO 13485?**

No. The document [IMDRF MDSAP WG N3](#) states that “IMDRF Regulatory Authorities have no official status within groups such as the IAF, or any voice in IAF governance or IAF mutual recognition agreements, that would allow the Regulatory Authorities to revise IAF documents to meet the needs of the regulators. It was also determined that the standard most commonly utilized is the ISO (the International Organization for Standardization) and IEC (the International Electro-Technical Commission) standard ISO/IEC 17021-1 entitled, “Conformity assessment – Requirements for bodies providing audit and certification of management systems.” Medical device Regulatory Authorities also have little influence in the standards

organization that produces this standard and cannot simply change the standard for medical device regulatory purposes.”

### **63. Is the CE certification included in the outcome of a successful MDSAP audit?**

The MDSAP Audit Approach [MDSAP AU P0002](#) does not incorporate the requirements from the European regulations. Nevertheless, the medical device regulatory Audit Report form [MDSAP AU F0019. 1](#) may be used for multipurpose audits and an Auditing Organization may incorporate the European requirements into the MDSAP audit criteria to eliminate duplicate reporting.

### **64. Can the RAs consider if one report can represent a multi-site audit?**

The Regulatory Authorities agreed that a separate report is necessary for each audited site unless the manufacturer meets the definition of a campus, as stated in Communication by AOs with RA on Organizations participating in MDSAP.

### **65. Do audit tasks have to be repeated during a multi-site audit?**

- The implementation of applicable QMS process elements should be audited at each site.
- Content of common procedures does not have to be audited again. However, the implementation of applicable QMS process elements should be audited at all applicable sites.
- The non-implementation of applicable QMS process elements may lead to nonconformities relating to document control (current, approved procedure not available at all sites); or failure to effectively train users of the procedure; or failure to effectively implement the procedure, among others.

### **66. What additional guidance can RAs provide AOs on the application of the MDSAP audit approach to multi-site audits and for suppliers?**

- The AO should determine the applicable QMS activities and corresponding audit tasks at each site included in the audit program.
- Content of common procedures does not have to be audited again. However, the implementation of applicable QMS process elements should be audited at all applicable sites.
- The audit team should pay attention to the interaction and coordination of activities between sites.

- MDSAP audit could be extended to a supplier facility if the manufacturer cannot demonstrate effective controls.

**67. How should an AO handle companies that have a legal address with no association to the company's daily operations?**

- Per IMDRF MDSAP WG N3, the AO shall audit all sites that will be recorded on the certificate.
- AOs can initially visit the site to confirm its activities and relationship to the QMS.
- Describe relationships/activities and site omissions in the audit report.
- Auditors should confirm if changes result in additions of sites to audit program.
- Non-operations/functional sites should not be audited/certified.

**68. Should a remote-audited facility be included on the certificate?**

According to [MDSAP AU P0026](#), section 7, “The certification document shall record all sites of the manufacturer’s quality management system that have been audited on-site.”

**69. How should AOs handle “virtual” manufacturers?**

Virtual Manufacturers shall be treated as manufacturers and shall be audited accordingly for all activities applicable to the devices designed or manufactured.

**70. Manufacturers indicated that the grading system was too complex to understand. Is there any plan to review it?**

- The grading system is based on GHTF/SG3/N19:2012. A guidelines document was developed to account for the change from the 2003 to the 2016 version of ISO 13485 and to clarify situations for escalation that are described in GHTF/SG3/N19:2012. The guidelines document is MDSAP AS P0037: *Guidelines on the use of GHTF/SG/N19:2012 for MDSAP purposes*.

**71. Can RAs provide additional guidance on how to distribute the audit activities among the audit team, using the audit approach?**

- Audits require effective pre-audit planning.

- While one auditor is reviewing a primary process of the audit approach (e.g., Management), another auditor can cover a supporting process. (e.g., Facility Registration)
- Auditors covering the same process can cover different audit tasks.
- Maintaining audit team communication is essential.

**72. How should an AO apply the audit approach when sites are not responsible for all QMS activities?**

- AO should determine the applicable QMS activities and corresponding audit tasks at each site included in the audit program. This can be done in Stage 1 of the audit.
- The audit time calculation procedure, MDSAP AU P0008, and associated spreadsheet MDSAP AU F0008.2 (Audit Model 2017) can assist in identifying/planning audit tasks.

**73. When should an AO employ a Technical Expert during an MDSAP audit?**

ISO/IEC 17021-1 states: “The criteria for the selection of technical experts are determined on a case-by-case basis by the needs of the audit team and the scope of the audit.”

**74. Can audit tasks be accomplished prior to on-site audit activities?**

Yes. RAs encourage AOs to use pre-audit planning, communications and other activities as a mechanism to complete or assist in the completion of audit tasks when appropriate.

**75. Under what circumstances would an MDSAP audit be followed by an RA inspection?**

A RA inspection may be required if:

- An MDSAP audit report failed to provide evidence required to support market authorization decisions.
- An audit reveals public health safety concerns or fraudulent activity.
- Combination product device manufacturers may still require RA audits/inspections. See question #39 of the MDSAP Q&A document for additional guidance on combination products.
- Some situations when the manufacturer is currently subject to regulatory action (see question #54)

**76. When should multi-site audit reports be submitted?**

Audit reports must be submitted following the audit of each site, as stated in MDSAP AU P0027, Post-Audit Activities and Timeline Policy.

**77. How should AOs handle sharing of audit reports with RAs that are not participating in MDSAP?**

This should be worked out between the AO and its clients and spelled out in contracts when necessary.

**78. Have the RAs defined the term “Public Health Threat”?**

Public Health Threat is synonymous to the GHTF/SG2/N54R8:2006 term, Serious Public Health Threat – *Any event type, which results in imminent risk of death, serious injury, or serious illness that requires prompt remedial action.*

**79. How should AO auditors structure nonconformity statements?**

Nonconformities should be written in accordance with GHTF/SG3/N19:2012, section 4.1; and section 5.0 Appendix A.

**80. Why have the RAs imposed an initial response period of fifteen (15) calendar days?**

RAs operate under time constraints that require an awareness of audit outcomes within a specified number of days. In order to make informed decisions about audit outcomes, the RAs must assess the manufacturer's response.

**81. For a consistent interpretation, could the RAs define the term “implementation” in MDSAP AU P0027 and AS F0015.1?**

- NCs cited by AOs after an MDSAP audit of a manufacturer: In the context of a manufacturer replying to nonconformities identified during an MDSAP audit, the term “implement” relates to the implementation of the actions specified in the manufacturer's correction and corrective action plan.
  - Please refer to [MDSAP AU P0027](#), sections 2 and 3.

- NCs cited by RAs following and assessment of an AO: In the context of an auditing organization replying to nonconformities identified during an RA assessment, the term “implementation” relates to the implementation, and confirmation of the effectiveness of corrections and corrective actions, subsequent to the review and acceptance by the RAs of the AO’s correction and corrective action plan.
  - Please refer to MDSAP AS F0015.1 AO Nonconformity Process Flowchart.

**82. What does the MDSAP certificate represent?**

- The MDSAP certificate is an attestation by the AO that the facilities listed in the certificate have been audited against the listed criteria for the listed scope and found to conform to those requirements, including the regulatory requirements for the specified jurisdictions of the RAs.
- It does not represent a marketing authorization nor does it oblige participating Regulatory Authorities to issue any such marketing authorization or endorsement of the manufacturer or its devices.

**83. Can the RAs provide additional guidance on what should be recorded if the minimum N4 requirements cannot be fulfilled by an initial start-up AO?**

- The RAs recognize that not all AOs will have the initial client participation to fulfill prerequisite annual experience requirements.
- AOs should document the circumstances and justify why requirements were not met in accordance with the principles for pre-requisite experience described in N4 Clause 6.2.
- RAs will consider each justification on a case-by-case basis.

**84. Can the RAs clarify the requirements for the transfer of certification for participating manufacturers?**

Transfer guidelines are detailed in ISO 17021-1:2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements.

**85. Can the RAs develop a single dispute resolution to minimize inconsistency if a manufacturer uses multiple AOs?**

[MDSAP P0031](#) – Documenting Differing Professional Opinion and Dispute Resolution Policy sets out a single mechanism for resolving disputes within the MDSAP program.

**86. How long will RAs allow an MDSAP certificate to reference a jurisdiction where no product is distributed?**

- MDSAP AOs can issue certificates referencing jurisdictions where the manufacturer does not yet have market authorization.
- Recognizing that market entry can take time, such certifications can be extended for a full three years.
- If at the end of three years, the manufacturer has not obtained or applied for market authorization, it is recommended that the requirements for the affected jurisdiction should be removed from the certificate until such time as the manufacturer can demonstrate implementation and effectiveness.

**87. Can the manufacturer exclude a jurisdiction or products from the scope of an MDSAP audit?**

A manufacturer may exclude the requirements of a jurisdiction where the organization does not intend to supply medical devices. In other words, audit criteria under the MDSAP include at a minimum ISO 13485 and the medical device regulations that are applicable in any of the participating regulatory authority's jurisdiction where the organization supplies medical devices. The MDSAP audit scope is expected to include all products that are supplied to a participating MDSAP jurisdiction.

**88. What constitutes a counterfeit medical device or a fraudulent activity requiring notification of Regulatory Authorities?**

For all practical purpose:

- A counterfeit medical device is a medical device that is represented as, and likely to be mistaken for, an authentic medical device with a valid marketing

authorization, or whose identity, nature and/or source are fraudulently misrepresented, or that is otherwise intended to defraud.

- A fraudulent activity is an intentional, reckless, dishonest and recurrent, or systematic, activity resulting, for example, in the production of a counterfeit product, or in the creation of fake records, false representations, or the alteration of genuine records to imply compliance. The unintentional failure to comply with requirements, despite due diligence, does not qualify as fraudulent activity.

#### **89. What is the expectation for Class 1 medical device manufacturers participating in MDSAP?**

The activities/processes, products or facilities that are eligible for exclusion from an MDSAP Program are outlined in the following table.

Jurisdiction	Consideration	Comments
Australia	Class I medical devices (non sterile, no measuring function) are not required to have a certified quality management system.	<p>TG(MD)R Schedule 3 Part 6 establishes obligations / requirements for manufacturers of Class I medical devices (non sterile, no measuring function) that includes process definition, adverse event and recall reporting. By default, a certified QMS is not required by legislation for Class I medical devices (non sterile, no measuring function). However, a manufacturer may:</p> <ul style="list-style-type: none"><li>- voluntarily choose to apply a more onerous conformity assessment procedure (e.g. Schedule 3 Part 1 or Part 4); OR</li><li>- request an Auditing Organization to include Class I medical devices (non sterile, no measuring function) within the scope of an MDSAP ISO13458 certification.</li></ul> <p>In these circumstances, the Auditing</p>

		Organization should treat the requirements of the relevant Conformity Assessment Procedure (Part 1, 4 or 6) as regulatory requirements when establishing audit criteria.
<b>Brazil</b>	<p>Class I and Class II medical devices are not subject to GMP Certification*.</p> <p>* However, ANVISA Resolution RDC 15/2014 still require that the manufacturer of the finished device have an effective QMS in place.</p>	If all devices in the scope of certification are class I or II, or if the audited facility's contribution to the scope of certification only applies to class I or class II medical devices, the audit at that facility may disregard the requirements of the Brazilian regulation for registration purposes.
<b>Canada</b>	Class I medical devices are not required to have a certified quality management system.	If all devices in the scope of certification are class I or if the audited facility's contribution to the scope of certification only applies to class I medical devices, the audit at that facility may disregard the requirements of the Canadian regulation.
<b>Japan</b>	Class I medical devices are not required to have a certified quality management system.	If all devices in the scope of certification are class I or if the audited facility's contribution to the scope of certification only applies to class I medical devices, the audit at that facility may disregard the requirements of the Japanese regulation.
<b>United States</b>	Some Class 1 medical devices are “GMP-exempt”, i.e. not subject to the US quality system regulation.	If all devices in the scope of certification are GMP-exempt or if the audited facility's contribution to the scope of certification only applies to GMP-exempt medical devices, the audit at that facility may disregard the requirements of the US Quality System regulation (21 CFR 820), with the exception of the requirements for

	<p>maintaining complaint files and recordkeeping. Additionally, requirements still apply for compliance to Medical Device Reporting (21 CFR 803), Medical Devices; Reports of Corrections and Removals (21 CFR 806), and Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices (21 CFR 807).</p>
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# OFFICIAL FEDERAL GAZETTE

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Body: Ministry of Health/National Health Surveillance Agency/Collegiate Board of Directors

## RDC RESOLUTION No. 665, OF MARCH 30, 2022

Provides for the Good Manufacturing Practices for Medical Products and In Vitro Diagnostic Products.

The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the powers conferred upon it by art. 15, III and IV, allied to art. 7, III and IV, of Law No. 9.782, of January 26, 1999, and art. 187, VI, paragraph 1 of the Internal Regulations approved by Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021, hereby decides to adopt the following Resolution, as resolved at a meeting held on March 30, 2022, and I, the Chief Executive Officer, hereby determine its publication.

### CHAPTER I INITIAL

#### PROVISIONS

##### Section I Purpose

Art. 1 This Resolution provides on the Good Manufacturing Practices (GMP) for Medical Products and In Vitro Diagnostic Products, establishing the requirements that describe the GMP for methods and controls used in the design, purchasing, manufacture, packaging, labeling, storage, distribution, installation and technical assistance applicable to the manufacture of medical products and in vitro diagnostic products.

§ 1 The requirements referred to in the caput of this article are intended to ensure that medical products and in vitro diagnostic products are safe and effective.

§ 2 This Resolution incorporates, into the national legal system, the MERCOSUR Common Market Group (GMC) Resolution No. 20, of November 17, 2011, MERCOSUR/GMC/RES. No. 20/11, "MERCOSUR Technical Regulation on Good Manufacturing Practices for Medical Products and In Vitro Diagnostic Products (Revocation of GMC Res. No. 04/95, 38/96, 65/96 and 131/96)".

##### Section II Scope

Art. 2 This Resolution applies to manufacturers, distributors, storages and importers of medical products and in vitro diagnostic products that are marketed in Brazil.

§ 1 When the manufacturers referred to in the caput of this article conclude that certain requirements established in this Resolution are not applicable to their processes, they shall document the rationale for such understanding.

§ 2 Distributors of medical products and in vitro diagnostic products shall comply, at least, with the following requirements of this Resolution:

I - Chapters I, VII and VIII, in their entirety;

II - Chapter II, in its entirety, except Section IV;

III - Chapter III, Section I;

IV - Chapter V, articles 67, 68, 69, 70, 71, 72, 73, 74, 75, 76 and 77, in addition to Section IV; and

V - Chapter VI, in its entirety, except art. 119.

§ 3 Storages of medical products and in vitro diagnostic products shall comply, at least, with the following requirements of this Resolution:

I - Chapters I and VII, in their entirety;

- II** - Chapter II, in its entirety, except Section IV;
- III** - Chapter III, Section I;
- IV** - Chapter V, articles 67, 68, 69, 70, 71, 72, 73, 74, 75, 76 and 77; and
- V** - Chapter VI, in its entirety, except art. 119.

§ 4 Importers of medical products and in vitro diagnostic products shall comply, at least, with the following requirements of this Resolution:

- I** - Chapters I, II, VII, VIII and IX in their entirety;
- II** - Chapter III, Section I and Section III;
- III** - Chapter IV, art. 63, clauses III, IV and V;
- IV** - Chapter V, articles 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 85, 86 and 87, in addition to Sections III and IV; and
- V** - Chapter VI, in its entirety, except art. 119.

§ 5 Companies that carry out more than one activity shall comply with the specific requirements defined for each activity.

§ 6 The minimum requirements to be complied with, defined in §§ 2, 3 and 4 of this article, are applicable to distributors, storages and importers, even if the provision only mentions the word manufacturer.

### Section III Definitions

Art. 3 For the purpose of this Resolution, the following definitions are adopted:

**I** - technical assistance: maintenance or repair of a finished product in order to return it to its specifications;

**II** - quality audit: an established, systematic, independent examination of a manufacturer's entire quality system, performed at regular intervals and with sufficient frequency to ensure that both the activities of the quality system and its results meet the procedures specified in its quality system;

**III** - component: raw material, substance, piece, part, software, hardware, packaging, labeling or instruction for use, used during the manufacture of a medical product and in vitro diagnostic product, intended to be included as part of the finished product;

**IV** - design input data: a description of the physical attributes, indication of use, performance, compatibility, safety, effectiveness, ergonomics, usability, information from previous designs, and risk management results, among other requirements of a medical product or in vitro diagnostic product that are used as the basis of their design;

**V** - design output data: result of the work in each phase of the design and its final result which, when finished, is the basis for the product master record (PMR);

**VI** - harm: physical injury or damage to a person's health, or damage to property or the environment;

**VII** - specifications: requirements to which products, components, production activities, technical assistance, services, quality system or any other activity shall conform with; **VIII** - establish: define, document in written or electronic form, and implement;

**IX** - manufacturer: any person who designs, manufactures, assembles, or processes a finished product, including those who perform contracted functions of sterilization, labeling, and packaging;

**X** - executive management: senior management of the company, responsible for providing resources and with the authority to establish or change the company's policy and quality system;

**XI** - risk management: the systematic application of policies, procedures, and management practices to the tasks of analyzing, assessing, controlling, and monitoring risks associated with a given product or process;

**XII** - batch or lot: quantity of a product produced in a manufacturing or sterilization cycle, the essential characteristic of which is homogeneity;

**XIII** - manufacturing material: material or substance employed in the manufacturing process or in order to facilitate this process, including cleaning agents, mold release agents, lubricating oils, sterilants, or other by-products of the manufacturing process;

**XIV** - non-conformity: failure to meet a previously specified requirement;

**XV** - serial or batch number: a distinct combination of letters or numbers, or both, from which the complete history of purchasing, manufacturing, packaging, labeling, and distribution of finished products can be determined;

**XVI** - danger: potential source of harm;

**XVII** - quality policy: the totality of an organization's intentions and guidelines with regard to quality, as expressed by the executive management;

**XVIII** - special process: any process whose results cannot be completely verified by subsequent inspections and tests;

**XIX** - production: all the operations involved in manufacturing a given product, from the receipt of the components, through processing and packaging, to obtaining the finished product;

**XX** - finished product: any product or accessory suitable for use, packaged and labeled;

**XXI** - quality: the totality of aspects and characteristics that enable a medical product or in vitro diagnostic product to meet the requirements on being suitable for use, including safety and performance;

**XXII** - complaint: written, oral or electronic communication with regard to the non-acceptance of the identity, quality, durability, reliability, safety, effectiveness or performance of a product;

**XXIII** - record: physical or electronic document that evidences data, facts, specific events, and results achieved in relation to conformity with quality system procedures and standards;

**XIV** - product history file: compilation of records containing the complete production history of a finished product;

**XV** - design history file: compilation of documents containing the complete history of the design of a finished product;

**XVI** - product master record (PMR): compilation of documents containing specifications, instructions, and procedures for obtaining a finished product, as well as for its installation, technical assistance, and maintenance;

**XVII** - rework: part or the totality of the manufacturing operation intended to correct non-conformity of a component, intermediate or finished product, so that it meets the specifications defined in the DMR;

**XVIII** - design review: a documented, systematic, and thorough examination performed during the course of the development of the design to assess its suitability to the established plan and objectives;

**XIX** - risk: combination between probability of occurrence and severity of harm;

**XXX** - quality system: organizational structure, responsibilities, procedures, specifications, processes and resources required for quality management;

**XXXI** - validation: confirmation by analysis and objective evidence that the requirements defined for a certain purpose consistently lead to the expected result;

**XXXII** - verification: confirmation, by analysis and presentation of objective evidence, that specified requirements have been met, including the process of examining the results of an activity to determine conformity with established specifications; and

**XXXIII** - shelf life: period of time estimated by the manufacturer in which a product correctly fulfills the functions for which it was designed.

§ 1 The procedures referred to in item II of the caput of this article shall be implemented in an efficient and suitable manner to achieve the objectives of the quality system.

§ 2 The quality audit referred to in item II of the caput of this article differs from other quality system activities required by this Resolution.

§ 3 Regarding a project, the validation referred to in item XXXI of the caput of this article means establishing and documenting objective evidence that the product specifications meet the user's needs and its intended use.

§ 4 Regarding a process, the validation referred to in item XXXI of the caput of this article means establishing and documenting objective evidence that the process will consistently produce a result that meets the predetermined specifications.

## CHAPTER II

### GENERAL REQUIREMENTS OF THE QUALITY SYSTEM

#### Section I General

##### Requirements

Art. 4 Each manufacturer shall establish and maintain a quality system to ensure that the requirements of this Resolution are met and that the products manufactured are safe, effective, and suitable for their intended use.

Sole paragraph. As part of its activities in the quality system mentioned in the caput of this article, each manufacturer shall:

I - establish and maintain effective quality system instructions and procedures in accordance with the requirements of this Resolution; and

II - establish procedures to meet the legal provisions provided for in the health legislation in force.

#### Section II

##### Management responsibility

###### Subsection I

###### Quality Policy

Art. 5 The executive management of each manufacturer shall establish its policy and objectives on commitment to quality, which shall be measurable and consistent with the established policy.

Art. 6 The executive management shall maintain the quality policy at all levels of the organization.

Art. 7 The executive management shall ensure that the quality policy is described in a quality manual and understood by all employees who may affect or influence the quality of a product.

###### Subsection II

###### Organization and responsibilities

###### Art. 8 Each manufacturer shall:

I - establish and maintain an appropriate organizational structure, represented by an organizational chart, with personnel sufficient to ensure that products are manufactured in accordance with the requirements of this Resolution;

**II** - establish the responsibility, authority, and interrelation of all personnel who manage, perform, and verify quality-related work, with the independence necessary in the exercise of their responsibilities; and

**III** - establish verification functions, provide suitable resources, and assign trained personnel to perform the verification activities.

Art. 9 The executive management of each manufacturer shall appoint an individual from the executive management itself who, regardless of other functionss, has the authority and responsibility to:

I - ensure that quality system requirements are established and maintained in accordance with this Resolution; and

II - report on the performance of the quality system to the executive management for review and provide information on improvement of the quality system.

Sole paragraph. The appointment referred to in the caput of this article shall be documented.

### Subsection III

#### Management review

Art. 10. The executive management of each manufacturer shall assess the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency to ensure that the quality system meets the requirements of this Resolution and meets the established quality policy objectives.

Art. 11. The management review shall be performed in accordance with established review procedures and the results of each quality system review shall be documented.

Art. 12. Matters related to audit results, post-marketing information, process performance and product conformity, status of corrective and preventive actions, changes that may affect the quality system or product conformity, regulatory requirements, among others, shall be taken into consideration for management review.

### Section III Personnel

Art. 13. Each manufacturer shall have sufficient personnel with education, experience, training and practice compatible with the duties of the position, in order to ensure that all activities provided for in this Resolution are correctly performed.

Art. 14. Descriptions defining authority, responsibility and necessary requirements of all personnel for the various tasks of the company shall be maintained.

Art. 15. Each manufacturer shall ensure that all personnel are trained to properly perform the tasks assigned to them.

§ 1 The training mentioned in the caput of this article shall be conducted in accordance with the procedures established by qualified persons to ensure that employees have an adequate understanding of their regular functions and of the requirements of this Resolution applicable to their functions.

§ 2 As part of the training referred to in the caput of this article, all employees shall be warned of product defects that may occur as a result of incorrect performance of their specific functions.

§ 3 The training of the personnel shall be documented.

Art. 16. Each manufacturer shall ensure that any consultant who advises on methods employed or controls used for the design, purchase, manufacture, packaging, labeling, storage, installation or technical assistance of products, has sufficient qualifications - education, training and experience - to advise on the matters for which they were hired.

Art. 17. The hiring of consultants shall be performed in accordance with the purchasing control requirements set forth in this Resolution.

### Section IV

## Risk management

Art. 18. Each manufacturer shall establish and maintain an ongoing risk management process that involves the entire life cycle of a medical product or in vitro diagnostic product, from its conception to discontinuation, to:

- I - identify the associated hazards;
- II - estimate and evaluate the risks involved;
- III - control the associated risks; and
- IV - assess the effectiveness of the established controls.

Art. 19. The ongoing risk management process shall include the following elements: I - analysis;

- II - assessment;
- III - control; and
- IV - risk monitoring.

Art. 20. The company's executive management shall appoint the professionals responsible, establish the policy for determining the criteria for risk acceptability, as well as determine a periodic review of risk management activities, in order to ensure the adequacy and effectiveness of these activities.

## Section V

### Purchasing controls

Art. 21. Each manufacturer shall establish and maintain procedures to ensure that components, manufacturing materials and finished products manufactured, processed, labeled or packaged by third parties, or stored by them under contract, are in conformity with the specifications.

Sole paragraph. Each manufacturer shall ensure that the services performed by third parties mentioned in the caput of this article are in conformity with the specifications established by it.

Art. 22. Each manufacturer shall establish and maintain, according to the impact on the quality of the final product, criteria for assessing suppliers, specifying the requirements, including quality requirements, which shall be met by suppliers.

Art. 23. Each manufacturer shall assess and select potential suppliers, according to their ability to meet previously established requirements, maintaining a record of approved suppliers.

Sole paragraph. Records of supplier assessment and results shall be maintained.

Art. 24. An agreement, in which the suppliers undertake to notify the manufacturer of any change to the product or service, so that the manufacturer can determine whether the change affects the quality of the finished product, shall be documented.

Art. 25. Each manufacturer shall maintain records of purchase orders that clearly describe or reference specifications, including quality requirements, for components, manufacturing materials, finished products, or services ordered or hired.

Art. 26. Each manufacturer shall review and approve the purchasing documents prior to their release.

Art. 27. Approval of purchase orders, including the date and manual or electronic signature of the person responsible, shall be documented.

## CHAPTER III

### DOCUMENTS AND QUALITY RECORDS

## Section I General Requirements

Art. 28. Each manufacturer shall establish and maintain document control procedures to ensure that all documents indicated in this Resolution are correct and suitable for their intended use, and that they are understood by all who may affect or influence the quality of a product.

Art. 29. Each manufacturer shall appoint people to assess and approve all documents established in this Resolution for adequacy prior to their issuance.

Sole paragraph. The approval referred to in the caput of this article, including the date and manual or electronic signature of the person responsible for approving the documents, shall be documented.

Art. 30. Each manufacturer shall ensure that all documents are up to date and available at application sites, and that all unnecessary or obsolete documents are withdrawn from use, or protected from unintended use.

Art. 31. Changes to specifications, methods, or procedures relating to the quality system shall be assessed, documented, reviewed, and approved by persons whose function and level of responsibility are equivalent to those who performed the original review and approval.

Art. 32. Each manufacturer shall maintain records of changes in documents that shall include:

- I** - description of the change;
- II** - identification of the documents changed;
- III** - identification of the documents affected;
- IV** - identification of the person responsible for the change;
- V** - date of approval of the change; and
- VI** - the date on which the change becomes effective.

Art. 33. A list of current documents shall be maintained to identify the current situation of the documents and ensure that only current and approved documents are in use.

Art. 34. All quality documents and records shall be legible and maintained as to minimize damage, prevent losses, and enable their quick retrieval.

Art. 35. All digitally archived documents and records shall be backed up.

Art. 36. Documents and records deemed confidential by the manufacturer may be flagged to alert the competent health authority.

Art. 37. All necessary documents and records relating to a product shall be maintained for a period of time equivalent to the shelf life of the product, counted from the date of its distribution, and in no case less than two years.

## Section II

### Product History File

Art. 38. Each manufacturer shall maintain product history files.

Art. 39. Each manufacturer shall establish and maintain procedures to ensure that the product history files are maintained for each batch or series to demonstrate that products have been manufactured in accordance with the product master record and the requirements of this Resolution.

Art. 40. The product history file shall include, or reference, the following information:

- I** - manufacture date;
- II** - components used;
- III** - quantity manufactured;

**IV - inspection and test results;**

**V - special process parameters;**

**VI - quantity released for distribution;**

**VII - labeling;**

**VIII - identification of serial number or production batch; and**

**IX - final product release.**

### Section III

#### Records of inspections and tests

Art. 41. Each manufacturer shall maintain records of the results of inspections and tests established, when these are directly related to critical quality attributes of the product.

Art. 42. The records of the inspections and tests established shall include the acceptance criteria, the results, the equipment/instrument used, and the date and manual or electronic signature of the person responsible.

### CHAPTER IV

#### DESIGN CONTROL AND PRODUCT MASTER RECORD (PMR)

##### Section I

###### Project Control

Art. 43. Each manufacturer shall establish and maintain product design control procedures to ensure that the specified design requirements are met.

Art. 44. Each manufacturer shall establish and maintain plans that describe or reference design and development activities, as well as the persons responsible for each activity.

§ 1 The plans referred to in the caput of this article shall include any interaction between the various organizational and technical groups that have some interface with the design.

§ 2 The plans referred to in the caput of this article shall be assessed, updated, and approved as the development of the design progresses.

Art. 45. Each manufacturer shall establish and maintain procedures to ensure that the requirements related to a product are appropriate and meet its intended use, including user and patient needs, and applicable legal and regulatory requirements.

Sole paragraph. The procedures referred to in the caput of this article shall include a mechanism that allows incomplete, ambiguous, or conflicting requirements to be identified and addressed.

Art. 46. Design input data shall be documented, assessed, and approved by a qualified appointed person.

Art. 47. Approval of design requirements, including the date and the manual or electronic signature of the person responsible for the approval, shall be documented.

Art. 48. Each manufacturer shall establish and maintain procedures for product design verification.

§ 1 Design verification shall be performed by an appointed person and shall ensure that the design output data meets the input data.

§ 2 The results of the project verification, including the identification of the verified design, the verification methods, the date and the name of the person responsible for the verification, shall be documented in the design history file.

Art. 49. Each manufacturer shall define and document the design output data as to allow the assessment of the design's conformity with the requirements established as input data.

§ 1 The design output data shall meet the input data requirements, include acceptance criteria, and identify design characteristics that are essential for the intended use of the product.

§ 2 The design output data shall be documented, reviewed, and approved prior to its release.

Art. 50. Each manufacturer shall establish and maintain procedures to ensure that assessments of design results are planned, conducted, and documented at the various stages of design development.

Sole paragraph. The procedures referred to in the caput of this article shall ensure that representatives of all functions directly related to the stage of the design being reviewed, as well as individuals from related areas, and the necessary specialists, are involved.

Art. 51. The results of the design review shall be documented in the design history file.

Art. 52. Each manufacturer shall establish and maintain procedures to ensure that the product design is correctly translated into production specifications.

Art. 53. Each manufacturer shall establish and maintain a procedure to validate the product design.

Art. 54. Design validation shall be performed under predetermined operating conditions, in the initial batch or unit production.

Art. 55. Design validation shall ensure that the product meets the user's needs and indication of use, and shall include product testing under real or simulated conditions of use.

Art. 56. Design validation shall include software validation, where appropriate.

Art. 57. The results of the design validation, including identification, methods, date and manual or electronic signature of those responsible, shall be documented in the design history file.

Art. 58. In design validation, stability studies shall be performed whenever applicable.

Art. 59. Each manufacturer shall ensure that the design is released for production only when it is approved by the persons appointed by the manufacturer.

§ 1 The appointed persons, mentioned in the caput of this article, shall review all records required for the design history file, in order to ensure that it is complete and that the final design is compatible with the approved plans, prior to its release.

§ 2 The release referred to in the caput of this article shall be documented, including the date and manual or electronic signature of the person responsible.

Art. 60. Each manufacturer shall establish and maintain procedures for identifying, documenting, validating, reviewing and approving design changes prior to their implementation, including a risk assessment within the risk management process.

Art. 61. Each manufacturer shall establish and maintain a design history file for each product.

Sole paragraph. The design history file shall contain or reference all records necessary to demonstrate that the project was developed in accordance with the approved design plan and the requirements of this Resolution.

## Section II

### Product Master Record (PMR)

Art. 62. Each manufacturer shall maintain product master records (PMRs).

Art. 63. The PMR for each product type shall include or reference the following information:

**I** - product specifications, including their respective drawings, composition, formulation, component specifications, software design specifications and their source codes;

**II** - specifications of the production process, including specifications of infrastructure, equipment, production methods and instructions, and production environmental specifications;

**III** - packaging and labeling specifications, including methods and processes used;

**IV** - inspection and testing procedures, with the respective acceptance criteria; and

**V** - methods and procedures for installation, maintenance, and technical assistance.

## CHAPTER V

### PROCESS AND PRODUCTION CONTROLS

#### Section I General Requirements

Art. 64. Each manufacturer shall design, conduct, control, and monitor all production processes in order to ensure that the product is in conformity with its specifications.

Art. 65. Each manufacturer shall establish and maintain process control procedures that describe the process controls necessary to ensure conformity with product specifications.

Sole paragraph. Process controls shall be established at any stage where deviation from product specifications may occur as a result of the manufacturing process.

Art. 66. Process controls shall include:

**I** - documented instructions, standard operating procedures, and methods that define and control the manner of production, installation, and maintenance;

**II** - monitoring and control of process parameters;

**III** - conformity with technical rules, standards, or reference codes; and **IV** - instructions for process start release.

Art. 67. The company's facilities shall be properly designed to: **I** - ensure adequate flow of people;

**II** - provide for the performance of all operations; and

**III** - prevent mix-ups or contamination of components, manufacturing materials, intermediate and finished products, and ensure the proper handling of these materials.

Art. 68. Each manufacturer shall provide suitable environmental conditions for production operations in order to prevent contamination or other adverse effects on the product.

Sole paragraph. For the purposes of the provisions in the caput of this article, the correct functioning of the established environmental control systems shall be monitored, and the corresponding records shall be maintained.

Art. 69. Each manufacturer shall establish and maintain adequate cleaning and sanitization procedures and a schedule that meets the requirements of the manufacturing process specifications.

Sole paragraph. Each manufacturer shall ensure that the personnel involved understand the cleaning and sanitization procedures.

Art. 70. Each manufacturer shall ensure that the personnel who are in contact with the product or its environment are clean, healthy, and appropriately dressed for the activity to be performed.

Art. 71. Any person who, by medical examination or by observation of supervisors, appears to be in a health condition that could affect the product, shall be removed from operations until the health condition is deemed adequate.

Sole paragraph. Personnel shall be instructed to report to supervisors when they are in a health condition that could affect the product.

Art. 72. Each manufacturer shall limit the consumption of food and beverages to specific locations so as not to affect the production areas.

Art. 73. Each manufacturer shall establish and maintain procedures to prevent contamination of equipment, components, manufacturing materials, intermediate and finished products by cleaning and disinfecting materials, including hazardous substances or contaminants generated by the manufacturing process.

Art. 74. A pest control program shall be established, and it shall be ensured that whenever chemical agents are used, these agents do not affect the quality of the product.

Art. 75. The treatment and disposal of waste, chemical effluents, and byproducts shall occur according to the applicable legislation in force.

Art. 76. Biological safety standards shall be observed in cases where a biological hazard is present.

Art. 77. Each manufacturer shall ensure conformity with applicable standards related to workers' health, including the use of personal protective equipment, that are compatible with the work processes performed.

Art. 78. Each manufacturer shall ensure that all equipment used in the manufacturing process is suitable for its intended use and properly designed, constructed, and installed for ease of maintenance, adjustment, cleaning, and use.

Art. 79. Each manufacturer shall establish and maintain a program for maintenance, adjustments, and, when necessary, cleaning of the equipment to ensure that all manufacturing specifications are met.

Sole paragraph. The maintenance program shall be in a place easily accessible to the personnel in charge of maintenance and use of the equipment.

Art. 80. The maintenance activities shall be registered, with the date they took place and the identification of the people in charge.

Art. 81. Each manufacturer shall ensure that any acceptable tolerances or inherent limitations are posted in a visible location or near equipment that requires periodic adjustment, or are readily available to personnel in charge of such adjustments.

Art. 82. Each manufacturer shall establish and maintain procedures for the use and removal of manufacturing materials to ensure that these materials are removed from the product or limited to a specified amount that does not adversely affect the quality of the product.

Art. 83. Special processes shall be conducted according to established procedures and parameters to ensure conformity with specifications.

Sole paragraph. Critical parameters of special processes shall be monitored and recorded in the product history file.

## Section II

### Controls on packaging, labeling and instructions for use

Art. 84. Each manufacturer shall establish procedures for the packaging of products in order to protect the product from any alteration, damage, or contamination during the processing, storage, handling, and distribution stages.

Art. 85. Each manufacturer shall establish and maintain procedures to ensure the integrity and prevent accidental mixing of labels, instructions for use, packaging materials, or identification tags.

Art. 86. Each manufacturer shall ensure that labels are designed, printed and, where applicable, applied so that they remain legible and adhered to the product during processing, storage, handling, and use.

Art. 87. Labels and instructions for use shall not be released for use until an authorized person has examined that they are in conformity with the information contained therein.

§ 1 Approval of labels and instructions for use shall be documented in the product history file, including date, name, and manual or electronic signature of the person responsible.

§ 2 In the case of importers, the documentation of the approval referred to in § 1 of this article can be registered in a document of its own instead of the product history file.

### Section III Inspection and Testing

Art. 88. Each manufacturer shall establish and maintain procedures for inspection, tests, or other means of verification to ensure conformity with specified requirements throughout the manufacturing chain.

Art. 89. Conformity with specified requirements shall be assessed on the receipt of components and manufacturing materials, as well as at intermediate stages of production and upon final acceptance of the finished product.

§ 1 The results of the activities referred to in the caput of this article shall be documented, including their conclusion - acceptance or rejection.

§ 2 The authority and responsibility for performing the activities referred to in the caput of this article shall be defined by the manufacturer.

Art. 90. Components and manufacturing materials received, as well as components, intermediate products and returned products, shall not be used or processed until they their conformity with the established requirements have been verified.

Art. 91. Each manufacturer shall establish and maintain procedures for retaining components, manufacturing materials, intermediate products, and returned products until inspections, tests, or other established verifications have been performed and documented.

Art. 92. Finished products can only be released when the activities specified in the PMR have been completed and the associated documentation and data have been reviewed, by an appointed person, to ensure that all acceptance criteria have been met.

Sole paragraph. The release of finished products shall be documented, including the date and manual or electronic signature of the person responsible.

### Section IV

#### Test and measurement equipment

Art. 93. Each manufacturer shall ensure that all test and measurement equipment, including mechanical, automated, or electronic equipment, is suitable for its intended purpose and capable of producing valid results.

Art. 94. Each manufacturer shall establish and maintain procedures to ensure that the test and measurement equipment is routinely calibrated, inspected, and controlled.

Art. 95. Each manufacturer shall establish and maintain calibration procedures that include specific guidelines and limits for accuracy and precision, as well as prescriptions for corrective action when the limits for accuracy and precision are not met.

Art. 96. Calibration shall be performed by personnel with the necessary education, training, practice, and experience.

Art. 97. Test and measurement equipment shall be identified as to provide for determining the calibration status.

Art. 98. Each manufacturer shall establish and maintain calibration standards for measurement equipment that are traceable to official national or international standards.

Sole paragraph. When no applicable calibration standard is available, the manufacturer shall establish and maintain its own standard.

Art. 99. Each manufacturer shall ensure the maintenance of records of the dates of calibration, measurements obtained, person in charge of such task, and the next date for this operation.

§ 1 The records mentioned in the caput of this article shall be maintained by the manufacturer.

§ 2 The records mentioned in the caput of this article shall be available to the personnel using the equipment and to those responsible for its calibration.

Art. 100. Each manufacturer shall establish and maintain procedures to ensure that the handling, preservation, and storage of test, inspection, and measurement equipment are performed as to preserve its accuracy and suitability for use.

Art. 101. Each manufacturer shall protect the inspection, test, and measurement facilities and equipment, including test hardware and software, from adjustments that could invalidate the calibration.

Art. 102. Each manufacturer shall establish procedures to assess the impact of previous measurement results when non-conformities in the measurement and test equipment are found, and the result of this assessment shall be documented.

#### Section V Validation

Art. 103. Special processes shall be validated according to previously established protocols and the results of the validations, including the date and identification of the person responsible for their approval, shall be recorded.

Art. 104. Analytical methods, ancillary process support or environmental control systems, automated computerized systems, and software that may adversely affect product quality or the quality system shall be validated.

Art. 105. Each manufacturer shall establish procedures to periodically verify its validated processes, analytical methods, ancillary process support or environmental control systems, automated computerized systems, and software and, where applicable, establish the frequency for revalidation.

Art. 106. Each manufacturer shall establish a change control procedure to control changes in ancillary systems, software, equipment, processes, methods, or other changes that could influence product quality, including a risk assessment within the risk management process.

§ 1 The procedure referred to in the caput of this article shall describe the actions to be taken, including, when applicable, the need for requalification or revalidation.

§ 2 The changes mentioned in the caput of this article shall be formally requested, documented, and approved prior to implementation.

### CHAPTER VI

#### HANDLING, STORAGE, DISTRIBUTION AND TRACEABILITY

##### Section I

###### Handling

Art. 107. Each manufacturer shall establish and maintain procedures to ensure that reversals (exchanges), damage, deterioration or other adverse effects affecting components, manufacturing materials, intermediate products, finished products and quality control samples do not occur during any stage of handling.

Art. 108. Each manufacturer shall establish and maintain procedures to identify conformity of components, manufacturing materials, intermediate products and finished products, in order to ensure that only those duly approved are used or distributed.

Art. 109. The procedures mentioned in art. 107 and art. 108 of this Resolution shall ensure that components, manufacturing materials, intermediate products or finished products:

I - are not used or distributed, when the quality or the condition of suitability for use deteriorates over time;

II - closest to their expiry date are distributed or used first; and III - are not distributed or used when expired.

## Section II

### Storage and Distribution

Art. 110. Each manufacturer shall establish and maintain procedures for identifying components, manufacturing materials, intermediate products, finished products, and quality control samples, in order to prevent reversals (exchanges) during storage.

Art. 111. Components, manufacturing materials, intermediate products, finished products, and quality control samples shall be stored under physical and environmental conditions that prevent damage, deterioration, or other adverse effects during the period in which they remain in storage.

Art. 112. Each manufacturer shall maintain distribution records, which include or refer to:

I - name and address of the consignee;

II - identification and quantity of products shipped, with shipping date; and III - any numerical control used for traceability.

## Section III

### Identification, traceability and non-conformities

Art. 113. Each manufacturer shall establish and maintain procedures for identifying components, manufacturing materials, intermediate products and finished products during all stages of storage, production, distribution and installation to avoid confusion and to ensure correct service of orders.

Art. 114. Each manufacturer shall identify each unit, batch, or shipping of products with a serial or batch number, and such identification shall be entered in the product history file.

Sole paragraph. Each manufacturer shall identify each unit, batch, or shipping of products with a serial or batch number, and such identification shall be entered in the product history file.

Art. 115. Each manufacturer shall establish and maintain procedures to ensure that components, manufacturing materials, intermediate products, finished products, and returned products, which are not in conformity with established requirements, are not inadvertently used or installed.

Sole paragraph. The procedures referred to in the caput of this article shall contain prescriptions for the identification, documentation, assessment, separation, and disposal of non-conforming components, manufacturing materials, intermediate products, and finished products.

Art. 116. The assessment of non-conforming components, manufacturing materials, intermediate products, and finished products shall include the need for investigation and notification of persons and/or organizations involved in the non-conformity.

Sole paragraph. The results of the assessments and any investigations referred to in the caput of this article shall be recorded.

Art. 117. Responsibility for review and authority to dispose of non-conforming components, manufacturing materials, intermediate products, finished products, and returned products shall be defined.

Art. 118. The process of reviewing and disposing of non-conforming components, manufacturing materials, intermediate products, finished products, and returned products shall be described in an established procedure.

§ 1 The disposal of the products mentioned in the caput of this article shall be documented, and a record of the justification and manual or electronic signature of the person responsible for the disposal shall be maintained.

§ 2 In case of authorization for the use of the products mentioned in the caput of this article, the decision shall be based on a technically justifiable risk assessment.

Art. 119. Each manufacturer shall establish and maintain procedures for the rework, reinspection, and re-assessment of intermediate or finished products after rework to ensure that they meet their original specifications.

Sole paragraph. The activities related to rework and re-assessment of the products referred to in the caput of this article, including problems arising from rework, shall be documented in the product history file.

## CHAPTER VII

### CORRECTIVE AND PREVENTIVE ACTIONS

#### Section I General Requirements

Art. 120. Each manufacturer shall establish and maintain procedures for:

**I** - analyzing processes, work operations, quality audit reports, quality records, technical assistance records, complaints, returned products, and other sources of quality data to identify existing and potential causes of non-conformities related to the product, process, or quality system;

**II** - investigate the cause of non-conformities related to the product, process or quality system;

**III** - identify and carry out the necessary actions to prevent the occurrence, correct what has happened, and prevent the recurrence of non-conformities;

**IV** - verify or validate the effectiveness of the corrective action and ensure that it does not adversely affect the product;

**V** - record the activities related to corrective and preventive actions;

**VI** - ensure that information regarding quality problems or non-conforming products is properly disseminated to those directly involved in maintaining product quality or preventing such problems from occurring;

**VII** - submit relevant information regarding identified quality problems and preventive and corrective actions to the executive management for awareness and follow-up, as well as to the competent health authority, when applicable; and

**VIII** - determine the recall of products and other field actions relevant in the case of products already distributed.

§ 1 The analysis referred to in item I of this article shall be based on a valid statistical technique for detecting recurring quality problems, when applicable.

§ 2 To meet the provisions of item IV of this article, any change made, when applicable, shall follow established change control procedures and validation protocols.

#### Section II

### Complaints Management

Art. 121. Each manufacturer shall establish and maintain procedures for receiving, examining, assessing, investigating and filing complaints, ensuring that:

**I** - complaints are received, documented, examined, assessed, investigated, and filed by a formally appointed unit;

**II** - complaints are notified to the competent health authority, when applicable;

**III** - complaints are examined to verify whether it is necessary to conduct an investigation;

**IV** - all complaints involving possible non-conformity of the product are examined, assessed and investigated;

**V** - records are maintained, when an investigation is conducted, containing the following information:

- a)** product name;
- b)** date of receipt of the complaint;
- c)** any control number used;
- d)** name, address and telephone number of the claimant;
- e)** nature of the complaint; and
- f)** date and results of the investigation, including actions taken.

§ 1 When the investigation mentioned in item III of this article is not conducted, the unit shall record the reason why the investigation was not conducted and the name of those responsible for the decision not to investigate.

§ 2 When any complaint referred to in item IV of this article is related to death, injury, or threat to the public health, it shall be immediately examined, assessed, and investigated.

### Section III

#### Quality Audit

Art. 122. Each manufacturer shall conduct and document quality audits to assess conformity of the quality system with the established requirements.

Art. 123. Quality audits shall be conducted by people who are demonstrably trained, in accordance with established auditing procedures, but are not directly responsible for the matters being audited.

Sole paragraph. Those responsible for conducting the quality audit shall not be directly responsible for the matters being audited.

Art. 124. Those responsible for the audited areas shall be notified regarding any non-conformities identified.

### CHAPTER VIII

#### INSTALLATION AND TECHNICAL ASSISTANCE

Art. 125. Each manufacturer shall establish and maintain adequate instructions and procedures for the correct installation of the products.

Art. 126. At the time of installation of the product, by the manufacturer or its authorized representative, it shall be verified that the product operates according to established criteria.

Sole paragraph. The results of the verification referred to in the caput of this article shall be recorded.

Art. 127. Each manufacturer shall ensure that installation instructions and procedures are distributed with the product, or are otherwise available to the person responsible for installing the product.

Art. 128. Each manufacturer shall establish and maintain procedures to ensure that finished products submitted to technical assistance by the manufacturer or its representative meet the specifications.

Art. 129. Each manufacturer shall establish and maintain procedures to ensure that technical assistance records are maintained and that they contain:

- I** - the product purpose of the service;
- II** - the control number used;

**III** - the date the service was performed;

**IV** - the identification of the service provider; **V** - the description of the service performed; and

**VI** - the results of inspections and tests for service approval.

Art. 130. Each manufacturer shall periodically review the technical assistance records.

Sole paragraph. In cases in which the analysis referred to in the caput of this article identifies failure trends that pose danger, or records involving death or serious injury, corrective/preventive action shall be initiated according to the requirements of this Resolution.

## CHAPTER IX

### STATISTICAL TECHNIQUES

Art. 131. Each manufacturer shall establish and maintain procedures to identify valid statistical techniques to verify quality system performance and process capability to meet established specifications.

Art. 132. Sampling plans shall be formalized in writing and based on valid statistical logic.

Art. 133. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are suitable for their intended use and that they are reviewed regularly.

Art. 134. The revision of sampling plans shall take into account the occurrence of product non-conformities, quality audit reports, complaints, and other indicators.

## CHAPTER X FINAL

### PROVISIONS

Art. 135. The documentation that proves compliance with the requirements set forth in this Resolution shall be available whenever requested by health surveillance agencies.

Art. 136. Non-compliance with the provisions contained in this Normative Instruction constitutes a health infraction, pursuant to Law No. 6.437, of August 20, 1977, without prejudice to the applicable civil, administrative and criminal liabilities.

Art. 137. The following are hereby revoked:

**I** - the Collegiate Board of Directors Resolution - RDC No. 16, of March 28, 2013, published in the Official Federal Gazette No. 61, of April 1, 2013, Section 1, p. 75; and

**II** - the Normative Instruction - IN No. 8, of December 26, 2013, published in the Official Federal Gazette No. 252, of December 30, 2013, Section 1, p. 758.

Art. 138. This Resolution enters into force on May 2, 2022.

**ANTONIO BARRA TORRES**

This content does not replace the text published in the certified version.

**COLLEGIATE BOARD  
RESOLUTION - RDC No.16 OF MARCH 28, 2013**

Approves the Technical Regulation for Good Manufacturing Practices of Medical Devices and In Vitro Diagnostic Devices and gives other provisions.

The Collegiate Board of the National Health Surveillance Agency, in the exercise of the attributions granted by item IV of Article 11 of the Regulation approved by Decree No. 3029 of April 16, 1999, and in view of the provisions of item II and 1<sup>st</sup> and 3<sup>rd</sup> Paragraph of Article 54 of the Internal Rules approved pursuant to Annex I of the ANVISA Ordinance No. 354, of August 11, 2006, republished in the Federal Official Gazette of August 21, 2006, in a meeting held on March 7, 2013,

Whereas the Law No. 6360 of September 23, 1976 and its regulations, the Decree No. 79094 of January 5, 1977;

Whereas the need to internalize the Resolution MERCOSUL / GMC / RES. No. 20/11, which approved the "MERCOSUL Technical Regulation of Good Manufacturing Practices of Medical Devices and In Vitro Diagnostic Devices (revocation of Resolution GMC No. 04/95, 38/96, 65/96 and 131/96)";

Whereas the regulation of Good Manufacturing Practices of Medical Devices and In Vitro Diagnostic Devices shall seek quality assurance, safety and efficacy of the products marketed in Brazil;

Whereas it is fundamental to promote the improvement of national systems aimed to regulate and control Medical Devices and In Vitro Diagnostic Devices;

Adopts the following Collegiate Board Resolution and I, the President-Director, determine its publication:

Article 1 - To approve the "Technical Regulation of Good Manufacturing Practices of Medical Devices and In Vitro Diagnostic Devices", which is included as Annex and is part of this Resolution.

Sole paragraph. This regulation incorporates to the national legal system the Resolution GMC MERCOSUL No. 20/2011 "MERCOSUL Technical Regulation on Good Manufacturing Practices of Medical Devices and In Vitro Diagnostic Devices (revocation of Resolution GMC Nos. 04/95, 38/96, 65/96 and 131/96)".

Article 2 - Revokes the Ordinance No. 686 of August 27, 1998; Resolution RDC No. 59 of June 27, 2000; and Resolution RDC No. 167 of July 2, 2004.

Article 3 - Distributors and storage agents of Medical Devices and In Vitro Diagnostic Devices shall meet the requirements of this Resolution, as applicable.

Article 4 - It is granted 180 days period from the date of incorporation of the normative instrument, in order to adopt necessary measures for the application of the Technical Regulation.

Article 5 - This Resolution enters into force on the date of its publication.

**DIRCEU BRÁS APARECIDO BARBANO**

**ANNEX**

**TECHNICAL REGULATION OF GOOD MANUFACTURING PRACTICES OF MEDICAL DEVICES AND  
IN VITRO DIAGNOSTIC DEVICES**

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**CHAPTER 9 - STATISTICAL TECHNIQUES****CHAPTER 1 - GENERAL PROVISIONS****1.1 - Applicability**

1.1.1. This Technical Regulation establishes requirements applicable to the manufacture of Medical Devices and In Vitro Diagnostic Devices. These requirements describe the Good Manufacturing Practices (GMP) for methods and controls used in the design, purchasing, manufacturing, packaging, labeling, storage, distribution, installation, and servicing of Medical Devices and In Vitro Diagnostic Devices. The requirements of this Technical Regulation are intended to ensure that Medical Devices and In Vitro Diagnostic Devices are safe and effective.

1.1.1.2. The requirements of this Technical Regulation are applicable to manufacturers and importers of Medical Devices and In Vitro Diagnostic Devices that are marketed in Brazil.

1.1.1.3. Whenever the manufacturer understands that some of the requirements of this resolution are not applicable to its processes, it shall document the justification for such understanding.

1.1.1.4. Importers of Medical Devices and In Vitro Diagnostic Devices shall meet the requirements of this Resolution, as applicable.

**1.1.2. Definitions**

For the purposes of this Technical Regulation, it is understood by:

1.2.1. **Servicing:** Maintenance or repair of a finished product in order to return it to its specifications.

1.2.2. **Quality audit:** means an established, systematic, and independent examination of the manufacturer quality system, that runs at regular intervals and with sufficient frequency to ensure that both the activities of the quality system and its results meet the procedures specified in its quality system, that these procedures are efficiently implemented and that are suitable for achieving the goals of the quality system. The quality audit is different from other activities of the quality system required by this Technical Regulation.

1.2.3. **Component:** raw material, substance, piece, part, software, hardware, package, label or instructions for use used during the manufacture of a medical device and in vitro diagnostic device, intended to be included as part of the finished product.

1.2.4. **Design input:** descriptions of physical attributes, indication of use, performance, compatibility, safety, efficacy, ergonomics, usability, information from previous designs and results of risk management, among other requirements of a medical device or in vitro diagnostic device that are used as the basis for the design.

1.2.5. **Design output:** result of the work in each phase of the design and its final result. The finished design output is the basis for the device master record (DMR)..

1.2.6. **Damage:** physical lesion or injury to the health of a person, or injury to property or environment.

1.2.7. **Specifications:** requirements to which products, components, production activities, servicing, services, quality system or any other activity shall conform.

1.2.8. Establish: define, document (by written or electronic means) and implement.

1.2.9. Manufacturer: any person who designs, manufacture, assemble or process a finished product, including those who perform functions by contract for sterilizing, labeling, packaging.

1.2.10. Executive Management: high management of the company, responsible for providing resources, with authority to establish or amend the policy and the quality system of the company.

1.2.11. Risk Management: systematic application of policies, procedures and practices of managing analysis, assessments, controls, and monitoring of risks associated with a particular finished product or process.

1.2.12. Lot or batch: quantity of a product produced in a manufacturing or sterilization cycle, whose fundamental feature is the homogeneity.

1.2.13. Manufacture material: material or substance employed in the process of manufacture or to facilitate this process, including cleaning agents, mold detach agents, lubricating oils, sterilizing agents, or other byproducts of the manufacturing process.

1.2.14. Non-conformity: failure to comply with a previously specified requirement.

1.2.15. Serial number or batch: combination of different letters or numbers, or both, from which can be determined the full history of purchasing, manufacturing, packaging, labeling and distribution of finished products.

1.2.16. Hazard: Potential source of harm.

1.2.17. Quality policy: all intentions and guidelines of an organization, with respect to quality, expressed by the executive management.

1.2.18. Special process: any process whose outcome cannot be fully verified by inspections and subsequent tests.

1.2.19. Production: all operations involved in the manufacture of a particular product, from receipt of components, through processing and packaging, up to obtaining the finished product.

1.2.20. Finished product: any product or accessory suitable for use, packaged, labeled.

1.2.21. Quality: all aspects and characteristics enabling a medical device or in vitro diagnostic device to meet the requirements of use suitability, including safety and performance.

1.2.22. Complaints: written, oral or electronic communication regarding the non-acceptance of identity, quality, durability, reliability, safety, effectiveness or performance of a product.

1.2.23. Record: physical or electronic document, which evidence data, facts, specific events and results achieved in relation to compliance of procedures and standards of the quality system.

1.2.24. Device history record: compilation of records containing the full production history of a finished product.

1.2.25. Design history file: compilation of documents containing the full design history of a finished product.

1.2.26. Device master record (DMR): compilation of documents containing specifications, instructions and procedures for obtaining a finished product, as well as installation, servicing and maintenance of the same.

1.2.27. Rework: partial or total manufacturing operation intended to correct a non-conformity of a component, intermediate product or finished product, so that it meets the specifications defined in the DMR

1.2.28. Design Review: documented, systematic and complete examination performed during the design development to assess the suitability to the planning and the objectives established.

1.2.29. Risk: combination between probability of occurrence and severity of damage.

1.2.30. Quality system: organizational structure, responsibilities, procedures, specifications, processes and resources needed for quality management.

1.2.31. Validation: confirmation by analysis and objective evidence that the requirements defined for a particular purpose consistently lead to the expected result. With respect to a design, it means to establish and document objective evidences that the product specifications meet the needs of the user and the intended use. With respect to a process, it means to establish and document objective evidence that the process will consistently produce a result that meets the predefined specifications.

1.2.32. Verifications: confirmation by analysis and submittal of objective evidences that the specified requirements have been met. The verification includes the process of examining the results of an activity to determine the compliance to the specifications established.

1.2.33. Shelf life: period of time estimated by the manufacturer during which the product correctly meets the functions to which it was designed.

## CHAPTER 2 - GENERAL QUALITY SYSTEM REQUIREMENTS

### 2.1. General Provisions

2.1.1. Each manufacturer shall establish and maintain a quality system to ensure that the requirements of this Technical Regulation are met and that the products produced are safe, effective and appropriate for the intended use. As part of the activities in the quality system, each manufacturer shall:

2.1.1.1. Establish and maintain effective procedures and instructions of the quality system according to the requirements of this Technical Regulation, and

2.1.1.2. Establish procedures for meeting the established legal provisions in the current health surveillance legislation.

## 2.2. Management responsibility

2.2.1. Quality Policy. The executive management of each manufacturer shall establish its quality policy and objectives, which shall be measurable and coherent with the established policy. The executive management shall keep the policy at all levels of the organization. The executive management shall ensure that this policy is described in a quality manual and understood by all the employees that may affect or influence the product quality.

2.2.2. Organization. Each manufacturer shall establish and maintain an appropriate organizational structure, represented by organization chart, with sufficient personnel to ensure that the products are manufactured in accordance with the requirements of this Technical Regulation.

2.2.3. Responsibility and Authority. Each manufacturer shall establish at each chapter of this Technical Regulation, the responsibility, authority, and interrelationships of all personnel involved with managing, performing, and checking the work related to quality, with the necessary independence to perform their responsibilities.

2.2.4. Resources and personnel for verification activities. Each manufacturer shall establish functions for verification activities and provide appropriate resources and designates trained personnel to perform the activities of verification.

2.2.5. Management Representative. The executive management of each manufacturer shall designate an individual and document this designation, which, regardless of other functions, will have authority and responsibility to:

2.2.5.1. Ensure that quality system requirements are established and maintained in accordance with this Technical Regulation;

2.2.5.2. Report the performance of the quality system to the executive management for review and provide information on improvements of the quality system.

2.2.6. Management review. The executive management of each manufacturer shall evaluate the suitability and effectiveness of the quality system at defined intervals and sufficient frequency to ensure that the quality system meets the requirements of this Technical Regulation and complies with the objectives of quality policy established. The management review shall be conducted according to established review procedures and the results of each quality system review shall be documented. Audit results, post-market information, process performance and product conformity, status of corrective and preventive actions, changes that may affect the quality system or product conformity, regulatory requirements, and other data shall be considered as inputs for management reviews.

## 2.3. Personnel

2.3.1. General instructions. Each manufacturer shall have sufficient personnel with instruction, expertise, training and practice compatible with the attributes of the function, in order to insure that all the activities provided for in this Technical Regulation are properly performed. It shall be documented authority, responsibility and requirements necessary for the various functions of the company..

2.3.2. Training. Each manufacturer shall ensure that all personnel are adequately trained to perform the tasks assigned to them. Training shall be conducted in accordance with procedures established by qualified persons to ensure that employees have a proper understanding on their regular functions and on the requirements of these Technical Regulations applicable to their functions. As part of their training, all employees shall be warned of defects in products that may occur as a result of improper performance of their specific functions. The employee training shall be documented.

2.3.3. Consultants. Each manufacturer shall ensure that any consultant guiding employees on methods or controls used for designing, purchasing, manufacturing, packaging, labeling, storage, installation or servicing of products have sufficient qualifications (instructions, training and expertise) to advise on matters for which he was hired. The hiring of consultants will be conducted in accordance with the requirements of purchase control provided for in this Technical Regulation.

## 2.4. Risk Management

2.4.1. Each manufacturer shall establish and maintain an ongoing process of risk management which involves the entire product lifecycle, from the conception to decommission, to identify the hazards associated to a medical device

or in vitro diagnostic device, to estimate and evaluate the risks involved, to control the risks and evaluate the effectiveness of established controls. This program shall include the following elements: analysis, assessment, control and risk monitoring.

2.4.2. The executive management shall designate responsible personnel, establish the policy to determine the risk acceptability criteria, and determine a periodic review of risk management activities to ensure its adequacy and effectiveness.

#### 2.5. Purchasing Controls

2.5.1. Each manufacturer shall establish and maintain procedures to ensure that the components, manufacturing materials, and finished products manufactured, processed, labeled, and packaged by third parties or stored by them under contract, comply with the specifications. Each manufacturer shall also ensure that the services performed by third parties comply with the established specifications.

2.5.2. Assessment of suppliers of products and services. Each manufacturer shall establish and maintain, according to the impact on the quality of the final product, criteria for assessing suppliers, specifying the requirements, including quality requirements, which they shall meet.

2.5.3. Each manufacturer shall evaluate and select potential suppliers according to their ability to meet established requirements, keeping records of approved suppliers. Assessment records shall be kept, as well as their results.

2.5.4. Purchase records. Each manufacturer shall maintain records of purchase orders that clearly describe or make reference to specifications, including quality requirements for components, manufacturing materials, finished products or services requested or contracted. The approval of orders, including the date and manual or electronic signature of the responsible, shall be documented.

2.5.5. An agreement shall be documented in which the suppliers undertake to notify the manufacturer about any change in the product or service, so that the manufacturer can determine if the change affects the quality of the finished product.

2.5.6. Each manufacturer shall review and approve the purchase documents before their release.

### CHAPTER 3 - QUALITY DOCUMENTS AND RECORDS

#### 3.1. General requirements.

3.1.1. Each manufacturer shall establish and maintain procedures for document control to ensure that all documents required in this Technical Regulation are correct and appropriate for the intended use, and are understood by all employees who may affect or influence the quality of a product.

3.1.2. Approval and issuance of documents. Each manufacturer shall designate persons to evaluate and approve all documents established in this Technical Regulation for adequacy before its issuance. The approval, including date and manual or electronic signature of the responsible for approving the documents shall be documented.

3.1.3. Distribution of documents. The manufacturer shall insure that all documents are updated and available at the sites of use and that all unnecessary or obsolete documents are removed from use, or protected from unintentional use.

3.1.4. Changes to documents. Changes to specifications, methods or procedures related to the quality system shall be evaluated, documented, reviewed, and approved by persons whose function and level of responsibility are equivalent to those who performed the original revision and approval.

3.1.5. Records of changes to documents. Each manufacturer shall maintain records of changes to documents, including a description of the change, identification of the changed documents and the affected documents, identification of the responsible person, date of approval and date on which the change shall enter into force. A list of valid documents shall be maintained in order to identify their current status and ensure that only updated and approved documents are in use.

3.1.6. Documents and Records Archive. All quality documents and records shall be legible and be stored so as to minimize damage, prevent losses, and promote quick recovery. All documents and records electronically filed shall have backups.

3.1.6.1. Confidentiality. The documents and records considered as confidential by the manufacturer may be marked to alert the competent health authority;

3.1.6.2. Period of retention of documents and records: all the required documents and records related to a product shall be maintained for a period of time equivalent to the shelf life of the product, but in no case less than two years from the date of its distribution.

#### 3.2. Device history record.

3.2.1. Each manufacturer shall maintain device history records. Each manufacturer shall establish and maintain procedures to ensure that the device history records are kept for each batch or series to demonstrate the products were manufactured according to the device master record and the requirements of this Technical Regulation. The device history record shall contain or make reference to the following information:

- 3.2.1.1. Manufacture Date;
- 3.2.1.2. Components used;
- 3.2.1.3. Quantity manufactured;
- 3.2.1.4. Results of tests and inspections;
- 3.2.1.5. Special processes parameters;
- 3.2.1.6. Quantity released for distribution;
- 3.2.1.7. Labeling;
- 3.2.1.8. Identification of serial number or batch of the device; and
- 3.2.1.9. final release of the device.

3.3. Inspections and tests records.

3.3.1. Each manufacturer shall maintain records of results of established tests and inspections, when directly related to critical quality attributes of the product. These records shall include acceptance criteria, results, equipment / instrument used, and date and manual or electronic signature of the responsible.

## CHAPTER 4 - DESING CONTROL AND DEVICE MASTER RECORD (DMR)

### 4.1. Design Control

4.1.1. General Instructions. Each manufacturer shall establish and maintain procedures to control product design to ensure that the specified requirements for the design are met.

4.1.2. Design planning and development. Each manufacturer shall establish and maintain plans that describe or make reference to design and development activities and the responsible for each activity. The plans shall describe or make reference to design development activities, including any interaction between different organizational and technical groups that may have some interface with the design. The plans shall be evaluated, updated, and approved as the design development progresses.

4.1.3. Design input. Each manufacturer shall establish and maintain procedures to ensure that the requirements relating to a product are appropriate and meet its intended use, including the needs of the user and patient and applicable legal and regulatory requirements. Procedures shall include a mechanism by which incomplete, ambiguous or conflicting requirements are identified and handled. The design input shall be documented, evaluated and approved by a designated qualified person. The approval of requirements, including the date and manual or electronic signature of the responsible for the approval, shall be documented.

4.1.4. Design verification. Each manufacturer shall establish and maintain procedures for product design verification . The design verification shall be performed by designated personnel and shall ensure that the design output meets the input. The results of design verification, including the identification of the design verified, verification methods, date and name of the person responsible for the verification, shall be documented in the design history file.

4.1.5. Design output. Each manufacturer shall establish and document the design output in order to allow the assessment of design's compliance to the requirements established as input. The design output shall meet the requirements of the input, and shall include the acceptance criteria and identify the design features that are fundamental to the intended use of the product. These shall be documented, reviewed and approved prior to release.

4.1.6. Design Review. Each manufacturer shall establish and maintain procedures to ensure that the assessments of design results are planned, conducted and documented in the various stages of design development. The procedures shall ensure that representatives from all functions directly related to the design stage being reviewed, as well as the individuals from related areas and experts needed, are involved. The results of design review shall be documented in the device history record.

4.1.7. Design Transfer. Each manufacturer shall establish and maintain procedures to ensure that the product design is correctly translated into production specifications.

4.1.8. Design validation. Each manufacturer shall establish and maintain procedure to validate the product design. The design validation shall be performed under pre-determined operation conditions, in the initial production of a batch or unit. The design validation shall ensure that the product meets the needs of the user and indication of use, and shall include tests of the products under real or simulated conditions of use. The design validation shall include software validation when appropriate. The results of design validation, including its identification, methods, data and manual or

electronic signature of the responsible shall be documented in the design history file. Stability studies shall be conducted whenever applicable.

4.1.9. Design release. Each manufacturer shall ensure the design will not be released for production until its approval by the persons assigned by the manufacturer. The persons assigned shall review all records required to the design history file in order to ensure it is complete and the final design is compatible with the approved plans, prior to its release. This release, including date and manual or electronic signature of the responsible shall be documented.

4.1.10. Design changes. Each manufacturer shall establish and maintain procedures to identify, document, validate, review and approve design changes before its implementation, including an assessment of the risks within the risk management process.

4.1.11. Design history file. Each manufacturer shall establish and maintain a design history file for each product. The design history file shall contain or make reference to all records necessary to demonstrate that the design was developed in accordance to the approved design plan and the requirements of this Technical Regulation.

#### 4.2. Device master record (DMR)

4.2.1. Each manufacturer shall maintain device master records (DMR's). The DMR for each type of product shall include or make reference to the following information:

4.2.1.1. Product specifications, including the corresponding drawings, composition, formula, components specifications, and software design specifications, and its source codes;

4.2.1.2. Production process specifications, including infrastructure specifications, equipment, production methods and instructions, and environmental specifications of production;

4.2.1.3. Packaging and labeling specifications, including methods and processes used;

4.2.1.4. Procedures for inspecting and testing with the respective acceptance criteria; and

4.2.1.5. Methods and procedures for installation, maintenance, and servicing.

### CHAPTER 5 - PROCESS AND PRODUCTION CONTROLS

#### 5.1. General Instructions

5.1.1. Each manufacturer shall design, conduct, control and monitor all production processes in order to ensure that the product comply with the specifications. Where any deviation in the product specifications may occur as a result of the manufacturing process, the manufacturer shall establish and maintain procedures of process control, which describe any process controls necessary to ensure compliance to the specification. The process controls shall include:

5.1.1.1. Documented instructions, standard operating procedures, and methods defining and controlling the method of production, installation and maintenance;

5.1.1.2. Monitoring and control of process parameters;

5.1.1.3. Compliance to technical rules, standards or reference codes; and

5.1.1.4. Instructions for releasing the beginning of the process;

5.1.2. The company facilities shall be properly designed to provide the performance of all operations, to prevent exchanges or contamination of components, manufacturing materials, intermediate products, and finished products, and ensure the proper handling thereof, including proper flow of people.

5.1.3. Environmental Control. Each manufacturer shall provide appropriate environmental conditions to production operations in order to prevent contamination or other adverse effects on the product. The correct functioning of established environmental control systems shall be monitored, keeping the corresponding records.

5.1.3.1. Clean and sanitization. Each manufacturer shall establish and maintain appropriate cleaning and sanitization procedures, as well as a program that meet the requirements of manufacturing process specifications. Each manufacturer shall insure that the employees involved understand these procedures.

5.1.3.2. Personal health and hygiene. Each manufacturer shall ensure that the employees and or others who are in contact with the product or with the environment are clean, healthy, and appropriately dressed for the activity to be performed. Any person who, by medical examination or observation of supervisors, seems to be in a health condition that may affect the product, shall be removed from the operations. Each manufacturer shall instruct the personnel to report such conditions to the supervisors.

5.1.3.3. Personnel habits. Each manufacturer shall limit the consumption of foods and beverages to specific locations in order not to affect the production areas.

5.1.3.4. Contamination control. Each manufacturer shall establish and maintain procedures to prevent the contamination of equipment, components, manufacturing materials, intermediates and finished products by cleaning and disinfection materials, including hazardous substances or contaminants generated by the production process. A pest control program shall be established, and whenever chemical agents are used, the company shall ensure they do not affect the product quality.

5.1.3.5. Removal of garbage and chemical waste. The treatment and destination of garbage, chemical wastes and by-products shall occur in accordance with the applicable legislation in force.

5.1.3.6. Biological safety standards shall be observed in the cases where there is biological risk.

5.1.4. Worker health. Each manufacturer shall ensure the compliance to applicable standards related to the health of workers, including the use of personal protective equipment, which is compatible with the labor processes performed.

5.1.5. Equipment. Each manufacturer shall ensure that all equipment used in the manufacturing process are appropriate for the intended use and properly designed, constructed, and installed to facilitate the maintenance, adjustments, cleaning and use.

5.1.5.1. Maintenance program. Each manufacturer shall establish and maintain a program for maintenance, adjustments, and, when appropriate, cleaning of equipment to ensure that all manufacturing specifications are being achieved. The maintenance program shall be in a place of easy access to the personnel responsible for the maintenance and use of the equipment. A record of the maintenance activities shall be performed, with date of performance and identification of the persons in charge.

5.1.5.2. Adjustments. Each manufacturer shall ensure that any acceptable tolerances or inherent limitations are attached in a visible place or near the equipment requiring periodic adjustment, or are easily available to the personnel in charge of these adjustments.

5.1.5.3. Manufacturing materials. Each manufacturer shall establish and maintain procedures for use and removal of manufacturing materials, to ensure that such materials are removed from the product or limited to a specified amount that does not adversely affect the product quality.

5.1.6. Special processes shall be conducted in accordance with established procedures and parameters in order to assure the compliance to the specifications. The critical parameters shall be monitored and recorded in the device history record.

## 5.2. Controls of packaging, labeling and instructions for use.

5.2.1. Product packaging. Each manufacturer shall establish procedures for product packaging in order to protect the product from any change, damage or contamination during the processing, storage, handling, and distribution processes.

### 5.2.2. Product labeling.

5.2.2.1. Each manufacturer shall establish and maintain procedures to ensure the integrity and prevent accidental mixing of labels, instructions for use, packaging materials or identification tags.

5.2.2.2. Each manufacturer shall ensure that labels are designed, printed, and, if applicable, applied so as to remain legible and attached to the product during processing, storage, handling, and use steps.

5.2.2.3. Inspection of labels and instructions for use. The labels and instructions for use shall not be released for use until an authorized person has examined their compliance to the information contained therein. The approval, including date, name and manual or electronic signature of the responsible, shall be documented in the device history record.

## 5.3. Inspection and tests

5.3.1. General Instructions. Each manufacturer shall establish and maintain procedures for inspections, tests or other means of verification, so as to ensure compliance to the specified requirements in the entire production chain. The results of the acceptance activities during the receipt of components and manufacturing materials, as well as intermediate production stages and final acceptance of the finished product, shall be documented, including its conclusion (accepted or rejected).

5.3.2. The authority and responsibility for such activities shall be defined by the manufacturer.

5.3.3. The components and manufacturing materials received, as well as components, intermediate products, and returned products shall not be used or processed until the verification of their compliance to the requirements. Each manufacturer shall establish and maintain procedures for the retention of components, manufacturing materials, intermediate products, and returned products until the inspections, tests or other verification have been completed and documented.

5.3.4. The finished products shall not be released until the activities specified in the DMR have been completed and until the documentation and the associated data have been reviewed by a person assigned to ensure that all acceptance criteria have been met. The release, including the date and manual or electronic signature of the responsible shall be documented.

## 5.4. Inspection, measurement and testing equipment.

5.4.1. Each manufacturer shall ensure that all measurement and testing equipment, including mechanical, automated or electronic equipment, are suitable for its intended purposes and are capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected and controlled. The measurement equipment shall be identified so as the calibration status can be determined.

5.4.2. Calibration. Each manufacturer shall establish and maintain calibration procedures that include special guides and precision and accuracy limits, as well as prescriptions for corrective actions when the precision and accuracy limits are not achieved. The calibration shall be performed by personnel who have the necessary instruction, training, practice and expertise.

5.4.3. Calibration standards. Each manufacturer shall establish and maintain calibration standards for measurement equipment that are traceable to the official national or international standards. If there is no applicable standard available, the manufacturer shall establish and maintain its own standard.

5.4.4. Calibration records. Each manufacturer shall insure the maintenance of calibration records, including dates, measurements obtained, employee in charge of this task, and the next date for this operation. Records shall be maintained by the manufacturer and shall be available for the personnel using this equipment and for those responsible for calibrating it.

5.4.5. Maintenance. Each manufacturer shall establish and maintain procedures to ensure that the handling, preservation, and custody of equipment for testing, measuring, and inspecting are performed in order to preserve its precision and suitability for use.

5.4.6. Facilities. Each manufacturer shall protect the facilities and equipment for inspection, testing, and measurement, including hardware and test software, from adjustments that would invalidate the calibration.

5.4.7. The manufacturer shall establish procedures to assess the impact of results from previous measurements when identifying non-conformities in testing and measurement equipment. The result of the assessment shall be documented.

## 5.5. Validation

5.5.1. Special processes shall be validated according to previously established protocols. The results of validations, including the date and identification of the responsible for the approval shall be recorded.

5.5.2. Analytical methods, auxiliary systems supporting the processes or environmental control, automated computerized systems, and software that may adversely affect the quality of the product or the quality system shall be validated.

5.5.3. The manufacturer shall establish procedures to periodically verify their processes, analytical methods, auxiliary systems supporting the processes and environment control, automated computerized systems, and validated software, and, when applicable, to establish the frequency for revalidation.

5.6. Change control. The manufacturer shall establish procedures for change control in order to control the changes in auxiliary systems, software, equipment, processes, methods or other changes that may influence the quality of the products, including a risk assessment within the risk management process.

5.6.1. The procedure shall describe the actions to be taken, including, when appropriate, the need to re-qualify or revalidate.

5.6.2. The changes shall be formally requested, documented and approved before their implementation.

# CHAPTER 6 - HANDLING, STORAGE, DISTRIBUTION AND TRACEABILITY

## 6.1. Handling

6.1.1. Each manufacturer shall establish and maintain procedures to ensure inversions (exchanges), damages, deterioration or other adverse effects affecting components, manufacturing materials, intermediate products, finished products, and samples for quality control do not occur during any stage of handling.

6.1.2. Each manufacturer shall establish and maintain procedures to identify the compliance of components, manufacturing materials, intermediate products, and finished products, in order to ensure that only those duly approved are used or distributed.

6.1.3. The procedures shall ensure that when the quality or condition of suitable for use of a component, manufacturing material, intermediate product or finished product, deteriorate over time, they are not used or distributed.

6.1.4. The procedures shall ensure that components, manufacturing materials, intermediate products or finished products nearest the expiry date are distributed or used firstly, and those out of the expiry date are not distributed or used.

## 6.2. Storage

6.2.1. Each manufacturer shall establish and maintain procedures to identify the components, manufacturing materials, intermediate products, finished products, and samples for quality control, in order to prevent inversions (exchanges). These shall be stored in physical and environmental conditions that prevent damages, deterioration or other adverse effects during the period of storage.

## 6.3. Distribution

6.3.1. Each manufacturer shall maintain distribution records, including or making reference to:

6.3.1.1. Names and addresses of the consignee;

6.3.1.2. Identification and amount of products shipped, with shipment date; and

6.3.1.3. Any numerical control used for traceability.

## 6.4. Identification and traceability

6.4.1. Each manufacturer shall establish and maintain procedures for identifying components, manufacturing materials, intermediate products, and finished products during all stages of storage, production, distribution and installation in order to prevent confusion and to ensure the correct order fulfillment.

6.4.2. Each manufacturer shall identify each unit, batch or lot of products with a serial or batch number. This identification shall be recorded in the device history record.

## 6.5. Non-conforming components and products

6.5.1. Each manufacturer shall establish and maintain procedures to ensure that components, manufacturing materials, intermediate products, finished products, and returned products, which do not comply with the requirements, are not installed or used inadvertently. The procedures shall contain prescriptions to identify, document, evaluate, segregate, and dispose non-conforming components, manufacturing materials, intermediate products, and finished products. The assessment of non-conformity shall include the need for investigation and notification of those people and organizations involved in such non-conformity. The results of assessments and eventual investigations shall be recorded.

6.5.2. The responsibility for the review and the authority for the decision on non-conforming components, manufacturing materials, intermediate products, finished products, and returned products shall be defined. The review and decision process shall be described in an established procedure. The decision shall be documented and the record of the rationale and manual or electronic signature(s) of the responsible(s) shall be kept. In case of authorization of use, the decision shall be based on risk assessment technically justifiable.

6.5.3. Each manufacturer shall establish and maintain procedures for re-work, re-inspection, and re-assessment of intermediate or finished products after re-work, to ensure that they meet the original specifications. The activities related to re-work and re-assessment of the product, including problems resulting from re-work, shall be documented in the device history record.

# CHAPTER 7 - CORRECTIVE ACTIONS

## 7.1. Corrective and preventive actions.

7.1.1. Each manufacturer shall establish and maintain procedures to:

7.1.1.1. Analyze processes, work operations, quality audit reports, quality records, servicing records, complaints, returned products, and other sources of quality data in order to identify existing and potential sources of non-conformities related to the product, process or quality system. When applicable, the analysis shall be based on valid statistical technique to detect recurrent quality problems;

7.1.1.2. Investigate the source of non-conformities related to the product, process or quality system;

7.1.1.3. Identify and implement the necessary actions to prevent the occurrence, to correct the event, and to prevent the recurrence of non-conformities;

7.1.1.4. Verify or validate the effectiveness of the corrective action to ensure it does not adversely affect the product. For this purpose, any changes made, when applicable, shall observe change control procedures and validation protocols established;

7.1.1.5. Record activities related to corrective and preventive actions;

7.1.1.6. Ensure the information concerning quality issues or non-conforming products are properly disseminated to those directly involved in the maintenance of product quality or in preventing the occurrence of such problems;

7.1.1.7. Submit relevant information on quality issues identified, and preventive and corrective actions, to the executive management for information and monitoring, as well as the competent health authority, when applicable;

7.1.1.8. Determine product recalls and other field actions that are relevant for products already distributed.

### 7.2. Complaints Management.

7.2.1. Each manufacturer shall establish and maintain procedures to receive, examine, evaluate, investigate, and file complaints. Such procedures shall ensure that:

7.2.1.1. Complaints are received, documented, examined, evaluated, investigated, and filed by a formally designated unit;

7.2.1.2. When applicable, the complaints are notified to the competent health authority;

7.2.1.3. Complaints are examined to evaluate whether an investigation is necessary. When no investigation is performed, the unit shall maintain a record including the reason why the investigation has not been performed and the name of the responsible for the decision to not investigate;

7.2.1.4. Each manufacturer shall examine, evaluate, and investigate all complaints involving possible product non-conformity. Any complaints related to death, injury or threaten to public health shall be immediately reviewed, evaluated and investigated.

7.2.1.5. When an investigation is performed, a record shall be kept, containing the following information:

7.2.1.5.1. Product name;

7.2.1.5.2. Date of receipt of the complaint;

7.2.1.5.3. Any control number used;

7.2.1.5.4. Name, address and telephone number of the claimant;

7.2.1.5.5. Nature of the complaint; and

7.2.1.5.6. Date and investigation results, including the actions taken.

### 7.3. Quality Audit.

7.3.1. Each manufacturer shall conduct and document quality audits to assess the quality system compliance to the requirements established.

7.3.2. Quality audits shall be conducted by trained persons, according to audit procedures established, with no direct responsibility for the matters being audited.

7.3.3. Those responsible for the audited areas shall be notified on non-conformities identified.

## CHAPTER 8 - INSTALLATION AND SERVICING

8.1. Installation. Each manufacturer shall establish and maintain appropriate instructions and procedures to correctly install the products. When the manufacturer or his authorized representative installs a product, it shall be verified for operation according to established criteria. The results of this verification shall be recorded. The manufacturer shall ensure the installation instructions and procedures are distributed along with the product or otherwise available to the responsible for installing the product.

8.2. Servicing. Each manufacturer shall establish and maintain procedures to ensure that finished products undergoing servicing by the manufacturer or his representative meet the specifications.

8.2.1. Servicing records. Each manufacturer shall establish and maintain procedures to ensure the servicing records are maintained and identify:

8.2.1.1. Product subject of service;

8.2.1.2. Control number used;

8.2.1.3. Date of service;

8.2.1.4. Identification of service provider;

8.2.1.5. Description of service performed; and

8.2.1.6. Results of tests and inspections for approving the service.

8.2.2. Each manufacturer shall regularly review the servicing records. Where the analysis identifies failure trends, which represent hazards, or records involving death or severe injury, the corrective / preventive action shall be implemented according to the requirements of this Technical Regulation.

## CHAPTER 9 - STATISTICAL TECHNIQUES

9.1. Each manufacturer shall establish and maintain procedures for identifying valid statistical techniques to assess the performance of the quality system and capability of the process to meet the established specifications.

9.2. Sampling plans shall be formalized in writing and based on valid statistical logic. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and are regularly

reviewed. The revision of sampling plans shall consider the occurrence of non-conformities of products, quality audit reports, complaints, and other indicators.

## **RESOLUTION – RDC N. 67, OF 21 DECEMBER, 2009**

Provisions regarding post-market surveillance applicable to registration holders of health product in Brazil.

The Collegiate Board of the National Health Surveillance Agency, in the exercise of the attributions granted by the item IV of the art. 11 of the Regulation approved by Decree n° 3029 of April 16, 1999, and in view of the provisions of item II and 1<sup>st</sup> and 3<sup>rd</sup> Paragraph of Article 54 of Internal Rules approved pursuant to Annex I of the ANVISA Ordinance No. 354, of August 11, 2006, republished in the Federal Official Gazette of August 21, 2006, in a meeting held in December 16, 2009, adopts the following Board of Directors Collegiate Resolution and I, President-Director, determine its publication:

### **CHAPTER I INITIAL PROVISIONS**

#### **Section I Purpose**

Art. 1 – This Resolution establishes general requirements for post-market surveillance to be implemented by registration holders of health product based in the national territory.

Art. 2 – For the purposes of this Resolution, post-market surveillance is understood to mean a system of surveillance of adverse events and malfunctions involving health products in the post-market phase, with the view to recommend the adoption of measures to ensure the protection and promotion of the health of the population.

Art. 3 – For the purposes of this Resolution, registration holder of health products is understood to mean holder of health product registrations at ANVISA.

Sole paragraph. Registration holder is legally responsible for the product registered under its name in Brazil, and as such shall respond, to health authorities, about any malfunctions, adverse events, situations presenting a serious threat to public health, alerts, field actions, and other events that represent a health risk and that are related to its products.

#### **Section II Definitions**

Art. 4 – For the purposes of this Resolution, the following definitions are adopted:

I – alert: written communication directed at health professionals, patients, users, the regulatory sector, and general communications, having for objective to inform with respect to the risk of occurrence of adverse events in relation to a health product;

II – field action: action performed by the manufacturer or holder of a health product registration, having for objective to reduce the risk of occurrence of adverse events related to the use of a marketed health product;

III- adverse event: any undesirable effect to humans resulting from the use of products subject to health surveillance;

IV – serious adverse event: an adverse event that meets at least one of the following:

- (a) leads to death;
- (b) causes a disability or permanent damage in a structure of the body;
- (c) requires medical or surgical intervention to prevent permanent harm to a function or structure of the body;
- (d) requires hospitalization of a patient or a prolongation of hospitalization;
- (e) leads to a disturbance or risk to a fetus, fetal death, or a congenital anomaly.

V – non serious adverse event: any other adverse event not included in the definition of a serious adverse event;

VI – risk management: systemic application of policies, procedures and practices with the objective to analyse, assess and control risks;

VII – instructions for use: manuals, brochures and other documents accompanying a health product that contain technical information about the product;

VIII – notification: the act of informing health authorities, or other organizations, about the occurrence of adverse events or malfunctions involving health products, by the registration holder;

IX – health product: a product falling into one of the following two categories:

- (a) medical product – a product, such as equipment, device, material, article or system having a use or application that is medical or dental or for laboratory use, that is intended to prevent, diagnose, treat, rehabilitate, or for contraception, and that does not rely on pharmaceutical, immunological, or metabolic means to achieve its primary function in humans, but may however be assisted by such means;
- (b) *in-vitro* diagnostic product: reagents, standards, calibrators, controls, materials, articles and instruments along with their instructions for use, used to perform a qualitative, quantitative, or semi-quantitative determination on a sample derived from the human body and is not intended to perform an anatomical, physical, or therapeutic function, nor to be ingested, injected or inoculated into humans, but is to be solely used to provide information about a sample derived from a human;

X – malfunction: notification of suspected adulteration or irregularity of a product or company in relation to technical or legal aspects, and that could, or not, cause harm to individual and collective health;

XI – traceability: the ability to describe the history, application, processes and the location of a product, in a particular organization, by means of records and identification;

XII – risk: the combination of the probability of occurrence of harm and the severity of the harm;

XIII – serious threat to public health: any type of occurrence that results in an imminent risk of death, serious lesions or serious disease, that requires rapid corrective measures;

XIV – National System of Health Surveillance (SNVS): constituted of the Ministry of Health, the National Health Surveillance Agency (ANVISA), and the Health Surveillance Centres of the States, Territories, and the Federal District.

## **CHAPTER II**

### **POST-MARKET SURVEILLANCE IN THE COMPANY**

Art. 5 – The registration holder shall designate, in a written document, at least one professional with college-level training, as responsible for post-market surveillance in the company.

Art. 6 – The registration holder shall organize and implement a system of post-market vigilance in its company, in order to:

- I – predict and provide the resources necessary to fulfill the provisions of this Resolution;
- II – standardize and ensure the effective implementation of post-market surveillance processes and procedures, in accordance with the company's quality system;
- III – ensure the effective management of risks associated with its products;
- VI – ensure that all professional roles and responsibilities are formally described, communicated, and understood by persons involved in post-market surveillance activities;
- V – develop, implement, monitor, and continuously evaluate training for professionals involved in activities described in this Resolution;
- VI – make available, processes, procedures, reports and other documents related to post-market vigilance, when requested by the National System of Health Surveillance (SNVS);
- VII – receive and document information regarding malfunctions, adverse events, situations presenting a serious threat to public health, counterfeiting, alerts, and field actions related to products registered in its name;
- VIII – evaluate information regarding malfunctions, adverse events, situations presenting a serious threat to public health, counterfeiting, alerts, and field action related to products registered in its name, in order to investigate these occurrences according to the severity and risk of each situation;
- IX – notify the SNVS of malfunctions, adverse events, situations presenting a serious threat to public health, and counterfeiting related to health products, that it becomes aware of, in accordance with the requirements of Article 8 of this Resolution;
- X – maintain an up-to-date and properly documented records of notifications related to malfunctions, adverse events, situations presenting a serious threat to public health, counterfeiting, alerts, and field actions related to products registered in its name, so as to ensure traceability of the information related to post-market surveillance actions performed in the company, including the rapid retrieval of data;
- XI – present its conclusions of the investigation to the notifier of the occurrence of malfunctions, adverse events, serious threats to public health or counterfeiting of health products, in writing, when requested by the notifier or health authorities, describing the relevant evidence; and
- XII – comply with other legislation pertinent to the surveillance of health products.

Sole paragraph: All records required by item X above shall be maintained for a period of time equivalent to the expected lifetime of the product, but not less than two years from the date of receipt of the notification by the registration holder.

Art. 7 – For the purposes of post-market surveillance, the registration holder shall conduct a priority review of the following occurrences in relation to a health product involving a patient, user, or other person:

- I – serious threat to public health;
- II- death;
- III – serious adverse event not leading to death;
- IV – malfunction having the potential to cause death or a serious adverse event;

V – non-serious adverse event;

VI – malfunction having the potential to cause a non-serious adverse event; and

VII - counterfeiting

### **CHAPTER III MANDATORY NOTIFICATION**

Art. 8 – The registration holder shall notify the SNVS as quickly as possible, in accordance with the following deadlines:

I – No later than 72 (seventy-two) hours after becoming aware of the following verified events within the national territory that are associated with health products registered in its name:

- a) death;
- b) serious threat to public health;
- c) counterfeiting.

II – No later than 10 (ten) days after becoming aware of the following verified events within the national territory that are associated with health products registered in its name:

- a) serious adverse events not involving death;
- b) non-serious adverse events, the re-occurrence of which has the potential to cause a serious adverse event to a patient, user, or other person.

III – No later than 30 (thirty) days after becoming aware, of a verified malfunction within the national territory and associated with a health product registered in its name, that could lead to a serious adverse event in a patient, user, or other person, provided that one of the following conditions applies:

- a) the possibility of re-occurrence of the malfunction is not remote;
- b) an event of the same type has caused or contributed to a death or serious harm to health in the last three years;
- c) the registration holder of the product needs, or needed, to perform an action to prevent danger to health;
- d) the possibility that an use error was caused by deficient design, labelling, or instructions.

IV – No later than 10 (ten) days after becoming aware, of the following verified events occurring in other countries and associated with health products registered in its name in Brazil:

- a) death;
- b) serious risk to public health;
- c) counterfeiting.

§ 1 – The registration holder shall notify where there is confirmation or strong suspicion that its health product caused, or contributed, to the event.

§ 2 – The notification of international events to which refers item IV of this Article is only applicable in cases were the registration holder, or a distributor authorized by the registration holder, has imported into Brazil lots or serial numbers affected by the same problem as the original event.

Art. 9 – The registration holder shall maintain the information referred in the notifications sent to the SNVS up-to-date, in accordance with the development of each case.

Art. 10. The adverse events and malfunctions described in Article 8 of this Resolution are exempt from notification requirements when one the following verified conditions apply:

I – the malfunction is normally detectable by the user prior to using the product, independent of existing precautions contained in the instructions for use provided with the product;

II – the registration holder has information that the adverse event was caused by the condition of the patient, whether pre-existing or acquired during the use of the health product under investigation;

III – the sole cause of the adverse event or malfunction is the use of the product after the expiry date or beyond the useful life established by the manufacturer;

IV – the product features a mechanism to prevent faults conditions that present a risk to the patient, user, or other person, and the fault-prevention mechanism functioned correctly to prevent the occurrence of a serious adverse event;

V – the events are planned and expected by the manufacturer or registration holder, are clearly identified in the labelling or instructions for use of the products, and are functionally or numerically predictable when the product is used in accordance with indications;

VI – the product is not used in accordance with the intended uses declared by the manufacturer, the instructions and warning contained in the labelling and instructions for use of the product, and did not cause a serious adverse event; and,

§ 1 – A situation described in item I of this Article is not applicable in cases where the adverse event is due to product non-conformity.

§ 2 – In order to justify situations found in item II, the registration holder shall have available sufficient information to conclude that the product did not cause or contribute to cause the adverse event.

§ 3 – The registration holder shall notify the SNVS about malfunctions, adverse events or other occurrences that, regardless of their inclusion in the conditions contained in items I to VI of this article, are related to a serious threat to public health.

§ 4 – In situations described in the previous paragraph, the deadline for notification is 72 hours, in accordance with item I of Article 8 of this Resolution.

Article 11 – For the purposes of notifying the SNVS of events in accordance with Article 8 of this Resolution, the holder of the registration shall use the SNVS electronic information system defined by ANVISA.

## **CHAPTER IV** **FINAL AND TRANSITIONAL PROVISIONS**

Article 12 – Adverse events and malfunction arising from use of health products, quoted in the notification to SNVS, and which may constitute a violation of federal health legislation will be investigated by appropriate administrative process.

Sole paragraph: The reporting of adverse events or malfunction to SNVS does not imply immediate responsibility of the registration holder by events causing harm to other due to the use of health products quoted in the notification.

Article 13 – Without damage of others legal sections, including criminal penalties, that are punishable its technical and legal guardians, the company will respond administratively and civilly for health infringements arising from failure of this Resolution and additional rules, under Law nº 6.437/77.

Article 14 - It's up to ANVISA and the others SNVS members, within their competence and through pacts of responsibility, to adopt measures or procedures for cases not provided in this Resolution.

Article 15 – It is established a period of 180 (a hundred and eighty) days for ANVISA provide the required tools and systems to compliance with the determinations set forth in this Resolution.

Article 16 – It is established a period of 360 (three hundred and sixty) days to registration holders of health products adopt necessary measures for the application of this Resolution.

Article 17 – This Resolution enters into force on the date of its publication.

DIRCEU RAPOSO DE MELLO



CANADA

CONSOLIDATION

CODIFICATION

## Medical Devices Regulations

## Règlement sur les instruments médicaux

SOR/98-282

DORS/98-282

Current to March 3, 2025

À jour au 3 mars 2025

Last amended on December 14, 2024

Dernière modification le 14 décembre 2024

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## OFFICIAL STATUS OF CONSOLIDATIONS

Subsections 31(1) and (3) of the *Legislation Revision and Consolidation Act*, in force on June 1, 2009, provide as follows:

### Published consolidation is evidence

**31 (1)** Every copy of a consolidated statute or consolidated regulation published by the Minister under this Act in either print or electronic form is evidence of that statute or regulation and of its contents and every copy purporting to be published by the Minister is deemed to be so published, unless the contrary is shown.

...

### Inconsistencies in regulations

**(3)** In the event of an inconsistency between a consolidated regulation published by the Minister under this Act and the original regulation or a subsequent amendment as registered by the Clerk of the Privy Council under the *Statutory Instruments Act*, the original regulation or amendment prevails to the extent of the inconsistency.

## LAYOUT

The notes that appeared in the left or right margins are now in boldface text directly above the provisions to which they relate. They form no part of the enactment, but are inserted for convenience of reference only.

## NOTE

This consolidation is current to March 3, 2025. The last amendments came into force on December 14, 2024. Any amendments that were not in force as of March 3, 2025 are set out at the end of this document under the heading "Amendments Not in Force".

## CARACTÈRE OFFICIEL DES CODIFICATIONS

Les paragraphes 31(1) et (3) de la *Loi sur la révision et la codification des textes législatifs*, en vigueur le 1<sup>er</sup> juin 2009, prévoient ce qui suit :

### Codifications comme élément de preuve

**31 (1)** Tout exemplaire d'une loi codifiée ou d'un règlement codifié, publié par le ministre en vertu de la présente loi sur support papier ou sur support électronique, fait foi de cette loi ou de ce règlement et de son contenu. Tout exemplaire donné comme publié par le ministre est réputé avoir été ainsi publié, sauf preuve contraire.

[...]

### Incompatibilité — règlements

**(3)** Les dispositions du règlement d'origine avec ses modifications subséquentes enregistrées par le greffier du Conseil privé en vertu de la *Loi sur les textes réglementaires* l'emportent sur les dispositions incompatibles du règlement codifié publié par le ministre en vertu de la présente loi.

## MISE EN PAGE

Les notes apparaissant auparavant dans les marges de droite ou de gauche se retrouvent maintenant en caractères gras juste au-dessus de la disposition à laquelle elles se rattachent. Elles ne font pas partie du texte, n'y figurant qu'à titre de repère ou d'information.

## NOTE

Cette codification est à jour au 3 mars 2025. Les dernières modifications sont entrées en vigueur le 14 décembre 2024. Toutes modifications qui n'étaient pas en vigueur au 3 mars 2025 sont énoncées à la fin de ce document sous le titre « Modifications non en vigueur ».

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Registration  
SOR/98-282 May 7, 1998

FOOD AND DRUGS ACT

**Medical Devices Regulations**

P.C. 1998-783 May 7, 1998

His Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsections 3(3), 30(1) and 37(1)<sup>a</sup> of the *Food and Drugs Act*, hereby makes the annexed *Medical Devices Regulations*.

Enregistrement  
DORS/98-282 Le 7 mai 1998

LOI SUR LES ALIMENTS ET DROGUES

**Règlement sur les instruments médicaux**

C.P. 1998-783 Le 7 mai 1998

Sur recommandation du ministre de la Santé et en vertu des paragraphes 3(3), 30(1) et 37(1)<sup>a</sup> de la *Loi sur les aliments et drogues*, Son Excellence le Gouverneur général en conseil prend le *Règlement sur les instruments médicaux*, ci-après.

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<sup>a</sup> S.C. 1993, c. 34, s. 73

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<sup>a</sup> L.C. 1993, ch. 34, art. 73

# Interpretation

**1** The definitions in this section apply in these Regulations.

**Act** means the *Food and Drugs Act*. (*Loi*)

**active device** means a medical device that depends for its operation on a source of energy other than energy generated by the human body or gravity. A medical device that transmits or withdraws energy or a substance to or from a patient without substantially altering the energy or the substance is not an active device. (*instrument actif*)

**active diagnostic device** means an active device that, whether used alone or in combination with another medical device, is intended to supply information for the purpose of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity. (*instrument diagnostique actif*)

**active therapeutic device** means an active device that, whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a biological function or structure for the purpose of treating or mitigating an illness or injury or a symptom of an illness or injury. (*instrument thérapeutique actif*)

**applicable requirements of sections 10 to 20** means

(a) in respect of a decorative contact lens, the requirements set out in section 10, subsections 11(2) and 12(2) and sections 13 to 17; and

(b) in respect of any other medical device, the requirements set out in section 10, subsections 11(1) and 12(1) and sections 13 to 20. (*exigences applicables prévues aux articles 10 à 20*)

**bar code** means a unique bar code in the symbology of the Universal Product Code (UPC), the Health Industry Business Communications Council (HIBCC) or the European Article Number (EAN), assigned to a medical device by the manufacturer. (*code à barres*)

**body orifice** means a natural opening or a permanent artificial opening in the body, such as a stoma. (*orifice du corps*)

# Définitions

**1** Les définitions qui suivent s'appliquent au présent règlement.

**certificat de système de gestion de la qualité** Certificat de système de gestion de la qualité valide visé aux alinéas 32(2)f), (3)j) ou (4)p), délivré par un registraire reconnu par le ministre aux termes de l'article 32.1. (*quality management system certificate*)

**certificat de système qualité** [Abrogée, DORS/2006-197, art. 1]

**chercheur compétent** Personne qui est membre en règle d'une association professionnelle de personnes habilitées en vertu des lois d'une province à y dispenser des soins de santé et qui a été désignée par le comité de déontologie d'un établissement de santé pour y effectuer un essai expérimental. (*qualified investigator*)

**code à barres** Code à barres unique établi selon la symbolisation du code universel des produits (CUP), du Health Industry Business Communications Council (HIBCC) ou de la numérotation européenne des produits (Genecod), qui est assigné à l'instrument médical par le fabricant. (*bar code*)

**commissaire aux brevets** Le commissaire aux brevets nommé en vertu du paragraphe 4(1) de la *Loi sur les brevets*. (*Commissioner of Patents*)

**décision du Conseil général** S'entend au sens du paragraphe 30(6) de la Loi. (*General Council Decision*)

**détérioration grave de l'état de santé** Maladie, désordre ou état physique anormal qui menace la vie, incapacité permanente d'une fonction corporelle ou dommage corporel permanent, ou état qui nécessite une intervention médicale ou chirurgicale imprévue afin de prévenir une telle maladie ou incapacité, ou un tel désordre, état physique ou dommage. (*serious deterioration in the state of health*)

**ensemble d'instruments** Instrument médical formé de plusieurs instruments médicaux, tels un ensemble d'instruments chirurgicaux ou un plateau, et vendu sous un seul nom. (*medical device group*)

**business day** means a day other than

- (a) a Saturday; or
- (b) a Sunday or other holiday. (*jour ouvrable*)

**central cardiovascular system** means the heart, pericardium, pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava, renal arteries, iliac arteries and femoral arteries. (*système cardiovasculaire central*)

**central nervous system** means the brain, meninges, spinal cord and cerebrospinal fluid. (*système nerveux central*)

**closed-loop system**, in respect of a medical device, means a system that enables the device to sense, interpret and treat a medical condition without human intervention. (*système à boucle fermée*)

**Commissioner of Patents** means the Commissioner of Patents appointed under subsection 4(1) of the Patent Act. (*commissaire aux brevets*)

**control number** means a unique series of letters, numbers or symbols, or any combination of these, that is assigned to a medical device by the manufacturer and from which a history of the manufacture, packaging, labelling and distribution of a unit, lot or batch of the device can be determined. (*numéro de contrôle*)

**custom-made device** means a medical device, other than a mass-produced medical device, that

(a) is manufactured in accordance with a health care professional's written direction giving its design characteristics;

(b) differs from medical devices generally available for sale or from a dispenser; and

(c) is

(i) for the sole use of a particular patient of that professional, or

(ii) for use by that professional to meet special needs arising in the course of his or her practice. (*instrument fait sur mesure*)

**decorative contact lens** means a device referred to in section 2.1 of the Act. (*lentilles cornéennes à but esthétique*)

**dental material** [Repealed, SOR/2002-190, s. 1]

**établissement de santé** Établissement qui fournit des services diagnostiques ou thérapeutiques à des patients. Est également visé tout regroupement de tels établissements dont les activités relèvent d'une même entité administrative. (*health care facility*)

**exigences applicables prévues aux articles 10 à 20**

a) À l'égard des lentilles cornéennes à but esthétique, les exigences prévues à l'article 10, aux paragraphes 11(2) et 12(2) et aux articles 13 à 17;

b) à l'égard de tout autre instrument médical, les exigences prévues à l'article 10, aux paragraphes 11(1) et 12(1) et aux articles 13 à 20. (*applicable requirements of sections 10 to 20*)

**exigences en matière de sûreté et d'efficacité** [Abrogée, DORS/2015-193, art. 1]

**fabricant** Personne qui vend l'instrument médical sous son propre nom ou sous un nom commercial, une marque de commerce, un dessin ou un autre nom ou marque qu'elle contrôle ou dont elle est propriétaire et qui est responsable de la conception, de la fabrication, de l'assemblage, du traitement, de l'étiquetage, de l'emballage, de la remise à neuf ou de la modification de l'instrument, ou de l'assignation d'une utilisation à cet instrument, que ces opérations soient effectuées par elle ou pour son compte. (*manufacturer*)

**famille d'ensembles d'instruments** S'entend des ensembles d'instruments qui sont fabriqués par le même fabricant, qui portent le même nom générique précisant l'utilisation à laquelle ils sont destinés et dont seul le nombre ou la combinaison des produits les formant peut différer d'un ensemble à l'autre. (*medical device group family*)

**famille d'instruments** S'entend des instruments médicaux qui sont fabriqués par le même fabricant, dont seule la forme, la couleur, la saveur ou la grandeur diffère d'un instrument à l'autre, et dont la conception et le processus de fabrication ainsi que l'utilisation à laquelle ils sont destinés sont les mêmes. (*medical device family*)

**identificateur** Série unique de lettres ou de chiffres, ou toute combinaison de ceux-ci, ou code à barres, qui est assigné à l'instrument médical par le fabricant et qui permet d'identifier l'instrument et de le distinguer d'instruments similaires. (*identifier*)

**implant** Instrument médical mentionné à l'annexe 2. (*implant*)

**directions for use**, in respect of a medical device, means full information as to the procedures recommended for achieving the optimum performance of the device, and includes cautions, warnings, contra-indications and possible adverse effects. (*mode d'emploi*)

**dispenser** means a person who is a member of a professional governing body and who is entitled, by virtue of their membership in that body, to manufacture or adapt a medical device in accordance with a health care professional's written directions in order to meet the specific requirements of a patient. (*préparateur*)

**General Council Decision** has the meaning assigned by subsection 30(6) of the Act. (*décision du Conseil général*)

**genetic testing** means the analysis of DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis. (*test génétique*)

**health care facility** means a facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has responsibility for the activities carried out in those facilities. (*établissement de santé*)

**health care professional** means a person who is entitled under the laws of a province to provide health services in the province. (*professionnel de la santé*)

**identifier** means a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices. (*identificateur*)

**implant** means a medical device that is listed in Schedule 2. (*implant*)

**invasive device** means a medical device that is intended to come into contact with the surface of the eye or penetrate the body, either through a body orifice or through the body surface. (*instrument effractif*)

**in vitro diagnostic device** or **IVDD** means a medical device that is intended to be used *in vitro* for the examination of specimens taken from the body. (*instrument diagnostique in vitro* ou *IDIV*)

**manufacturer** means a person who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing,

**instrument actif** Instrument médical dont le fonctionnement dépend d'une source d'énergie, autre que l'énergie produite par la force musculaire ou la pesanteur. Ne sont pas visés les instruments médicaux qui transmettent au patient, ou qui retirent de celui-ci, de l'énergie ou une substance sans qu'elles soient sensiblement modifiées. (*active device*)

**instrument chirurgical ou dentaire** Instrument médical réutilisable qui est destiné à des fins de chirurgie ou de dentisterie et qui peut accomplir, sans raccord à un instrument actif, un acte tel que couper, forer, scier, râcler, comprimer, marteler, percer, dilater, rétracter ou agrafer. (*surgical or dental instrument*)

**instrument diagnostique actif** Instrument actif qui, utilisé seul ou en combinaison avec un autre instrument médical, est destiné à fournir des renseignements en vue de détecter, de contrôler ou de traiter des troubles physiologiques, des états de santé, des maladies ou des malformations congénitales. (*active diagnostic device*)

**instrument diagnostique clinique in vitro** Instrument diagnostique *in vitro* qui est destiné à servir à l'extérieur d'un laboratoire, aux fins d'analyse au domicile ou au lieu où sont donnés des soins, notamment dans une pharmacie ou le cabinet d'un professionnel de la santé, ou au chevet d'un malade. (*near patient in vitro diagnostic device* or *near patient IVDD*)

**instrument diagnostique in vitro** ou **IDIV** Instrument médical destiné à être utilisé *in vitro* pour examiner des prélèvements provenant du corps. (*in vitro diagnostic device* or *IVDD*)

**instrument effractif** Instrument médical destiné à entrer en contact avec la surface de l'œil ou à pénétrer dans le corps, soit par un de ses orifices soit à travers sa surface. (*invasive device*)

**instrument effractif chirurgical** Instrument effractif destiné à pénétrer dans le corps par une ouverture artificielle donnant accès aux structures ou fluides du corps. (*surgically invasive device*)

**instrument fait sur mesure** Instrument médical — non fabriqué en série — qui, à la fois :

**a)** est fabriqué selon les directives écrites d'un professionnel de la santé précisant ses caractéristiques de conception;

**b)** s'écarte des instruments médicaux qui généralement se trouvent dans le commerce ou peuvent être obtenus d'un préparateur;

labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf. (*fabricant*)

**medical device** means a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals. (*instrument médical*)

**medical device family** means a group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use. (*famille d'instruments*)

**medical device group** means a medical device comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name. (*ensemble d'instruments*)

**medical device group family** means a collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use, and that differ only in the number and combination of products that comprise each group. (*famille d'ensembles d'instruments*)

**name of the device**, in respect of a medical device, includes any information necessary for the user to identify the device and to distinguish it from similar devices. (*nom de l'instrument*)

**near patient in vitro diagnostic device or near patient IVDD** means an *in vitro* diagnostic device that is intended for use outside a laboratory, for testing at home or at the point of care, such as a pharmacy, a health care professional's office or the bedside. (*instrument diagnostique clinique in vitro*)

**objective evidence** means information that can be proved true, based on facts obtained through observation, measurement, testing or other means, as set out in the definition **objective evidence** in section 2.19 of International Organization for Standardization standard ISO 8402:1994, *Quality management and quality assurance - Vocabulary*, as amended from time to time. (*preuve tangible*)

**person** includes a partnership and an association. (*personne*)

**qualified investigator** means a person who is a member in good standing of a professional association of persons entitled under the laws of a province to provide health care in the province and who is designated, by the ethics committee of the health care facility at which

**c) est destiné :**

**(i)** soit à l'usage exclusif d'un patient donné du professionnel,

**(ii)** soit à l'usage du professionnel afin de répondre à des besoins spéciaux dans l'exercice de sa profession. (*custom-made device*)

**instrument médical** S'entend d'un instrument, au sens de la Loi, à l'exclusion des instruments destinés à être utilisés à l'égard des animaux. (*medical device*)

**instrument thérapeutique actif** Instrument actif qui, utilisé seul ou en combinaison avec un autre instrument médical, est destiné à soutenir, modifier, remplacer ou rétablir des fonctions ou des structures biologiques en vue de traiter ou d'atténuer une maladie ou une blessure, ou leurs symptômes. (*active therapeutic device*)

**jour ouvrable** Jour autre que :

**a)** le samedi;

**b)** le dimanche ou un autre jour férié. (*business day*)

**lentilles cornéennes à but esthétique** Instruments visés à l'article 2.1 de la Loi. (*decorative contact lens*)

**Loi** La *Loi sur les aliments et drogues*. (*Act*)

**mode d'emploi** S'entend de tous les renseignements relatifs aux procédés recommandés pour obtenir le rendement optimal de l'instrument médical, y compris les précautions, mises en garde, contre-indications et effets nocifs possibles. (*directions for use*)

**modification importante** Toute modification qui pourrait vraisemblablement influer sur la sûreté ou l'efficacité de l'instrument médical. Est également visée toute modification d'un des éléments suivants :

**a)** les procédés, les installations ou l'équipement de fabrication;

**b)** les procédures de contrôle de la qualité de la fabrication, notamment les méthodes, essais ou procédures utilisés pour contrôler la qualité, la pureté et la stérilité de l'instrument ou de ses matériaux de fabrication;

**c)** la conception de l'instrument, notamment les principes de fonctionnement, les caractéristiques de rendement et les spécifications des matériaux, de la source d'énergie, du logiciel ou des accessoires;

**d)** l'utilisation à laquelle l'instrument est destiné, notamment toute utilisation nouvelle ou supplémentaire,

investigational testing is to be conducted, as the person to conduct the testing. (*chercheur compétent*)

**quality management system certificate** means a valid quality management system certificate described in paragraph 32(2)(f), 3(j) or (4)(p), as applicable, that is issued by a registrar recognized by the Minister under section 32.1. (*certificat de système de gestion de la qualité*)

**quality system certificate** [Repealed, SOR/2006-197, s. 1]

**recall** means

(a) a recall ordered by the Minister under section 21.3 of the Act; or

(b) any action taken by a manufacturer, importer or distributor of a medical device, after the device has been sold, to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device

(i) may present a risk of injury to health,

(ii) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety, or

(iii) may not meet the requirements of the Act or these Regulations. (*rappel*)

**regulatory agency** means a government agency or other entity outside Canada that has a legal right to control the manufacturing, use or sale of medical devices within its jurisdiction and that may take enforcement action to ensure that medical devices marketed within its jurisdiction comply with the applicable legal requirements. (*organisme de réglementation*)

**safety and effectiveness requirements** [Repealed, SOR/2015-193, s. 1]

**serious deterioration in the state of health** means a life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage. (*déterioration grave de l'état de santé*)

**shortage**, in respect of a medical device, means a situation in which the manufacturer of the device is unable to meet the demand for the device in Canada. (*pénurie*)

tout ajout ou suppression de contre-indications et toute modification de la période servant à fixer la date de péremption. (*significant change*)

**nom de l'instrument** Vise également tout renseignement nécessaire à l'utilisateur pour identifier l'instrument médical et le distinguer d'instruments similaires. (*name of the device*)

**numéro de contrôle** Série unique de lettres, de chiffres ou de symboles, ou toute combinaison de ceux-ci, qui est assignée à l'instrument médical par le fabricant et qui permet de retracer les étapes de fabrication, d'emballage, d'étiquetage et de distribution d'une unité ou d'un lot. (*control number*)

**organisme de réglementation** Organisme gouvernemental ou autre entité, ailleurs qu'au Canada, qui est habilité à contrôler la fabrication, l'utilisation ou la vente d'instruments médicaux sur le territoire relevant de sa compétence et qui peut prendre des mesures d'exécution pour veiller à ce que les instruments médicaux qui y sont commercialisés satisfassent aux exigences légales qui s'appliquent. (*regulatory agency*)

**orifice du corps** Ouverture naturelle du corps ou ouverture artificielle permanente dans celui-ci, telle une stomie. (*body orifice*)

**pénurie** S'entend, à l'égard d'un instrument médical, d'une situation où le fabricant de l'instrument médical est incapable de répondre à la demande pour l'instrument au Canada. (*shortage*)

**personne** Y sont assimilées les sociétés de personnes et les associations. (*person*)

**préparateur** Membre d'un organisme de régie d'une profession qui est habilité, du fait de sa qualité de membre, à fabriquer ou adapter, selon les directives écrites d'un professionnel de la santé, un instrument médical pour répondre aux besoins spécifiques d'un patient. (*dispenser*)

**preuve tangible** Information dont la véracité peut être démontrée, fondée sur des faits obtenus par observation, mesurage, essai ou autres moyens, selon la définition figurant à l'article 2.19 de la norme ISO 8402:1994 de l'Organisation internationale de normalisation, intitulée *Management de la qualité et assurance de la qualité – Vocabulaire*, avec ses modifications successives. (*objective evidence*)

**produit dentaire** [Abrogée, DORS/2002-190, art. 1]

**significant change** means a change that could reasonably be expected to affect the safety or effectiveness of a medical device. It includes a change to any of the following:

- (a) the manufacturing process, facility or equipment;
- (b) the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture;
- (c) the design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories; and
- (d) the intended use of the device, including any new or extended use, any addition or deletion of a contraindication for the device and any change to the period used to establish its expiry date. (*modification importante*)

**surgical or dental instrument** means a reusable medical device that is intended for surgical or dental use, including cutting, drilling, sawing, scraping, clamping, hammering, puncturing, dilating, retracting or clipping, without connection to an active device. (*instrument chirurgical ou dentaire*)

**surgically invasive device** means an invasive device that is intended to enter the body through an artificially created opening that provides access to body structures and fluids. (*instrument effractif chirurgical*)

**system** means a medical device comprising a number of components or parts intended to be used together to fulfil some or all of the device's intended functions, and that is sold under a single name. (*système*)

**test kit** means an *in vitro* diagnostic device that consists of reagents or articles, or any combination of these, and that is intended to be used to conduct a specific test. (*trousse d'essai*)

**validation** means confirmation by examination and the provision of objective evidence that the requirements for a specific intended use have been fulfilled, as set out in the definition **validation** in section 2.18 of International Organization for Standardization standard ISO 8402:1994, *Quality management and quality assurance - Vocabulary*, as amended from time to time. (*validation*)

SOR/2002-190, s. 1; SOR/2003-173, s. 1; SOR/2005-142, s. 1; SOR/2006-197, s. 1; 2014, c. 20, s. 366(E); SOR/2015-193, s. 1; SOR/2019-44, s. 1(F); SOR/2020-262, s. 6; SOR/2021-199, s. 6; SOR/2024-136, s. 6.

**professionnel de la santé** Personne autorisée en vertu des lois d'une province à y fournir des services de santé. (*health care professional*)

**rappel** L'une ou l'autre des mesures suivantes :

- a) le rappel ordonné par le ministre en vertu de l'article 21.3 de la Loi;
- b) toute mesure prise par le fabricant, l'importateur ou le distributeur d'un instrument médical, après la vente de celui-ci, visant à en effectuer le rappel, à y apporter des correctifs ou à aviser le propriétaire ou l'utilisateur de sa défectuosité — réelle ou potentielle —, après avoir eu connaissance que l'instrument, selon le cas :
  - (i) peut présenter un risque de préjudice à la santé,
  - (ii) peut ne pas être conforme aux affirmations du fabricant ou de l'importateur relativement à son efficacité, à ses avantages, à ses caractéristiques de rendement ou à sa sûreté,
  - (iii) peut ne pas être conforme à la Loi ou au présent règlement. (*recall*)

**système** Instrument médical qui est formé de composants ou parties destinés à être utilisés ensemble pour remplir certaines ou la totalité des fonctions auxquelles il est destiné et qui est vendu sous un seul nom. (*system*)

**système à boucle fermée** Système de l'instrument médical qui permet de détecter, d'interpréter et de traiter un état pathologique sans intervention humaine. (*closed-loop system*)

**système cardiovasculaire central** Le cœur, le péricard, les veines pulmonaires, les artères pulmonaires, les veines cardiaques, les artères coronaires, les artères carotides communes, les artères cérébrales, l'artère brachiocephalique, l'aorte, les veines caves inférieure et supérieure, les artères rénales, les artèresiliaques et les artères fémorales. (*central cardiovascular system*)

**système de gestion de la qualité** Vaut mention de l'expression « système de management de la qualité » figurant à la norme nationale du Canada CAN/CSA-ISO 13485 intitulée *Dispositifs médicaux – Systèmes de management de la qualité – Exigences à des fins réglementaires*, avec ses modifications successives. (*French version only*)

**système nerveux central** Le cerveau, les méninges, l'épine dorsale et le liquide céphalorachidien. (*central nervous system*)

**test génétique** Analyse de l'ADN, de l'ARN ou des chromosomes, à des fins telles la prédition de maladies ou de risques de transmission verticale, ou la surveillance, le diagnostic ou le pronostic. (*genetic testing*)

**trousse d'essai** Instrument diagnostique in vitro qui consiste en des réactifs ou des articles, ou toute combinaison de ceux-ci, et qui est destiné à être utilisé pour effectuer un essai spécifique. (*test kit*)

**validation** Confirmation par examen et apport de preuves tangibles que les exigences particulières pour une utilisation donnée sont respectées, selon la définition figurant à l'article 2.18 de la norme ISO 8402:1994 de l'Organisation internationale de normalisation, intitulée *Management de la qualité et assurance de la qualité — Vocabulaire*, avec ses modifications successives. (*validation*)

DORS/2002-190, art. 1; DORS/2003-173, art. 1; DORS/2005-142, art. 1; DORS/2006-197, art. 1; 2014, ch. 20, art. 366(A); DORS/2015-193, art. 1; DORS/2019-44, art. 1(F); DORS/2020-262, art. 6; DORS/2021-199, art. 6; DORS/2024-136, art. 6.

## Application

**2** These Regulations apply to

- (a)** the sale and advertising for sale of a medical device; and
- (b)** the importation of a medical device for sale or for use on individuals, other than importation for personal use.

**3 (1)** These Regulations also apply to an *in vitro* diagnostic product that is a drug or that contains a drug, as if the product were an *in vitro* diagnostic device.

**(2)** Subsection (1) does not apply to a *drug*, as defined in subsection 1(2) of the *Cannabis Regulations*, containing *cannabis*, as defined in subsection 2(1) of the *Cannabis Act*, or a drug listed in Schedule E or F to the Act, in the schedule to Part G or J of the *Food and Drug Regulations*, in the schedules to the *Controlled Drugs and Substances Act* or in the schedule to the *Narcotic Control Regulations*.

SOR/2018-144, s. 371.

**4** Only sections 26 to 31, 37, 70, 75, 80, 86 and 87 apply to a dispenser.

**5** These Regulations do not apply to a medical gas piping system that is assembled on site at a health care facility and permanently built into the structure of the facility.

SOR/2017-18, s. 22.

## Champ d'application

**2** Le présent règlement s'applique :

- a)** à la vente des instruments médicaux et à la publicité en vue de leur vente;
- b)** à l'importation de ceux-ci en vue de la vente ou de leur utilisation à l'égard de particuliers, autre que l'importation à des fins personnelles.

**3 (1)** Outre les instruments médicaux, le présent règlement s'applique aux produits diagnostiques in vitro qui sont des drogues ou qui en renferment, comme s'il s'agissait d'instruments diagnostiques in vitro.

**(2)** Ne sont pas visées par le paragraphe (1) les *drogues* au sens du paragraphe 1(2) du *Règlement sur le cannabis* qui contiennent du *cannabis* au sens du paragraphe 2(1) de la *Loi sur le cannabis* et les drogues mentionnées aux annexes E et F de la Loi, aux annexes des parties G et J du *Règlement sur les aliments et drogues*, aux annexes de la *Loi réglementant certaines drogues et autres substances* et à l'annexe du *Règlement sur les stupéfiants*.

DORS/2018-144, art. 371.

**4** Seuls les articles 26 à 31, 37, 70, 75, 80, 86 et 87 s'appliquent aux préparateurs.

**5** Sont exemptés de l'application du présent règlement les réseaux de canalisations de gaz médicaux qui sont assemblés sur les lieux d'un établissement de santé et fixés à demeure sur sa structure.

DORS/2017-18, art. 22.

# Classification of Medical Devices

**6** Medical devices are classified into one of Classes I to IV by means of the classification rules set out in Schedule 1, where Class I represents the lowest risk and Class IV represents the highest risk.

**7** If a medical device can be classified into more than one class, the class representing the higher risk applies.

## PART 1

### General

#### Application

**8** This Part applies to medical devices that are not subject to Part 2 or 3.

#### Manufacturer's Obligations

**9 (1)** A manufacturer shall ensure that the medical device meets the applicable requirements of sections 10 to 20.

**(2)** A manufacturer shall keep objective evidence to establish that the medical device meets those requirements.

SOR/2015-193, s. 7.

#### Safety and Effectiveness Requirements

**10** A medical device shall be designed and manufactured to be safe, and to this end the manufacturer shall, in particular, take reasonable measures to

- (a)** identify the risks inherent in the device;
- (b)** if the risks can be eliminated, eliminate them;
- (c)** if the risks cannot be eliminated,
  - (i)** reduce the risks to the extent possible,
  - (ii)** provide for protection appropriate to those risks, including the provision of alarms, and
  - (iii)** provide, with the device, information relative to the risks that remain; and

# Classification

**6** Les instruments médicaux sont classés dans l'une des classes I à IV, conformément aux règles de classification prévues à l'annexe 1, la classe I étant celle présentant le risque le plus faible et la classe IV, celle présentant le risque le plus élevé.

**7** L'instrument médical qui peut être classé dans plus d'une classe est considéré comme appartenant à celle présentant le risque le plus élevé.

## PARTIE 1

### Dispositions générales

#### Champ d'application

**8** La présente partie s'applique aux instruments médicaux qui ne sont pas visés par les parties 2 ou 3.

#### Obligation du fabricant

**9 (1)** Le fabricant doit veiller à ce que l'instrument médical satisfasse aux exigences applicables prévues aux articles 10 à 20.

**(2)** Il doit conserver des preuves tangibles permettant d'établir que l'instrument satisfait à ces exigences.

DORS/2015-193, art. 7.

#### Exigences en matière de sûreté et d'efficacité

**10** L'instrument médical doit être conçu et fabriqué de façon qu'il soit sécuritaire. À cette fin, le fabricant doit, entre autres, prendre des mesures raisonnables pour :

- a)** identifier les risques inhérents à l'instrument;
- b)** éliminer ces risques, si cela est possible;
- c)** lorsque les risques ne peuvent être éliminés :
  - (i)** les réduire dans la mesure du possible,
  - (ii)** prévoir les mesures de protection indiquées contre ces risques, en incluant notamment des fonctions d'alarme,

**(d)** minimize the hazard from potential failures during the projected useful life of the device.

SOR/2022-197, s. 12(F).

**11 (1)** A medical device other than a decorative contact lens shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold or represented, adversely affect the health or safety of a patient, user or other person, except to the extent that a possible adverse effect of the device constitutes an acceptable risk when weighed against the benefits to the patient and the risk is compatible with a high level of protection of health and safety.

**(2)** A decorative contact lens shall not adversely affect the health or safety of a user, except to the extent that a possible adverse effect of the device constitutes a risk that is compatible with a high level of protection of health and safety.

SOR/2015-193, s. 2.

**12 (1)** A medical device other than a decorative contact lens shall perform as intended by the manufacturer and shall be effective for the medical conditions, purposes and uses for which it is manufactured, sold or represented.

**(2)** A decorative contact lens shall perform as intended by the manufacturer.

SOR/2015-193, s. 2.

**13** During the projected useful life of a medical device, its characteristics and performance shall not deteriorate under normal use to such a degree that the health or safety of a patient, user or other person is adversely affected.

**14** The characteristics and performance of a medical device shall not be adversely affected by transport or conditions of storage, taking into account the manufacturer's instructions and information for transport and storage.

**15** Reasonable measures shall be taken to ensure that every material used in the manufacture of a medical device shall be compatible with every other material with which it interacts and with material that may come into contact with it in normal use, and shall not pose any undue risk to a patient, user or other person.

**(iii)** fournir avec l'instrument des renseignements concernant les risques résiduels;

**d)** réduire au minimum les risques découlant d'une défaillance éventuelle de l'instrument au cours de sa durée de vie utile projetée.

DORS/2022-197, art. 12(F).

**11 (1)** L'instrument médical autre que les lentilles cornéennes à but esthétique ne doit pas compromettre la santé ou la sûreté des patients, utilisateurs ou autres personnes, lorsqu'il sert aux états pathologiques, fins ou utilisations pour lesquels il est fabriqué, vendu ou présenté, sauf dans la mesure où ses effets nocifs possibles constituent un risque acceptable au regard des avantages pour les patients et compatible avec un niveau élevé de protection de la santé et de la sûreté.

**(2)** Les lentilles cornéennes à but esthétique ne doivent pas compromettre la santé ou la sûreté des utilisateurs, sauf dans la mesure où leurs effets nocifs possibles constituent un risque qui est compatible avec un niveau élevé de protection de la santé et de la sûreté.

DORS/2015-193, art. 2.

**12 (1)** L'instrument médical autre que les lentilles cornéennes à but esthétique doit fournir le rendement prévu par le fabricant et être efficace à l'égard des états pathologiques, fins et utilisations pour lesquels il est fabriqué, vendu ou présenté.

**(2)** Les lentilles cornéennes à but esthétique doivent fournir le rendement prévu par le fabricant.

DORS/2015-193, art. 2.

**13** Au cours de la durée de vie utile projetée de l'instrument médical et dans des conditions d'utilisation normales, ses caractéristiques et son rendement ne doivent pas se dégrader au point de compromettre la santé ou la sûreté des patients, utilisateurs ou autres personnes.

**14** Compte tenu des instructions et des renseignements fournis par le fabricant à cet égard, le transport et les conditions d'entreposage de l'instrument médical ne doivent pas nuire à son rendement ni à ses caractéristiques.

**15** Des mesures raisonnables doivent être prises pour que les matériaux de fabrication de l'instrument médical soient compatibles avec tout autre matériau avec lequel ils interagissent ou avec lequel ils pourraient entrer en contact dans des conditions d'utilisation normales. Les matériaux ne doivent présenter aucun risque indu pour les patients, utilisateurs ou autres personnes.

**16** The design, manufacture and packaging of a medical device shall minimize any risk to a patient, user or other person from reasonably foreseeable hazards, including

- (a) flammability or explosion;
- (b) presence of a contaminant or chemical or microbial residue;
- (c) radiation;
- (d) electrical, mechanical or thermal hazards; and
- (e) fluid leaking from or entering into the device.

**17** A medical device that is to be sold in a sterile condition shall be manufactured and sterilized under appropriately controlled conditions, and the sterilization method used shall be validated.

**18** A medical device that is part of a system shall be compatible with every other component or part of the system with which it interacts and shall not adversely affect the performance of that system.

SOR/2023-247, s. 8(F).

**19** A medical device that performs a measuring function shall be designed to perform that function within tolerance limits that are appropriate for the medical conditions, purposes and uses for which the device is manufactured, sold or represented.

**20** If a medical device consists of or contains software, the software shall be designed to perform as intended by the manufacturer, and the performance of the software shall be validated.

## Labelling Requirements

**21 (1)** No person shall import or sell a medical device unless the device has a label that sets out the following information:

- (a) the name of the device;
- (b) the name and address of the manufacturer;
- (c) the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (d) in the case of a Class III or IV device, the control number;

**16** L'instrument médical doit être conçu, fabriqué et emballé de façon à réduire au minimum les risques pour les patients, utilisateurs ou autres personnes que présentent des dangers raisonnablement prévisibles, notamment :

- a) l'inflammabilité ou les explosions;
- b) la présence de contaminants ou de résidus chimiques ou microbiens;
- c) les rayonnements;
- d) les dangers de nature électrique, mécanique ou thermique;
- e) les fuites ou les infiltrations de liquides.

**17** L'instrument médical destiné à être vendu à l'état stérile doit être fabriqué et stérilisé dans les conditions contrôlées appropriées, la méthode de stérilisation devant être validée.

**18** L'instrument médical faisant partie d'un système doit être compatible avec les autres composants ou parties du système avec lesquels il interagit et ne doit pas nuire au rendement du système.

DORS/2023-247, art. 8(F).

**19** L'instrument médical de mesure doit être conçu de façon que les mesures soient conformes aux limites de tolérance indiquées pour les états pathologiques, fins et utilisations pour lesquels il est fabriqué, vendu ou présenté.

**20** L'instrument médical qui est un logiciel ou qui en contient un doit être conçu de façon à fournir le rendement prévu par le fabricant, le rendement du logiciel devant être validé.

## Étiquetage

**21 (1)** Il est interdit d'importer ou de vendre un instrument médical, sauf s'il est accompagné d'une étiquette qui porte les renseignements suivants :

- a) le nom de l'instrument;
- b) les nom et adresse du fabricant;
- c) l'identificateur de l'instrument, y compris celui de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;
- d) dans le cas d'un instrument de classe III ou IV, le numéro de contrôle;

- (e) if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units;
- (f) the word “Sterile”, if the manufacturer intends the device to be sold in a sterile condition;
- (g) the expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life;
- (h) unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, as well as the performance specifications of the device if those specifications are necessary for proper use;
- (i) the directions for use, unless directions are not required
- (i) in the case of a decorative contact lens, for the device to be used safely, and
  - (ii) in the case of any other medical device, for the device to be used safely and effectively; and
- (j) any special storage conditions applicable to the device.

(2) The information required pursuant to subsection (1) shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user.

SOR/2002-190, s. 2; SOR/2015-193, s. 3.

**21.1** Despite section 21, any person who imports for sale a medical device that is not labelled in accordance with these Regulations shall ensure

- (a) if that person holds an establishment licence to import the medical device, that they send prior notice of the proposed importation to the Minister or, if they do not hold such a licence, that the manufacturer of the medical device sends the prior notice; and
- (b) before selling the medical device, that the manufacturer of the medical device has relabelled it in accordance with these Regulations within three months after the date of its importation.

SOR/2018-225, s. 1.

- e) lorsque le contenu n'est pas facilement visible, une indication de ce que contient l'emballage, en termes qui conviennent à l'instrument, tels la grandeur, le poids net, la longueur, le volume ou le nombre d'unités;
- f) la mention « stérile », si le fabricant destine l'instrument à la vente à l'état stérile;
- g) s'il y a lieu, la date de péremption, déterminée par le fabricant en fonction du composant dont la durée de vie utile projetée est la plus courte;
- h) à moins qu'ils ne soient évidents pour l'utilisateur auquel est destiné l'instrument, les états pathologiques, fins et utilisations pour lesquels l'instrument est fabriqué, vendu ou présenté, ainsi que ses spécifications de rendement lorsqu'elles sont nécessaires à sa bonne utilisation;
- i) le mode d'emploi, sauf lorsque l'instrument peut être utilisé sans son mode d'emploi :
- (i) dans le cas de lentilles cornéennes à but esthétique, en toute sécurité,
  - (ii) dans le cas de tout autre instrument médical, en toute sécurité et de façon efficace;
- j) les conditions d'entreposage particulières de l'instrument.

(2) Les renseignements doivent être intelligibles à l'utilisateur auquel est destiné l'instrument. Ils doivent également être lisibles, marqués de façon permanente et placés bien en vue sur l'étiquette.

DORS/2002-190, art. 2; DORS/2015-193, art. 3.

**21.1** Malgré l'article 21, la personne qui importe à des fins de vente un instrument médical qui n'est pas étiqueté conformément au présent règlement doit satisfaire aux exigences suivantes :

- a) si elle est titulaire d'une licence d'établissement autorisant l'importation, elle envoie au ministre un préavis de l'importation prévu ou, si elle n'est pas titulaire d'une telle licence, elle veille à ce que le fabricant de l'instrument médical envoie ce préavis;
- b) elle veille, avant de vendre l'instrument, à ce que celui-ci ait fait l'objet d'un nouvel étiquetage par le fabricant de l'instrument médical conformément au présent règlement dans les trois mois suivant la date de l'importation.

DORS/2018-225, art. 1.

**21.2** Any person who imports for sale a medical device that is not labelled in accordance with these Regulations shall ensure that the manufacturer of the medical device notifies the Minister in writing of the name of the person who will relabel it in Canada if it is to be relabelled on the manufacturer's behalf.

SOR/2018-225, s. 1.

**22 (1)** Subject to subsection (2), if a medical device is intended to be sold to the general public, the information required by subsection 21(1) shall

- (a) be set out on the outside of the package that contains the device; and
- (b) be visible under normal conditions of sale.

**(2)** Where a package that contains a medical device is too small to display all the information in accordance with section 21, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sale.

**23 (1)** Subject to subsection (3), the information required by subsection 21(1) shall, as a minimum, be in either English or French.

**(2)** Subject to subsection (3), where the directions for use are supplied in only one official language at the time of sale, directions for use in the other official language shall be made available by the manufacturer as soon as possible at the request of the purchaser.

**(3)** In respect of a medical device to be sold to the general public, the information required by paragraphs 21(1)(a) and (e) to (j) shall, as a minimum, be in both English and French.

SOR/2002-190, s. 3.

## Contraceptive Devices — Advertising

**24 (1)** For the purposes of subsections 3(1) and (2) of the Act and subject to section 27, a condom may be advertised and sold to the general public for the purpose of preventing the transmission of sexually transmitted diseases if the advertisement and the label of the condom claim only that the condom reduces the risk of transmitting sexually transmitted diseases.

**(2)** For the purpose of subsection 3(3) of the Act and subject to section 27, contraceptive devices, other than intrauterine devices, may be advertised to the general

**21.2** La personne qui importe à des fins de vente un instrument médical qui n'est pas étiqueté conformément au présent règlement, mais qui fera l'objet d'un nouvel étiquetage au Canada par une autre personne au nom du fabricant, veille à ce que le fabricant avise par écrit le ministre du nom de celle-ci.

DORS/2018-225, art. 1.

**22 (1)** Sous réserve du paragraphe (2), dans le cas d'un instrument médical qui est destiné à la vente au grand public, les renseignements visés au paragraphe 21(1) doivent :

- a) d'une part, figurer sur l'extérieur de l'emballage;
- b) d'autre part, être visibles dans les conditions habituelles de vente.

**(2)** Si l'emballage de l'instrument médical est trop petit pour accueillir tous les renseignements conformément à l'article 21, le mode d'emploi n'a pas à figurer sur l'extérieur de l'emballage ni à être visible dans les conditions habituelles de vente. Il doit toutefois accompagner l'instrument.

**23 (1)** Sous réserve du paragraphe (3), les renseignements visés au paragraphe 21(1) doivent figurer au moins en français ou en anglais.

**(2)** Sous réserve du paragraphe (3), si, au moment de la vente, le mode d'emploi ne figure que dans l'une des langues officielles, le fabricant doit, à la demande de l'acheteur, le mettre à sa disposition dans les plus brefs délais dans l'autre langue officielle.

**(3)** En ce qui concerne les instruments médicaux destinés à la vente au grand public, les renseignements visés aux alinéas 21(1)a et e) à j) doivent figurer au moins en français et en anglais.

DORS/2002-190, art. 3.

## Moyens contraceptifs — publicité

**24 (1)** Pour l'application des paragraphes 3(1) et (2) de la Loi et sous réserve de l'article 27, il est permis de vendre des condoms au grand public — ou d'en faire la publicité auprès de celui-ci — afin de prévenir la transmission de maladies transmises sexuellement, à la condition que la publicité et le libellé de l'étiquette du condom indiquent seulement que celui-ci réduit le risque de transmission de maladies transmises sexuellement.

**(2)** Pour l'application du paragraphe 3(3) de la Loi et sous réserve de l'article 27, il est permis de faire auprès du grand public la publicité de moyens anticonceptionnels, autres que les appareils intra-utérins, sauf par la

public by any means other than by the distribution of samples of the devices door-to-door or through the mail.

SOR/2002-190, s. 4; SOR/2007-289, s. 3.

distribution d'échantillons de porte en porte ou par la poste.

DORS/2002-190, art. 4; DORS/2007-289, art. 3.

## Class I Medical Devices

**25 (1)** If the Minister believes on reasonable grounds, after reviewing a report or information brought to his or her attention, that a Class I medical device may not meet the applicable requirements of sections 10 to 20, the Minister may request the manufacturer to submit, on or before the day specified in the request, an analysis or other information to enable him or her to determine whether the device meets those requirements.

**(2)** The Minister may direct the manufacturer to stop the sale of the medical device if

- (a)** the manufacturer has not complied with the request on or before the day specified in the request; or
- (b)** the Minister determines, on the basis of the information submitted, that the device does not meet the applicable requirements of sections 10 to 20.

**(3)** The Minister shall lift the direction to stop the sale if

- (a)** the Minister determines, on the basis of the information submitted, that the medical device meets the applicable requirements of sections 10 to 20;
- (b)** corrective action has been taken to ensure that the medical device meets the applicable requirements of sections 10 to 20; or
- (c)** the Minister's determination was unfounded.

SOR/2015-193, s. 7; SOR/2020-262, s. 7.

## Instruments médicaux de classe I

**25 (1)** Si le ministre a des motifs raisonnables de croire, à la suite de l'examen de tout rapport ou renseignement portés à sa connaissance, qu'un instrument médical de classe I peut ne pas satisfaire aux exigences applicables prévues aux articles 10 à 20, il peut demander au fabricant de lui fournir, dans le délai précisé, une analyse ou tout autre renseignement visant à lui permettre de déterminer si l'instrument satisfait ou non à ces exigences.

**(2)** Le ministre peut ordonner au fabricant de cesser la vente de l'instrument médical dans les cas suivants :

- a)** le fabricant n'a pas obtempéré à la demande de renseignements dans le délai qui y était précisé;
- b)** le ministre détermine, à la suite de l'examen des renseignements fournis, que l'instrument ne satisfait pas aux exigences applicables prévues aux articles 10 à 20.

**(3)** Le ministre lève l'ordre de cessation de vente dans les cas suivants :

- a)** le ministre détermine, selon les renseignements fournis, que l'instrument médical satisfait aux exigences applicables prévues aux articles 10 à 20;
- b)** des mesures correctives ont été prises pour que l'instrument médical satisfasse aux exigences applicables prévues aux articles 10 à 20;
- c)** la détermination du ministre n'était pas fondée.

DORS/2015-193, art. 7; DORS/2020-262, art. 7.

## Class II, III and IV Medical Devices

### Prohibition

**26** Subject to section 37, no person shall import or sell a Class II, III or IV medical device unless the manufacturer of the device holds a licence in respect of that device or, if the medical device has been subjected to a change described in section 34, an amended medical device licence.

**27** No person shall advertise a Class II, III or IV medical device for the purpose of sale unless

## Instruments médicaux de classe II, III et IV

### Interdictions

**26** Sous réserve de l'article 37, il est interdit d'importer ou de vendre un instrument médical de classe II, III ou IV, sauf si le fabricant est titulaire, à l'égard de l'instrument, d'une homologation ou, dans le cas où l'instrument a fait l'objet d'une modification visée à l'article 34, d'une homologation modifiée.

**27** Il est interdit de faire la publicité d'un instrument médical de classe II, III ou IV en vue de la vente, sauf dans les cas suivants :

**(a)** the manufacturer of the device holds a licence in respect of that device or, if the device has been subjected to a change described in section 34, an amended medical device licence;

**(a.1)** the manufacturer of the device holds an authorization issued under section 68.12 in respect of that device or, if the device has been subjected to a change described in section 68.13, an amended authorization; or

**(b)** the advertisement is placed only in a catalogue that includes a clear and visible warning that the devices advertised in the catalogue may not have been licensed in accordance with Canadian law.

SOR/2023-19, s. 1.

**a)** le fabricant est titulaire, à l'égard de l'instrument, d'une homologation ou, dans le cas où l'instrument a fait l'objet d'une modification visée à l'article 34, d'une homologation modifiée;

**a.1)** le fabricant est titulaire, à l'égard de l'instrument, d'une autorisation délivrée au titre de l'article 68.12 ou, dans le cas où l'instrument a fait l'objet d'une modification visée à l'article 68.13, d'une autorisation modifiée;

**b)** la publicité ne se fait que par catalogue et celui-ci comporte, lisiblement et bien en vue, un avertissement portant que les instruments qui y sont annoncés peuvent ne pas avoir été homologués conformément à la législation canadienne.

DORS/2023-19, art. 1.

## Medical Devices Deemed Licensed

**28** If a system is licensed, all of its components or parts that are manufactured by the manufacturer of the system are deemed, for the purposes of its importation, sale or advertisement, to have been licensed.

**29** If a test kit is licensed, all of its reagents or articles that are manufactured by the manufacturer of the test kit are deemed, for the purposes of its importation, sale or advertisement, to have been licensed.

**30** If a medical device or a medical device group is licensed and forms part of a medical device family or a medical device group family, as the case may be, all other medical devices or medical device groups in the family are deemed to have been licensed.

**31 (1)** If all the medical devices that form part of a medical device group are licensed, that medical device group is deemed to have been licensed.

**(2)** If a medical device group is licensed, all the medical devices that form part of the medical device group are deemed, for the purposes of its importation, sale or advertisement, to have been licensed.

## Application for a Medical Device Licence

**32 (1)** An application for a medical device licence shall be submitted to the Minister by the manufacturer of the medical device in a format established by the Minister and shall contain the following:

**(a)** the name of the device;

## Présomptions d'homologation

**28** Si un système est homologué, tous ses composants ou parties qui sont fabriqués par le fabricant du système sont réputés avoir été homologués aux fins de l'importation, de la vente ou de la publicité de celui-ci.

**29** Si une trousse d'essai est homologuée, tous ses réactifs ou articles qui sont fabriqués par le fabricant de la trousse sont réputés avoir été homologués aux fins de l'importation, de la vente ou de la publicité de celle-ci.

**30** Si un instrument médical ou un ensemble d'instruments est homologué et qu'il fait partie, selon le cas, d'une famille d'instruments ou d'une famille d'ensembles d'instruments, les autres instruments médicaux ou ensembles d'instruments de la famille sont réputés avoir été homologués.

**31 (1)** L'ensemble d'instruments dont tous les instruments médicaux sont homologués est réputé avoir été homologué.

**(2)** Si un ensemble d'instruments est homologué, tous les instruments médicaux qui font partie de l'ensemble sont réputés avoir été homologués aux fins de l'importation, de la vente ou de la publicité de celui-ci.

## Demande d'homologation

**32 (1)** La demande d'homologation d'un instrument médical est présentée par le fabricant au ministre, en la forme fixée par celui-ci, et contient les renseignements et documents suivants :

**a)** le nom de l'instrument;

- (b)** the class of the device;
- (c)** the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (d)** the name and address of the manufacturer as it appears on the device label; and
- (e)** the name and address of the establishment where the device is being manufactured, if different from the one referred to in paragraph (d).
- (2)** An application for a Class II medical device licence shall contain, in addition to the information and documents set out in subsection (1), the following:
- (a)** a description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented;
- (b)** a list of the standards complied with in the manufacture of the device to satisfy the applicable requirements of sections 10 to 20;
- (c)** an attestation by a senior official of the manufacturer that the manufacturer has objective evidence to establish that the device meets the applicable requirements of sections 10 to 20;
- (d)** a copy of the device label;
- (e)** in the case of a near patient *in vitro* diagnostic device, an attestation by a senior official of the manufacturer that investigational testing has been conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use; and
- (f)** a copy of the quality management system certificate certifying that the quality management system under which the device is manufactured meets the requirements set out in the National Standard of Canada CAN/CSA-ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*, as amended from time to time.
- (3)** An application for a Class III medical device licence shall contain, in addition to the information and documents set out in subsection (1), the following:
- (a)** a description of the device and of the materials used in its manufacture and packaging;
- b)** la classe de l'instrument;
- c)** l'identificateur de l'instrument, y compris celui de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;
- d)** les nom et adresse du fabricant qui figurent sur l'étiquette de l'instrument;
- e)** les nom et adresse de l'établissement où l'instrument est fabriqué, s'ils diffèrent de ceux visés à l'alinéa d).
- (2)** Dans le cas d'un instrument médical de classe II, la demande doit en outre contenir les renseignements et documents suivants :
- a)** la description des états pathologiques, des fins et des utilisations pour lesquels l'instrument est fabriqué, vendu ou présenté;
- b)** la liste des normes de fabrication de l'instrument qui ont été respectées afin d'assurer la conformité aux exigences applicables prévues aux articles 10 à 20;
- c)** une attestation d'un dirigeant du fabricant portant que celui-ci détient des preuves tangibles permettant d'établir que l'instrument satisfait aux exigences applicables prévues aux articles 10 à 20;
- d)** une copie de l'étiquette de l'instrument;
- e)** dans le cas d'un instrument diagnostique clinique *in vitro*, une attestation d'un dirigeant du fabricant portant que l'instrument a fait l'objet d'un essai expérimental avec des sujets humains constituant un échantillon représentatif des utilisateurs auxquels l'instrument est destiné et dans des conditions similaires aux conditions d'utilisation;
- f)** une copie du certificat de système de gestion de la qualité attestant que le système de gestion de la qualité auquel est soumise la fabrication de l'instrument satisfait aux exigences de la norme nationale du Canada CAN/CSA-ISO 13485 intitulée *Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires*, avec ses modifications successives.
- (3)** Dans le cas d'un instrument médical de classe III, la demande doit en outre contenir les renseignements et documents suivants :
- a)** la description de l'instrument, ainsi que ses matériaux de fabrication et d'emballage;

- (b)** a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented;
- (c)** a list of the countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries;
- (d)** a list of the standards complied with in the design and manufacture of the device to satisfy the applicable requirements of sections 10 to 20;
- (e)** in the case of a device to be sold in a sterile condition, a description of the sterilization method used;
- (f)** a summary of all studies on which the manufacturer relies to ensure that the device meets the applicable requirements of sections 10 to 20, and the conclusions drawn from those studies by the manufacturer;
- (g)** a copy of the device label;
- (h)** in the case of a near patient *in vitro* diagnostic device, a summary of investigational testing conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use;
- (i)** a bibliography of all published reports dealing with the use, safety and effectiveness of the device; and
- (j)** a copy of the quality management system certificate certifying that the quality management system under which the device is designed and manufactured meets the requirements set out in the National Standard of Canada CAN/CSA-ISO 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes*, as amended from time to time.
- (4)** An application for a Class IV medical device licence shall contain, in addition to the information and documents set out in subsection (1), the following:
- (a)** a description of the device and of the materials used in its manufacture and packaging;
- (b)** a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented;
- b)** l'énoncé des caractéristiques de l'instrument qui permettent de l'utiliser pour les états pathologiques, les fins et les utilisations pour lesquels il est fabriqué, vendu ou présenté;
- c)** la liste des pays étrangers où il a été vendu, le nombre total d'unités vendues dans ces pays et un sommaire des problèmes signalés et des rappels effectués dans ces pays;
- d)** la liste des normes de conception et de fabrication de l'instrument qui ont été respectées afin d'assurer la conformité aux exigences applicables prévues aux articles 10 à 20;
- e)** dans le cas d'un instrument destiné à être vendu à l'état stérile, une description de la méthode de stérilisation utilisée;
- f)** un sommaire des études sur lesquelles le fabricant se fonde pour veiller à ce que l'instrument satisfasse aux exigences applicables prévues aux articles 10 à 20, ainsi que les conclusions que le fabricant en a tirées;
- g)** une copie de l'étiquette de l'instrument;
- h)** dans le cas d'un instrument diagnostique clinique *in vitro*, le sommaire d'un essai expérimental effectué à l'égard de celui-ci avec des sujets humains constituant un échantillon représentatif des utilisateurs auxquels l'instrument est destiné et dans des conditions similaires aux conditions d'utilisation;
- i)** la bibliographie des rapports publiés relativement à l'utilisation, la sûreté et l'efficacité de l'instrument;
- j)** une copie du certificat de système de gestion de la qualité attestant que le système de gestion de la qualité auquel sont soumises la conception et la fabrication de l'instrument satisfait aux exigences de la norme nationale du Canada CAN/CSA-ISO 13485 intitulée *Dispositifs médicaux – Systèmes de management de la qualité – Exigences à des fins réglementaires*, avec ses modifications successives.
- (4)** Dans le cas d'un instrument médical de classe IV, la demande doit en outre contenir les renseignements et documents suivants :
- a)** la description de l'instrument, ainsi que ses matériaux de fabrication et d'emballage;
- b)** l'énoncé des caractéristiques de l'instrument qui permettent de l'utiliser pour les états pathologiques, les fins et les utilisations pour lesquels il est fabriqué, vendu ou présenté;

**(c)** a list of the countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries;

**(d)** a risk assessment comprising an analysis and evaluation of the risks, and the risk reduction measures adopted to satisfy the applicable requirements of sections 10 to 20;

**(e)** a quality plan setting out the specific quality practices, resources and sequence of activities relevant to the device;

**(f)** the specifications of the materials used in the manufacture and packaging of the device;

**(g)** the manufacturing process of the device;

**(h)** a list of the standards complied with in the design and manufacture of the device to satisfy the applicable requirements of sections 10 to 20;

**(i)** detailed information on all studies on which the manufacturer relies to ensure that the device meets the applicable requirements of sections 10 to 20, including

**(i)** pre-clinical and clinical studies,

**(ii)** process validation studies,

**(iii)** if appropriate, software validation studies, and

**(iv)** literature studies;

**(j)** in the case of a medical device other than an *in vitro* diagnostic device, manufactured from or incorporating animal or human tissue or their derivative, objective evidence of the biological safety of the device;

**(k)** in the case of a near patient *in vitro* diagnostic device, detailed information on investigational testing conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use;

**(l)** a summary of the studies referred to in paragraph (i) and the conclusions drawn from those studies by the manufacturer;

**(m)** a summary of the investigational testing referred to in paragraph (k) and the conclusions drawn from that testing by the manufacturer;

**c)** la liste des pays étrangers où il a été vendu, le nombre total d'unités vendues dans ces pays et un sommaire des problèmes signalés et des rappels effectués dans ces pays;

**d)** l'appréciation du risque qui consiste en une analyse et une évaluation des risques, ainsi que les mesures de réduction des risques adoptées afin que les exigences applicables prévues aux articles 10 à 20 soient respectées;

**e)** un plan qualité énonçant les pratiques, les moyens et la séquence des activités liées à la qualité qui sont propres à l'instrument;

**f)** les spécifications des matériaux de fabrication et d'emballage de l'instrument;

**g)** le processus de fabrication de l'instrument;

**h)** la liste des normes de conception et de fabrication de l'instrument qui ont été respectées afin d'assurer la conformité aux exigences applicables prévues aux articles 10 à 20;

**i)** le détail des études sur lesquelles le fabricant se fonde pour veiller à ce que l'instrument satisfasse aux exigences applicables prévues aux articles 10 à 20, y compris :

**(i)** les études pré-cliniques et cliniques,

**(ii)** les études de validation des procédés,

**(iii)** le cas échéant, les études de validation des logiciels,

**(iv)** les études documentaires;

**j)** dans le cas d'un instrument médical, autre qu'un instrument diagnostique *in vitro*, fabriqué à partir de tissus humains ou animaux ou de leurs dérivés, ou contenant de tels tissus ou dérivés, les preuves tangibles de la sûreté biologique de l'instrument;

**k)** dans le cas d'un instrument diagnostique clinique *in vitro*, le détail d'un essai expérimental effectué à l'égard de celui-ci avec des sujets humains constituant un échantillon représentatif des utilisateurs auxquels l'instrument est destiné et dans des conditions similaires aux conditions d'utilisation;

**l)** un sommaire des études visées à l'alinéa i), ainsi que les conclusions que le fabricant en a tirées;

(n) a bibliography of all published reports dealing with the use, safety and effectiveness of the device;

(o) a copy of the device label; and

(p) a copy of the quality management system certificate certifying that the quality management system under which the device is designed and manufactured meets the requirements set out in the National Standard of Canada CAN/CSA-ISO 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes*, as amended from time to time.

SOR/2003-173, s. 2; SOR/2006-197, s. 2; SOR/2015-193, ss. 4, 7; SOR/2019-44, s. 2; SOR/2020-262, s. 8.

(m) un sommaire de l'essai expérimental visé à l'alinéa k), ainsi que les conclusions que le fabricant en a tirées;

(n) la bibliographie des rapports publiés relativement à l'utilisation, la sûreté et l'efficacité de l'instrument;

(o) une copie de l'étiquette de l'instrument;

(p) une copie du certificat de système de gestion de la qualité attestant que le système de gestion de la qualité auquel sont soumises la conception et la fabrication de l'instrument satisfait aux exigences de la norme nationale du Canada CAN/CSA-ISO 13485 intitulée *Dispositifs médicaux – Systèmes de management de la qualité – Exigences à des fins réglementaires*, avec ses modifications successives.

DORS/2003-173, art. 2; DORS/2006-197, art. 2; DORS/2015-193, art. 4 et 7; DORS/2019-44, art. 2; DORS/2020-262, art. 8.

## Quality Management System Certificate

**32.1** The Minister shall recognize a person as a registrar for the purpose of issuing, renewing, suspending or cancelling quality management system certificates if the person

(a) has sufficient training, experience and technical knowledge in the design and manufacture of medical devices and in the effective implementation of quality management systems to determine whether a quality management system satisfies a standard referred to in paragraph 32(2)(f), (3)(j) or (4)(p); and

(b) conducts quality management system audits and issues, renews, suspends and cancels quality management system certificates in accordance with the applicable guidelines and practices established by the International Organization for Standardization.

SOR/2003-173, s. 3; SOR/2006-197, s. 3; SOR/2009-303, s. 1.

## Certificat de système de gestion de la qualité

**32.1** Aux fins de délivrance, de renouvellement, de suspension ou d'annulation d'un certificat de système de gestion de la qualité, le ministre reconnaît comme registraire toute personne qui, à la fois :

a) possède, en matière de conception et de fabrication d'instruments médicaux ainsi que de mise en application efficace de systèmes de gestion de la qualité, les connaissances techniques, la formation et l'expérience suffisantes pour établir si un système de gestion de la qualité satisfait aux normes mentionnées aux alinéas 32(2)f, (3)j ou (4)p;

b) procède à l'audit de systèmes de gestion de la qualité et à la délivrance, au renouvellement, à la suspension et à l'annulation de certificats de système de gestion de la qualité selon les lignes directrices et les pratiques établies par l'Organisation internationale de normalisation.

DORS/2003-173, art. 3; DORS/2006-197, art. 3; DORS/2009-303, art. 1.

**32.2** A quality management system certificate is valid for the period, not exceeding three years, specified in it.

SOR/2003-173, s. 3; SOR/2006-197, s. 4.

**32.2** Le certificat de système de gestion de la qualité est valide pour la période mentionnée qui ne peut excéder trois ans.

DORS/2003-173, art. 3; DORS/2006-197, art. 4.

**32.3** A registrar shall notify the Minister in writing within 15 days after suspending or cancelling a quality management system certificate.

SOR/2003-173, s. 3; SOR/2006-197, s. 4.

**32.3** Le registraire doit envoyer, dans les quinze jours suivant la suspension ou l'annulation d'un certificat de système de gestion de la qualité, un avis écrit en ce sens au ministre.

DORS/2003-173, art. 3; DORS/2006-197, art. 4.

**32.4** A registrar shall notify the Minister in writing within 15 days after the expiry of a quality management system certificate if the certificate has not been renewed.

SOR/2003-173, s. 3; SOR/2006-197, s. 4.

**32.5 (1)** Subject to subsection (2), the Minister may cease to recognize a person as a registrar if the Minister has reasonable grounds to believe that the person no longer meets the requirements of section 32.1 or fails to comply with section 32.3 or 32.4.

**(2)** Subject to section 32.6, the Minister shall not cease to recognize a person as a registrar unless

**(a)** the Minister has sent the registrar a written notice that sets out the reason for the proposed cessation of recognition, any corrective action required to be taken and the time within which it must be taken;

**(b)** if corrective action is required, the time set out in the notice has passed without the action having been taken; and

**(c)** the registrar has been given an opportunity to be heard in respect of the proposed cessation of recognition.

SOR/2003-173, s. 3; SOR/2009-303, s. 2.

**32.6 (1)** The Minister may cease to recognize a person as a registrar without giving the registrar an opportunity to be heard if it is necessary to do so to prevent injury to the health or safety of patients, users or other persons, by giving the registrar a notice in writing that states the reason for the cessation of recognition.

**(2)** A registrar may ask the Minister, in writing, that the cessation of recognition be reconsidered.

**(3)** The Minister shall, within 45 days after the date of receiving the request for reconsideration, provide the registrar with an opportunity to be heard.

SOR/2009-303, s. 2.

**32.7** The Minister shall reinstate the recognition of a person as a registrar if the situation that gave rise to the cessation of recognition has been corrected or if the cessation of recognition was unfounded.

SOR/2009-303, s. 2; SOR/2011-322, s. 1.

## Foreign Manufacturers

**33 (1)** If an application for a medical device licence is submitted by a manufacturer of a country other than Canada, the information and documents described in subsections 32(2) to (4) need not be submitted if

**32.4** Le registraire doit envoyer, dans les quinze jours suivant l'expiration d'un certificat de système de gestion de la qualité qui n'a pas été renouvelé, un avis écrit en ce sens au ministre.

DORS/2003-173, art. 3; DORS/2006-197, art. 4.

**32.5 (1)** Sous réserve du paragraphe (2), le ministre peut retirer la reconnaissance comme registraire à toute personne s'il a des motifs raisonnables de croire que celle-ci ne satisfait plus aux exigences prévues à l'article 32.1 ou ne se conforme pas aux articles 32.3 ou 32.4.

**(2)** Sous réserve de l'article 32.6, le ministre ne retire la reconnaissance comme registraire que si les conditions suivantes sont réunies :

**a)** il a envoyé au registraire un avis écrit faisant état de son intention de lui retirer sa reconnaissance, des motifs du retrait et, le cas échéant, des mesures correctives qui s'imposent ainsi que du délai accordé pour les prendre;

**b)** dans le cas où l'avis prévoit des mesures correctives, celles-ci n'ont pas été prises dans le délai accordé;

**c)** le registraire a eu la possibilité de se faire entendre à l'égard du retrait projeté.

DORS/2003-173, art. 3; DORS/2009-303, art. 2.

**32.6 (1)** Le ministre peut, si cela est nécessaire pour prévenir des risques pour la santé ou la sûreté des patients, utilisateurs ou autres personnes, procéder au retrait sans donner au registraire la possibilité de se faire entendre, en lui faisant parvenir un avis motivé.

**(2)** Le registraire peut demander par écrit au ministre de revoir sa décision de lui retirer sa reconnaissance.

**(3)** Le ministre doit, dans les quarante-cinq jours suivant la date de réception de la demande, donner au registraire la possibilité de se faire entendre à l'égard du retrait.

DORS/2009-303, art. 2.

**32.7** Le ministre rétablit la reconnaissance si la situation y ayant donné lieu a été corrigée ou si le retrait était non fondé.

DORS/2009-303, art. 2; DORS/2011-322, art. 1.

## Fabricants étrangers

**33 (1)** Si la demande d'homologation est présentée par le fabricant d'un pays étranger, les renseignements et documents visés aux paragraphes 32(2) à (4) n'ont pas à être fournis si :

- (a)** the applicant is governed, in that country, by a regulatory authority that is recognized by the Minister; and
- (b)** the application is accompanied by a certificate of compliance and a supporting summary report, issued by a conformity assessment body of that country that is recognized by the Minister, which certify that the medical device meets the applicable requirements of sections 10 to 20.

**(2)** For the purposes of subsection (1), the Minister may recognize a regulatory authority and a conformity assessment body of a country other than Canada only if it has the ability to determine whether the device meets the applicable requirements of sections 10 to 20.

**(3)** The Minister shall, on request, make available to any interested persons the list of recognized regulatory authorities and conformity assessment bodies of countries other than Canada.

SOR/2015-193, s. 7.

## Application for a Medical Device Licence Amendment

**34** If the manufacturer proposes to make one or more of the following changes, the manufacturer shall submit to the Minister, in a format established by the Minister, an application for a medical device licence amendment including the information and documents set out in section 32 that are relevant to the change:

- (a)** in the case of a Class III or IV medical device, a significant change;
- (b)** a change that would affect the class of the device;
- (c)** a change in the name of the manufacturer;
- (d)** a change in the name of the device;
- (e)** a change in the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (f)** in the case of a Class II medical device other than a decorative contact lens, a change in the medical conditions, purposes or uses for which the device is manufactured, sold or represented.

SOR/2015-193, s. 5.

**a)** d'une part, le demandeur est régi dans ce pays par un organisme de réglementation reconnu par le ministre;

**b)** d'autre part, la demande est accompagnée d'un certificat de conformité et d'un rapport sommaire à l'appui qui sont délivrés par un organisme d'évaluation de la conformité de ce pays, reconnu par le ministre, et qui attestent que l'instrument médical satisfait aux exigences applicables prévues aux articles 10 à 20.

**(2)** Aux fins du paragraphe (1), le ministre ne peut reconnaître un organisme de réglementation et un organisme d'évaluation de la conformité d'un pays étranger que s'ils ont la compétence voulue pour déterminer la conformité d'un instrument médical aux exigences applicables prévues aux articles 10 à 20.

**(3)** Le ministre met à la disposition de quiconque en fait la demande la liste des organismes de réglementation et des organismes d'évaluation de la conformité d'un pays étranger qu'il a reconnus.

DORS/2015-193, art. 7.

## Demande de modification de l'homologation

**34** Le fabricant qui se propose d'apporter une ou plusieurs des modifications suivantes doit présenter au ministre, en la forme fixée par celui-ci, une demande de modification de l'homologation qui contient les renseignements et documents visés à l'article 32 relatifs à la modification en cause :

- a)** dans le cas d'un instrument de classe III ou IV, une modification importante;
- b)** une modification ayant pour effet de modifier la classe de l'instrument;
- c)** une modification du nom du fabricant;
- d)** une modification du nom de l'instrument;
- e)** une modification de l'identificateur de l'instrument, ou de celui de tout instrument médical qui fait partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;

- f)** dans le cas d'un instrument de classe II autre que les lentilles cornéennes à but esthétique, une modification des états pathologiques, des fins ou des utilisations pour lesquels l'instrument est fabriqué, vendu ou présenté.

DORS/2015-193, art. 5.

## Additional Information and Samples

**35 (1)** If the information and documents submitted in respect of an application for a medical device licence or a medical device licence amendment are insufficient to enable the Minister to determine whether a medical device meets the applicable requirements of sections 10 to 20, the Minister may request the manufacturer to submit, on or before a specified day, additional information necessary for making the determination.

**(2)** In the course of examining the application, the Minister may require the applicant to provide samples of the medical device.

SOR/2015-193, s. 7.

## Issuance

**36 (1)** If the Minister determines that a medical device in respect of which an application is submitted meets the applicable requirements of sections 10 to 20, the Minister shall

**(a)** issue to the manufacturer of the device a medical device licence, in the case of an application for a medical device licence; or

**(b)** amend the medical device licence, in the case of an application for a medical device licence amendment.

**(2)** The Minister may set out in a medical device licence terms and conditions respecting

**(a)** the tests to be performed on a device to ensure that it continues to meet the applicable requirements of sections 10 to 20; and

**(b)** the requirement to submit the results and protocols of any tests performed.

**(3)** The Minister may amend the terms and conditions of the medical device licence to take into account any new development with respect to the device.

**(4)** The holder of the medical device licence shall comply with the terms and conditions of the licence.

SOR/2015-193, s. 7.

## Renseignements complémentaires et échantillons

**35 (1)** Lorsque les renseignements et documents contenus dans la demande d'homologation ou de modification de celle-ci sont insuffisants pour permettre au ministre de déterminer si l'instrument médical satisfait ou non aux exigences applicables prévues aux articles 10 à 20, celui-ci peut demander au fabricant de lui fournir, dans le délai précisé, des renseignements complémentaires.

**(2)** Au cours de l'examen de la demande, le ministre peut exiger que le fabricant fournit des échantillons de l'instrument médical.

DORS/2015-193, art. 7.

## Délivrance

**36 (1)** S'il détermine que l'instrument médical faisant l'objet de la demande satisfait aux exigences applicables prévues aux articles 10 à 20, le ministre :

**a)** délivre au fabricant de l'instrument une homologation à l'égard de l'instrument, s'il s'agit d'une demande d'homologation;

**b)** modifie l'homologation, s'il s'agit d'une demande de modification de celle-ci.

**(2)** Le ministre peut assortir l'homologation de conditions concernant :

**a)** les essais à effectuer à l'égard de l'instrument pour veiller à ce que celui-ci satisfasse toujours aux exigences applicables prévues aux articles 10 à 20;

**b)** l'obligation de soumettre le protocole d'essai et les résultats de ces essais.

**(3)** Le ministre peut modifier les conditions de l'homologation pour tenir compte de tout fait nouveau concernant l'instrument.

**(4)** Le titulaire de l'homologation doit se conformer aux conditions de l'homologation.

DORS/2015-193, art. 7.

## Lot of *In Vitro* Diagnostic Devices

**37** No person shall sell a medical device from a lot of licensed *in vitro* diagnostic devices in respect of which terms and conditions were set out in the licence pursuant to section 36, unless

- (a) the results and protocol of any test performed on the device in accordance with those terms and conditions have been provided to the Minister; and
- (b) the Minister determines, on the basis of the information received under paragraph (a), that the device continues to meet the applicable requirements of sections 10 to 20.

SOR/2015-193, s. 7.

## Refusal to Issue

**38 (1)** The Minister may refuse to issue or amend a medical device licence if

- (a) the applicant does not comply with these Regulations or any provisions of the Act relating to medical devices;
  - (b) the applicant has made a false or misleading statement in the application;
  - (c) the medical device does not comply with the labelling requirements set out in sections 21 to 23; or
  - (d) the applicant has not complied with a request for additional information or samples made pursuant to section 35 by the day specified in the request.
- (2)** The Minister shall refuse to issue or amend a medical device licence if the medical device does not meet the applicable requirements of sections 10 to 20 or if the information or samples provided pursuant to section 35 are insufficient to enable the Minister to determine whether the medical device meets those requirements.

**(3)** If the Minister refuses to issue or amend a medical device licence, the Minister shall

- (a) notify the applicant in writing of the reasons for the refusal; and
- (b) give the applicant an opportunity to be heard.

SOR/2015-193, s. 7.

## Lot d'instruments diagnostiques in vitro

**37** Il est interdit de vendre tout instrument d'un lot d'instruments diagnostiques in vitro à l'égard desquels des conditions ont été prescrites en application de l'article 36, sauf si :

- a) d'une part, le protocole d'essai et les résultats de tout essai effectué conformément à ces conditions ont été soumis au ministre;
- b) d'autre part, le ministre détermine, selon les renseignements soumis en application de l'alinéa a), que l'instrument satisfait toujours aux exigences applicables prévues aux articles 10 à 20.

DORS/2015-193, art. 7.

## Refus

**38 (1)** Le ministre peut refuser de délivrer ou de modifier une homologation dans les cas suivants :

- a) le demandeur ne se conforme pas au présent règlement ou aux dispositions de la Loi relatives aux instruments médicaux;
- b) le demandeur a fait une déclaration fausse ou trompeuse dans sa demande;
- c) l'instrument médical n'est pas étiqueté conformément aux articles 21 à 23;
- d) le demandeur n'obtempère pas à la demande de renseignements complémentaires ou d'échantillons visée à l'article 35 dans le délai imparti.

**(2)** Le ministre refuse de délivrer ou de modifier une homologation si l'instrument médical ne satisfait pas aux exigences applicables prévues aux articles 10 à 20 ou si les renseignements ou les échantillons fournis en application de l'article 35 sont insuffisants pour lui permettre de déterminer si l'instrument médical satisfait ou non à ces exigences.

**(3)** S'il refuse de délivrer ou de modifier l'homologation, le ministre :

- a) en avise le demandeur par écrit, motifs à l'appui;
- b) lui donne la possibilité de se faire entendre.

DORS/2015-193, art. 7.

## Requests by Minister

**39** If the Minister believes on reasonable grounds, after reviewing a report or information brought to his or her attention, that a licensed medical device may not meet the applicable requirements of sections 10 to 20, the Minister may request the manufacturer to submit, on or before the day specified in the request, samples — or an analysis or other information — to enable him or her to determine whether the device meets those requirements.

SOR/2015-193, s. 7; SOR/2020-262, s. 9.

## Suspension

**40 (1)** Subject to subsection (3), the Minister may suspend a medical device licence if the Minister has reasonable grounds to believe that

- (a)** the licensee has contravened these Regulations or any provision of the Act relating to medical devices;
- (b)** the licensee has made a false or misleading statement in the application;
- (c)** the licensee has failed to comply with the terms and conditions of the licence;
- (d)** the licensee has not complied with a request made under section 39 on or before the day specified in the request;
- (d.1)** the samples — or the analysis or other information — submitted by the licensee in response to a request made under section 39 are insufficient to enable the Minister to determine whether the medical device meets the applicable requirements of sections 10 to 20;
- (e)** the medical device no longer meets the applicable requirements of sections 10 to 20; or
- (f)** on the basis of information obtained after the device was licensed, the quality management system under which the device has been designed, in the case of a Class III or IV device, or manufactured, assembled, processed, packaged, refurbished or modified, in the case of a Class II, III or IV device, is inadequate to ensure that the device meets its specifications.

**(2)** Before suspending a medical device licence, the Minister shall consider

## Demandes du ministre

**39** Si le ministre a des motifs raisonnables de croire, à la suite de l'examen de tout rapport ou renseignement portés à sa connaissance, qu'un instrument médical homologué peut ne pas satisfaire aux exigences applicables prévues aux articles 10 à 20, il peut demander au fabricant de lui fournir, dans le délai précisé, des échantillons, une analyse ou tout autre renseignement visant à lui permettre de déterminer si l'instrument satisfait ou non à ces exigences.

DORS/2015-193, art. 7; DORS/2020-262, art. 9.

## Suspension

**40 (1)** Sous réserve du paragraphe (3), le ministre peut suspendre l'homologation s'il a des motifs raisonnables de croire que :

- a)** le titulaire de l'homologation a enfreint le présent règlement ou toute disposition de la Loi relative aux instruments médicaux;
- b)** il a fait une déclaration fausse ou trompeuse dans sa demande;
- c)** il ne s'est pas conformé aux conditions de l'homologation;
- d)** il n'a pas obtempéré à une demande faite en vertu de l'article 39 dans le délai qui y était précisé;
- d.1)** les échantillons, l'analyse ou les autres renseignements fournis par le titulaire en réponse à une demande faite en vertu de l'article 39 sont insuffisants pour permettre au ministre de déterminer si l'instrument médical satisfait ou non aux exigences applicables prévues aux articles 10 à 20;
- e)** l'instrument ne satisfait plus aux exigences applicables prévues aux articles 10 à 20;
- f)** selon les renseignements obtenus après l'homologation de l'instrument, le système de gestion de la qualité en vertu duquel l'instrument a été conçu, dans le cas d'un instrument de classe III ou IV, ou fabriqué, assemblé, traité, emballé, restauré ou modifié, dans le cas d'un instrument de classe II, III ou IV, ne suffit pas pour assurer le respect des spécifications de l'instrument.

**(2)** Avant de suspendre l'homologation, le ministre prend en considération les faits suivants :

- (a)** the licensee's history of compliance with these Regulations and with the provisions of the Act relating to medical devices; and
- (b)** the risk that allowing the licence to continue to be in force would constitute for the health or safety of patients, users or other persons.

**(3)** Subject to section 41, the Minister shall not suspend a medical device licence until

- (a)** the Minister has sent the licensee a written notice that sets out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;
- (b)** if corrective action is required, the time set out in the notice has passed without the action having been taken; and
- (c)** the licensee has been given an opportunity to be heard in respect of the suspension.

SOR/2006-197, s. 4; SOR/2015-193, s. 7; SOR/2020-262, s. 10.

**41 (1)** The Minister may suspend a medical device licence without giving the licensee an opportunity to be heard if it is necessary to do so to prevent injury to the health or safety of patients, users or other persons, by giving the licensee a notice in writing that states the reason for the suspension.

**(2)** A licensee may ask the Minister, in writing, that the suspension be reconsidered.

**(3)** The Minister shall, within 45 days after the date of receiving the request, provide the licensee with an opportunity to be heard.

**41.1** The Minister may suspend a medical device licence if, after he or she has, under section 21.31 of the Act, ordered the licensee to conduct an assessment of the medical device in order to provide evidence establishing that the benefits associated with the device outweigh the risks to the health or safety of patients, users or other persons,

- (a)** the licensee has not complied with the order; or
- (b)** the licensee has complied with the order but the Minister determines that the results of the assessment are not sufficient to establish that the benefits associated with the device outweigh the risks to the health or safety of patients, users or other persons.

SOR/2020-262, s. 11.

**a)** les antécédents du titulaire pour ce qui est de la conformité au présent règlement et aux dispositions de la Loi relatives aux instruments médicaux;

**b)** le risque que présenterait le maintien de l'homologation pour la santé ou la sûreté des patients, utilisateurs ou autres personnes.

**(3)** Sous réserve de l'article 41, le ministre ne peut suspendre l'homologation que si, à la fois :

**a)** le ministre a envoyé au titulaire un avis écrit précisant les motifs de la suspension et, le cas échéant, les mesures correctives qui s'imposent ainsi que le délai accordé pour les prendre;

**b)** lorsque l'avis prévoit des mesures correctives, le titulaire ne les a pas prises dans le délai prévu;

**c)** le titulaire a eu la possibilité de se faire entendre à l'égard de la suspension.

DORS/2006-197, art. 4; DORS/2015-193, art. 7; DORS/2020-262, art. 10.

**41 (1)** Le ministre peut, lorsque cela est nécessaire pour prévenir des risques pour la santé ou la sûreté des patients, utilisateurs ou autres personnes, suspendre l'homologation sans donner au titulaire la possibilité de se faire entendre, en lui faisant parvenir un avis motivé.

**(2)** Le titulaire peut demander par écrit au ministre que la suspension soit révisée.

**(3)** Le ministre doit, dans les 45 jours suivant la date de réception de la demande, donner au titulaire la possibilité de se faire entendre.

**41.1** Le ministre peut suspendre l'homologation d'un instrument médical si, après avoir ordonné au titulaire en vertu de l'article 21.31 de la Loi d'effectuer une évaluation de l'instrument en vue de fournir des preuves établissant que les avantages liés à l'instrument l'emportent sur les risques pour la santé ou la sûreté des patients, des utilisateurs ou d'autres personnes :

**a)** le titulaire ne s'est pas conformé à l'ordre;

**b)** le titulaire s'est conformé à l'ordre, mais le ministre conclut que les résultats de l'évaluation sont insuffisants pour établir que les avantages liés à l'instrument l'emportent sur les risques pour la santé ou la sûreté des patients, des utilisateurs ou d'autres personnes.

DORS/2020-262, art. 11.

**42** The Minister may reinstate a medical device licence if the situation giving rise to the suspension has been corrected or if the reason for the suspension was unfounded.

## Obligation to Inform

**43 (1)** Every manufacturer of a licensed medical device shall, annually before November 1 and in a form authorized by the Minister, furnish the Minister with a statement signed by the manufacturer or by a person authorized to sign on the manufacturer's behalf

(a) confirming that all the information and documents supplied by the manufacturer with respect to the device are still correct; or

(b) describing any change to the information and documents supplied by the manufacturer with respect to the device, other than those to be submitted under section 34 or 43.1.

(2) If the manufacturer fails to comply with subsection (1), the Minister may cancel the medical device licence.

(3) If the holder of a medical device licence discontinues the sale of the medical device in Canada, the licensee shall inform the Minister within 30 days after the discontinuance, and the licence shall be cancelled at the time that the Minister is informed.

SOR/2003-173, s. 4.

## Obligation to Submit Certificate

**43.1** Subject to section 34, if a new or modified quality management system certificate is issued in respect of a licensed medical device, the manufacturer of the device shall submit a copy of the certificate to the Minister within 30 days after it is issued.

SOR/2003-173, s. 5; SOR/2006-197, s. 4.

## Disclosure of Information in Respect of Clinical Studies or Investigational Testing

**43.11** In sections 43.12 and 43.13, ***information in respect of a clinical study or investigational testing*** means information in respect of a clinical study, or investigational testing, involving human subjects that is contained in an application for a Class III or IV medical device licence made under section 32 or in an application to amend such a licence made under section 34.

SOR/2019-63, s. 1.

**42** Le ministre peut lever la suspension de l'homologation si la situation y ayant donné lieu a été corrigée ou si le motif de la suspension était non fondé.

## Obligation d'informer

**43 (1)** Avant le 1<sup>er</sup> novembre de chaque année, le fabricant d'un instrument médical homologué doit fournir au ministre, en la forme fixée par celui-ci, une déclaration signée par lui-même ou en son nom par une personne autorisée :

a) qui atteste que tous les renseignements et documents qu'il a présentés au sujet de l'instrument sont toujours exacts;

b) sinon, qui précise toutes les modifications de ces renseignements et documents, à l'exclusion de ceux à présenter en vertu des articles 34 ou 43.1.

(2) Si le fabricant ne se conforme pas au paragraphe (1), le ministre peut annuler l'homologation.

(3) Le titulaire de l'homologation d'un instrument médical qui en cesse la vente au Canada doit en informer le ministre dans les 30 jours suivant la cessation, et l'homologation est annulée dès que le ministre en est informé.

DORS/2003-173, art. 4.

## Obligation de présenter un certificat

**43.1** Sous réserve de l'article 34, le fabricant d'un instrument médical homologué doit présenter au ministre une copie de tout nouveau certificat de système de gestion de la qualité ou de tout certificat modifié, relatifs à cet instrument, dans les trente jours suivant sa délivrance.

DORS/2003-173, art. 5; DORS/2006-197, art. 4.

## Communication de renseignements relatifs à des études cliniques ou des essais expérimentaux

**43.11** Aux articles 43.12 et 43.13, ***renseignements relatifs à une étude clinique ou un essai expérimental*** s'entend des renseignements qui sont relatifs à une étude clinique ou à un essai expérimental effectués avec des sujets humains et qui sont contenus dans la demande d'homologation d'un instrument médical de classe III ou IV présentée au titre de l'article 32, ou dans la demande de

**43.12 (1)** Information in respect of a clinical study or investigational testing that is confidential business information ceases to be confidential business information when one of the following circumstances occurs with respect to the application:

- (a)** the Minister issues a licence under paragraph 36(1)(a);
- (b)** the Minister amends a licence under paragraph 36(1)(b);
- (c)** the Minister refuses to issue a licence or amend a licence under section 38.

**(2)** Subsection (1) does not apply to information in respect of a clinical study or investigational testing that

- (a)** was not used by the manufacturer in the application to support the information referred to in paragraph 32(3)(b) or paragraph 32(4)(b); or
- (b)** describes tests, methods or assays that are used exclusively by the manufacturer.

SOR/2019-63, s. 1.

**43.13** The Minister may disclose, without notifying the person to whose business or affairs the information relates or obtaining their consent, any information in respect of a clinical study or investigational testing that has ceased to be confidential business information.

SOR/2019-63, s. 1.

## Medical Devices to Be Sold for the Purposes of Implementing the General Council Decision

### Application

**43.2** Sections 43.3 to 43.6 apply, for the purposes of implementing the General Council Decision, to a medical device in respect of which a manufacturer has applied to the Commissioner of Patents for an authorization under section 21.04 of the *Patent Act*.

SOR/2005-142, s. 2; SOR/2011-42, s. 1.

modification d'une telle homologation présentée au titre de l'article 34.

DORS/2019-63, art. 1.

**43.12 (1)** Les renseignements relatifs à une étude clinique ou un essai expérimental qui sont des renseignements commerciaux confidentiels cessent d'être des renseignements commerciaux confidentiels au moment où l'une des circonstances ci-après survient relativement à la demande :

- a)** le ministre délivre une homologation en application de l'alinéa 36(1)a);
- b)** le ministre modifie une homologation en application de l'alinéa 36(1)b);
- c)** le ministre refuse de délivrer ou de modifier une homologation en vertu de l'article 38.

**(2)** Le paragraphe (1) ne s'applique pas aux renseignements relatifs à une étude clinique ou un essai expérimental suivants :

- a)** ceux que le fabricant n'a pas utilisés dans la demande pour étayer les renseignements visés aux alinéas 32(3)b ou 32(4)b;
- b)** ceux qui décrivent les tests, méthodes et essais utilisés exclusivement par le fabricant.

DORS/2019-63, art. 1.

**43.13** Le ministre peut communiquer les renseignements relatifs à une étude clinique ou un essai expérimental qui se rapportent à l'entreprise d'une personne ou à ses activités et qui ont cessé d'être des renseignements commerciaux confidentiels, et ce, sans obtenir son consentement et sans l'aviser.

DORS/2019-63, art. 1.

## Vente d'instruments médicaux aux fins de mise en œuvre de la décision du Conseil général

### Champ d'application

**43.2** Les articles 43.3 à 43.6 s'appliquent, aux fins de mise en œuvre de la décision du Conseil général, à l'instrument médical à l'égard duquel le fabricant a présenté au commissaire aux brevets une demande d'autorisation aux termes de l'article 21.04 de la *Loi sur les brevets*.

DORS/2005-142, art. 2; DORS/2011-42, art. 1.

## Notices to Commissioner of Patents

**43.3** The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.04(3)(b) of the Patent Act that the manufacturer's medical device meets the requirements of the Act and these Regulations if

- (a) the manufacturer holds a medical device licence in respect of the device issued in accordance with section 36;
- (b) the Minister is satisfied that the manufacturer and the device comply with the Act and these Regulations;
- (c) the manufacturer has submitted to the Minister a copy of the application filed by the manufacturer with the Commissioner of Patents under section 21.04 of the *Patent Act*;
- (d) the manufacturer has submitted to the Minister information regarding the manner in which the mark referred to in paragraph 43.5(1)(a) is applied to all permanent components of the device; and
- (e) the manufacturer has submitted to the Minister a sample of the label for the device that includes the information required by paragraph 43.5(1)(b).

SOR/2005-142, s. 2.

**43.4** The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.13(b) of the *Patent Act* in the event that the Minister is of the opinion that the manufacturer's medical device referred to in section 43.2 has ceased to meet the requirements of the Act and these Regulations.

SOR/2005-142, s. 2.

## Marking and Labelling

**43.5 (1)** No person shall sell a medical device referred to in section 43.2 unless

- (a) the mark "XCL" is displayed on all permanent components of the device; and
- (b) the label of the device displays the mark "XCL" followed by the control number referred to in paragraph 21(1)(d) and the words "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA." or "POUR EXPORTATION AUX TERMES DE LA DÉCISION DU CONSEIL GÉNÉRAL. VENTE INTERDITE AU CANADA.".

## Avis au commissaire aux brevets

**43.3** Le ministre avise le fabricant et le commissaire aux brevets, pour l'application de l'alinea 21.04(3)b) de la *Loi sur les brevets*, que l'instrument médical satisfait aux exigences de la Loi et du présent règlement si les conditions suivantes sont réunies :

- a) le fabricant est titulaire, à l'égard de l'instrument, d'une homologation délivrée en application de l'article 36;
- b) le ministre est convaincu que le fabricant et l'instrument satisfont aux exigences de la Loi et du présent règlement;
- c) le fabricant a fourni au ministre un exemplaire de la demande qu'il a présentée au commissaire aux brevets aux termes de l'article 21.04 de la *Loi sur les brevets*;
- d) le fabricant a fourni au ministre des renseignements sur la méthode suivie pour apposer la marque visée à l'alinea 43.5(1)a) sur les composants permanents de l'instrument;
- e) le fabricant a fourni au ministre un échantillon de l'étiquette de l'instrument sur laquelle figurent les renseignements prévus à l'alinea 43.5(1)b).

DORS/2005-142, art. 2.

**43.4** Le ministre avise le fabricant et le commissaire aux brevets, pour l'application de l'alinea 21.13b) de la *Loi sur les brevets*, s'il est d'avis que l'instrument médical du fabricant visé à l'article 43.2 ne satisfait plus aux exigences de la Loi et du présent règlement.

DORS/2005-142, art. 2.

## Marquage et étiquetage

**43.5 (1)** Il est interdit de vendre l'instrument médical visé à l'article 43.2 à moins que :

- a) les composants permanents de l'instrument ne portent la marque « XCL »;
- b) l'étiquette de l'instrument ne porte la marque « XCL » suivie du numéro de contrôle visé à l'alinea 21(1)d) et de la mention « POUR EXPORTATION AUX TERMES DE LA DÉCISION DU CONSEIL GÉNÉRAL. VENTE INTERDITE AU CANADA. » ou « FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA. ».

**(2)** The information required by subsection (1) shall be expressed in a legible, permanent and prominent manner.

SOR/2005-142, s. 2.

## Notice to Minister

**43.6** The manufacturer of a medical device referred to in section 43.2 shall notify the Minister in writing not less than 15 days prior to commencing the manufacture of the device.

SOR/2005-142, s. 2.

## Establishment Licence

### Prohibition

**44 (1)** No person shall import or sell a medical device unless the person holds an establishment licence.

**(2)** Subsection (1) does not apply to the importation or sale of a medical device by

- (a)** a retailer;
- (b)** a health care facility;
- (c)** in the case of a Class II, III or IV medical device, the manufacturer of the medical device; or

**(d)** in the case of a Class I device, the manufacturer of the medical device, if the manufacturer imports or distributes solely through a person who holds an establishment licence.

**(3)** Any person who imports a medical device shall ensure that the person from whom they import it holds an establishment licence.

**(4)** Subsection (3) does not apply where a person imports

**(a)** in the case of a Class I medical device, from the manufacturer of that medical device if the person importing it holds an establishment licence; and

**(b)** in the case of a Class II, III or IV medical device, from the manufacturer of that medical device.

SOR/2018-225, s. 2.

## Application

**45** A person who wishes to apply for an establishment licence shall submit an application to the Minister, in a

**(2)** Les renseignements visés au paragraphe (1) doivent être lisibles, marqués de façon permanente et placés bien en vue.

DORS/2005-142, art. 2.

## Avis au ministre

**43.6** Le fabricant de l'instrument médical visé à l'article 43.2 est tenu d'aviser le ministre par écrit au moins quinze jours avant de commencer à fabriquer l'instrument.

DORS/2005-142, art. 2.

## Licence d'établissement

### Interdiction

**44 (1)** Il est interdit d'importer ou de vendre un instrument médical, à moins d'être titulaire d'une licence d'établissement.

**(2)** Le paragraphe (1) ne s'applique ni à l'importation ni à la vente d'un instrument médical par :

- a)** les détaillants;
- b)** les établissements de santé;
- c)** dans le cas d'un instrument de classe II, III ou IV, son fabricant;
- d)** dans le cas d'un instrument de classe I, son fabricant, s'il le distribue ou l'importe uniquement par l'entremise d'une personne qui est titulaire d'une licence d'établissement.

**(3)** La personne qui importe un instrument médical veille à ce que la personne de laquelle elle l'importe soit titulaire d'une licence d'établissement.

**(4)** Le paragraphe (3) ne s'applique pas dans les cas suivants :

- a)** s'agissant d'un instrument médical de classe I, la personne l'importe de son fabricant et est titulaire d'une licence d'établissement;
- b)** s'agissant d'un instrument médical de classe II, III ou IV, la personne l'importe de son fabricant.

DORS/2018-225, art. 2.

## Demande

**45** La demande de licence d'établissement est présentée au ministre, en la forme fixée par lui, et contient les renseignements et documents suivants :

form established by the Minister, that contains the following information and documents:

- (a)** the name and address of the establishment;
- (a.1)** any other name under which the person previously conducted activities under these Regulations;
- (b)** the name, title and contact information of the representative of the establishment to contact for information concerning the application;
- (c)** a statement as to whether the activity of the establishment is importation or distribution, or both;
- (d)** the names and addresses of the manufacturers of the devices that are being imported or distributed;
- (e)** for each manufacturer, in respect of a medical device other than a decorative contact lens, the medical specialities in respect of which the device is imported or distributed;
- (f)** for each manufacturer, the classes of the devices that are being imported or distributed;
- (g)** an attestation by a senior official of the establishment that the establishment has documented procedures in place in respect of distribution records, complaint handling and recalls;
- (h)** if the establishment imports Class I medical devices, an attestation by a senior official of the establishment that the establishment has documented procedures in place in respect of the making of reports under subsections 59(1) and (1.1);
- (h.1)** if the establishment imports Class II, III or IV medical devices, an attestation by a senior official of the establishment that the establishment has documented procedures in place in respect of the making of reports under subsection 59(1) and the provision of information under section 61.2;
- (i)** if the establishment imports or distributes Class II, III or IV devices, an attestation by a senior official of the establishment that the establishment has documented procedures in place, where applicable, for handling, storage, delivery, installation, corrective action and servicing in respect of those devices; and
- (j)** the address of each building where the procedures described in paragraphs (g) to (i) are in place.

SOR/2011-82, s. 1(E); SOR/2015-193, s. 6; SOR/2018-225, s. 3; SOR/2020-262, s. 12; SOR/2024-136, s. 7.

- a)** les nom et adresse de l'établissement;
- a.1)** tout autre nom sous lequel le demandeur a exercé des activités en vertu du présent règlement;
- b)** les nom, titre et coordonnées du représentant de l'établissement avec lequel communiquer pour obtenir tout renseignement concernant la demande;
- c)** le type d'activité auquel se livre l'établissement, à savoir l'importation ou la distribution, ou les deux;
- d)** les nom et adresse des fabricants des instruments médicaux importés ou distribués;
- e)** pour chaque fabricant, à l'égard d'un instrument médical autre que les lentilles cornéennes à but esthétique, les spécialités médicales pour lesquelles l'instrument médical est importé ou distribué;
- f)** pour chaque fabricant, les classes d'instruments médicaux qui sont importés ou distribués;
- g)** une attestation d'un dirigeant de l'établissement portant que celui-ci a mis en œuvre une procédure écrite concernant les registres de distribution, les plaintes et les rappels;
- h)** dans le cas d'un établissement qui importe des instruments médicaux de classe I, une attestation d'un dirigeant de l'établissement portant que celui-ci a mis en œuvre une procédure écrite concernant la présentation de rapports en application des paragraphes 59(1) et (1.1);
  - h.1)** dans le cas d'un établissement qui importe des instruments médicaux de classe II, III ou IV, une attestation d'un dirigeant de l'établissement portant que celui-ci a mis en œuvre une procédure écrite concernant la présentation de rapports en application du paragraphe 59(1) et la fourniture de renseignements en application de l'article 61.2;
  - i)** dans le cas d'un établissement qui importe ou distribue des instruments médicaux de classe II, III ou IV, une attestation d'un dirigeant de l'établissement portant que celui-ci a mis en œuvre des procédures écrites concernant, le cas échéant, la manutention, le stockage, la livraison, l'installation, les mesures correctives et l'entretien à l'égard de ces instruments;
  - j)** l'adresse de chaque immeuble où les procédures visées aux alinéas g) à i) sont mises en œuvre.

DORS/2011-82, art. 1(A); DORS/2015-193, art. 6; DORS/2018-225, art. 3; DORS/2020-262, art. 12; DORS/2024-136, art. 7.

## Issuance

**46** Subject to section 47, the Minister shall issue an establishment licence if the Minister determines that the application meets the requirements of section 45.

SOR/2011-82, s. 2.

## Annual Review of Licence

**46.1 (1)** The holder of an establishment licence that is not suspended shall submit an application for the review of their licence to the Minister before April 1 of each year and include with it the information and documents referred to in section 45.

**(2)** The Minister shall conduct an annual review of the licence on the basis of the information and documents submitted by the holder and any other relevant information in the Minister's possession.

SOR/2011-82, s. 2.

## Refusal

**47 (1)** The Minister may refuse to issue an establishment licence if the applicant has made a false or misleading statement in the application.

**(2)** The Minister shall refuse to issue an establishment licence if the Minister has reasonable grounds to believe that issuing such a licence would constitute a risk to the health or safety of patients, users or other persons.

**(3)** If the Minister refuses to issue an establishment licence, the Minister shall

- (a)** notify the applicant in writing of the reasons for the refusal; and
- (b)** give the applicant an opportunity to be heard.

## Notification

**48** If, following the issuance of an establishment licence, there is a change to any of the information referred to in paragraph 45(a) or (b), the holder of the establishment licence shall submit the new information to the Minister within 15 days of the change.

SOR/2024-136, s. 8(E).

## Terms and Conditions

**48.1** The Minister may, at any time, impose terms and conditions on an establishment licence, or amend those

## Délivrance

**46** Sous réserve de l'article 47, le ministre délivre au demandeur une licence à l'égard de l'établissement s'il conclut que la demande satisfait aux exigences de l'article 45.

DORS/2011-82, art. 2.

## Examen annuel de la licence

**46.1 (1)** Le titulaire d'une licence d'établissement qui n'est pas suspendue doit, avant le 1<sup>er</sup> avril de chaque année, présenter au ministre la demande d'examen de sa licence accompagnée des renseignements et documents visés à l'article 45.

**(2)** Le ministre fait un examen annuel de la licence en se fondant sur les renseignements et documents fournis par le titulaire et sur toute autre information utile qu'il a en sa possession.

DORS/2011-82, art. 2.

## Refus

**47 (1)** Le ministre peut refuser de délivrer une licence d'établissement si le demandeur a fait une déclaration fausse ou trompeuse dans sa demande.

**(2)** Le ministre refuse de délivrer une licence d'établissement s'il a des motifs raisonnables de croire que la délivrance d'une telle licence constituerait un risque pour la santé ou la sûreté des patients, utilisateurs ou autres personnes.

**(3)** S'il refuse de délivrer la licence d'établissement, le ministre :

- a)** en avise le demandeur par écrit, motifs à l'appui;
- b)** lui donne la possibilité de se faire entendre.

## Avis de modification

**48** Si les renseignements visés aux alinéas 45a) ou b) sont modifiés après la délivrance de la licence d'établissement, le titulaire de la licence doit fournir au ministre les nouveaux renseignements dans les quinze jours suivant la modification.

DORS/2024-136, art. 8(A).

## Conditions

**48.1** Le ministre peut, en tout temps, assortir de conditions la licence d'établissement ou modifier de telles

terms and conditions, after considering the following factors:

- (a)** whether there are uncertainties relating to the manner in which an activity is or will be conducted;
- (b)** whether the requirements under the Act are sufficient to protect patients, users or other persons from risks to health or safety;
- (c)** whether compliance with the proposed terms and conditions is feasible; and
- (d)** whether there are less burdensome ways to meet the objectives of the proposed terms and conditions.

SOR/2024-136, s. 9.

## Suspension

**49 (1)** Subject to subsection (3), the Minister may suspend an establishment licence if the Minister has reasonable grounds to believe that

- (a)** the licensee has contravened these Regulations or any provision of the Act relating to medical devices;
- (b)** the licensee has made a false or misleading statement in the application; or
- (c)** failure to suspend the establishment licence would constitute a risk to the health or safety of patients, users or other persons.

**(2)** Before suspending an establishment licence, the Minister shall consider

- (a)** the licensee's history of compliance with these Regulations and with the provisions of the Act relating to medical devices; and
- (b)** the risk that allowing the licence to continue to be in force would constitute a risk to the health or safety of patients, users or other persons.

**(3)** Subject to section 50, the Minister shall not suspend an establishment licence until

- (a)** the Minister has sent the licensee a written notice that sets out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;

conditions après avoir pris en compte les facteurs suivants :

- a)** la question de savoir si la façon dont une activité est menée ou le sera fait l'objet d'incertitudes;
- b)** la question de savoir si les exigences prévues sous le régime de la Loi sont suffisantes pour protéger les patients, utilisateurs ou autres personnes contre les risques à leur santé ou sûreté;
- c)** la question de savoir si le respect des conditions projetées est réalisable;
- d)** la question de savoir si des moyens moins exigeants existent pour atteindre les objectifs des conditions projetées.

DORS/2024-136, art. 9.

## Suspension

**49 (1)** Sous réserve du paragraphe (3), le ministre peut suspendre la licence d'établissement s'il a des motifs raisonnables de croire que :

- a)** le titulaire de la licence a enfreint le présent règlement ou toute disposition de la Loi relative aux instruments médicaux;
- b)** il a fait une déclaration fausse ou trompeuse dans sa demande;
- c)** le maintien de la licence constituerait un risque pour la santé ou la sûreté des patients, utilisateurs ou autres personnes.

**(2)** Avant de suspendre la licence d'établissement, le ministre prend en considération les faits suivants :

- a)** les antécédents du titulaire pour ce qui est de la conformité au présent règlement et aux dispositions de la Loi relatives aux instruments médicaux;
- b)** le risque que présenterait le maintien de la licence pour la santé ou la sûreté des patients, utilisateurs ou autres personnes.

**(3)** Sous réserve de l'article 50, le ministre ne peut suspendre la licence d'établissement que si, à la fois :

- a)** le ministre a envoyé au titulaire un avis écrit précisant les motifs de la suspension et, le cas échéant, les mesures correctives qui s'imposent ainsi que le délai accordé pour les prendre;
- b)** lorsque l'avis prévoit des mesures correctives, le titulaire ne les a pas prises dans le délai prévu;

**(b)** if corrective action is required, the time set out in the notice has passed without the action having been taken; and

**(c)** the licensee has been given an opportunity to be heard in respect of the suspension.

**50 (1)** The Minister may suspend an establishment licence without giving the licensee an opportunity to be heard if it is necessary to do so to prevent risk to the health or safety of patients, users or other persons, by giving the licensee a notice in writing that states the reason for the suspension.

**(2)** A licensee may ask the Minister, in writing, that the suspension be reconsidered.

**(3)** The Minister shall, within 45 days after the date of receiving the request, provide the licensee with an opportunity to be heard.

SOR/2021-46, s. 12(E).

**51** The Minister shall reinstate an establishment licence if the situation that gave rise to the suspension has been corrected or if the reason for the suspension was unfounded.

SOR/2011-82, s. 3.

## Cancellation

**51.1** The Minister shall cancel an establishment licence in either of the following circumstances:

- (a)** the licence has been suspended for a period of more than 12 months, or
- (b)** the licence holder has failed to submit an application for the review of their licence in accordance with subsection 46.1(1).

SOR/2011-82, s. 3.

## Distribution Records

**52 (1)** The manufacturer, importer and distributor of a medical device shall each maintain a distribution record in respect of each device.

**(2)** Subsection (1) does not apply to

- (a)** a retailer; or
- (b)** a health care facility in respect of a medical device that is distributed for use within that facility.

**c)** le titulaire a eu la possibilité de se faire entendre à l'égard de la suspension.

**50 (1)** Le ministre peut, lorsque cela est nécessaire pour prévenir des risques pour la santé ou la sûreté des patients, utilisateurs ou autres personnes, suspendre la licence d'établissement sans donner au titulaire la possibilité de se faire entendre, en lui faisant parvenir un avis motivé.

**(2)** Le titulaire peut demander par écrit au ministre que la suspension soit révisée.

**(3)** Le ministre doit, dans les 45 jours suivant la date de réception de la demande, donner au titulaire la possibilité de se faire entendre.

DORS/2021-46, art. 12(A).

**51** Le ministre lève la suspension de la licence d'établissement si la situation y ayant donné lieu a été corrigée ou si le motif de la suspension était non fondé.

DORS/2011-82, art. 3.

## Annulation

**51.1** Le ministre annule une licence dans les circonstances suivantes :

- a)** la licence a été suspendue pour plus de douze mois;
- b)** le titulaire a omis de présenter une demande d'examen annuel de sa licence conformément au paragraphe 46.1(1).

DORS/2011-82, art. 3.

## Registre de distribution

**52 (1)** Le fabricant, l'importateur et le distributeur d'un instrument médical doivent chacun tenir un registre de distribution de celui-ci.

**(2)** Le paragraphe (1) ne s'applique :

- a)** ni aux détaillants;
- b)** ni aux établissements de santé, en ce qui concerne les instruments médicaux distribués pour utilisation interne.

**53** The distribution record shall contain sufficient information to permit the complete and rapid recall of the medical device.

SOR/2024-136, s. 10.

**54 (1)** The distribution record maintained by a manufacturer of an implant shall also contain a record of the information received on the implant registration cards forwarded to the manufacturer from a health care facility pursuant to section 67.

**(2)** The manufacturer of an implant shall update the information referred to in subsection (1) in accordance with any information received from the health care facility or the patient.

**55** The manufacturer, importer and distributor shall retain the distribution record maintained in respect of a medical device for the longer of

- (a)** the projected useful life of the device, and
- (b)** two years after the date the device is shipped.

**56** Distribution records shall be maintained in a manner that will allow their timely retrieval.

## Complaint Handling

**57 (1)** The manufacturer, importer and distributor of a medical device shall each maintain records of the following:

- (a)** reported problems relating to the performance characteristics or safety of the device, including any consumer complaints, received by the manufacturer, importer or distributor after the device was first sold in Canada; and
- (b)** all actions taken by the manufacturer, importer or distributor in response to the problems referred to in paragraph (a).

**(2)** Subsection (1) does not apply to

- (a)** a retailer; or
- (b)** a health care facility in respect of a medical device that is distributed for use within that facility.

**58** The manufacturer, importer and distributor of a medical device shall each establish and implement documented procedures that will enable the manufacturer, importer or distributor to carry out

**53** Le registre de distribution doit contenir suffisamment de renseignements pour permettre le rappel rapide et complet de l'instrument médical.

DORS/2024-136, art. 10.

**54 (1)** Le registre de distribution que tient le fabricant d'un implant doit également contenir les renseignements inscrits sur les fiches d'enregistrement qu'il reçoit des établissements de santé en application de l'article 67.

**(2)** Le fabricant d'un implant doit mettre à jour ces renseignements d'après tout renseignement qui lui est transmis par les établissements de santé et les patients.

**55** Le fabricant, l'importateur et le distributeur doivent conserver leur registre de distribution pendant la plus longue des périodes suivantes :

- a)** la durée de vie utile projetée de l'instrument médical;
- b)** deux ans suivant la date d'expédition de l'instrument.

**56** Le registre de distribution doit être tenu de façon à être facilement accessible.

## Plaintes

**57 (1)** Le fabricant, l'importateur et le distributeur d'un instrument médical doivent chacun tenir des dossiers sur :

- a)** les problèmes au sujet des caractéristiques de rendement ou de la sûreté de l'instrument, y compris les plaintes des consommateurs, qui lui ont été signalés après la vente initiale de l'instrument au Canada;
- b)** les mesures qu'il a prises à la suite de ces problèmes.

**(2)** Le paragraphe (1) ne s'applique :

- a)** ni aux détaillants;
- b)** ni aux établissements de santé, en ce qui concerne les instruments médicaux distribués pour utilisation interne.

**58** Le fabricant, l'importateur et le distributeur d'un instrument médical doivent chacun établir et mettre en œuvre des procédures écrites leur permettant d'effectuer :

- (a) an effective and timely investigation of the problems referred to in paragraph 57(1)(a); and
- (b) an effective and timely recall of the device.

## Incident Reporting

[SOR/2020-262, s. 13]

**59 (1)** The manufacturer and the importer of a medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring in Canada that involves the device if

- (a) the device is sold in Canada; and
- (b) the incident
  - (i) is related to a failure of the device or a deterioration in its effectiveness or any inadequacy in its labelling or in its directions for use, and
  - (ii) has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were the incident to recur.

**(1.1)** Subject to subsection (2), the manufacturer and the importer of a Class I medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring outside Canada that involves the device if the conditions in paragraphs (1)(a) and (b) are met.

**(2)** The requirement to report an incident that occurs outside Canada does not apply unless the manufacturer has indicated, to a regulatory agency of the country in which the incident occurred, the manufacturer's intention to take corrective action, or unless the regulatory agency has required the manufacturer to take corrective action.

SOR/2020-262, s. 14.

**60 (1)** A preliminary report shall be submitted to the Minister

- (a) in respect of an incident that occurs in Canada
  - (i) within 10 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, or

- a) d'une part, une enquête sur les problèmes visés à l'alinéa 57(1)a) de façon efficace et en temps opportun;
- b) d'autre part, le rappel de l'instrument de façon efficace et en temps opportun.

## Rapports d'incident

[DORS/2020-262, art. 13]

**59 (1)** Le fabricant et l'importateur d'un instrument médical présentent chacun au ministre un rapport préliminaire et un rapport final sur tout incident dont ils ont connaissance qui s'est produit au Canada et qui met en cause l'instrument lorsque, à la fois :

- a) l'instrument est vendu au Canada;
- b) les conditions ci-après sont réunies :
  - (i) d'une part, l'incident est lié à une défaillance de l'instrument, à une dégradation de son efficacité ou à un étiquetage ou un mode d'emploi défectueux,
  - (ii) d'autre part, l'incident a entraîné la mort ou une détérioration grave de l'état de santé d'un patient, d'un utilisateur ou d'une autre personne, ou serait susceptible de le faire s'il se reproduisait.

**(1.1)** Sous réserve du paragraphe (2), le fabricant et l'importateur d'un instrument médical de classe I présentent chacun au ministre un rapport préliminaire et un rapport final sur tout incident dont ils ont connaissance qui s'est produit à l'étranger et qui met en cause l'instrument lorsque les conditions énoncées aux alinéas (1)a) et b) sont réunies.

**(2)** L'obligation de faire rapport au sujet d'un incident qui s'est produit à l'étranger ne s'applique que si le fabricant a avisé l'organisme de réglementation du pays en cause de son intention de prendre des mesures correctives ou que si cet organisme lui a demandé de prendre de telles mesures.

DORS/2020-262, art. 14.

**60 (1)** Le rapport préliminaire est présenté au ministre :

- a) dans le cas d'un incident qui s'est produit au Canada :
  - (i) dans les 10 jours suivant le moment où le fabricant ou l'importateur a eu connaissance de l'incident, dans le cas d'un incident qui a entraîné la mort ou une détérioration grave de l'état de santé d'un patient, utilisateur ou autre personne,

(ii) within 30 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were it to recur; and

(b) in respect of an incident that occurs outside Canada, as soon as possible after the manufacturer has indicated, to the regulatory agency referred to in paragraph 59(2), the manufacturer's intention to take corrective action, or after the regulatory agency has required the manufacturer to take corrective action.

(2) The preliminary report shall contain the following information:

(a) the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;

(b) if the report is made by

(i) the manufacturer, the name and address of that manufacturer and of any known importer, and the name, title and telephone and facsimile numbers of a representative of the manufacturer to contact for any information concerning the incident, or

(ii) the importer of the device, the name and address of the importer and of the manufacturer, and the name, title and telephone and facsimile numbers of a representative of the importer to contact for any information concerning the incident;

(c) the date on which the incident came to the attention of the manufacturer or importer;

(d) the details known in respect of the incident, including the date on which the incident occurred and the consequences for the patient, user or other person;

(e) the name, address and telephone number, if known, of the person who reported the incident to the manufacturer or importer;

(f) the identity of any other medical devices or accessories involved in the incident, if known;

(g) the manufacturer's or importer's preliminary comments with respect to the incident;

(h) the course of action, including an investigation, that the manufacturer or importer proposes to follow in respect of the incident and a timetable for carrying

(ii) dans les 30 jours suivant le moment où le fabricant ou l'importateur a eu connaissance de l'incident, dans le cas d'un incident qui n'a pas entraîné la mort ou une détérioration grave de l'état de santé d'un patient, utilisateur ou autre personne, mais qui serait susceptible de le faire s'il se reproduisait;

b) dans le cas d'un incident qui s'est produit à l'étranger, dans les plus brefs délais après que le fabricant a avisé l'organisme de réglementation visé au paragraphe 59(2) de son intention de prendre des mesures correctives ou après que celui-ci lui a demandé de prendre de telles mesures.

(2) Le rapport préliminaire contient les renseignements suivants :

a) les nom et identificateur de l'instrument, y compris l'identificateur de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;

b) dans le cas où le rapport est présenté :

(i) par le fabricant, ses nom et adresse et ceux de tout importateur connu, ainsi que les nom, titre et numéros de téléphone et de télécopieur d'un représentant du fabricant avec lequel communiquer pour tout renseignement concernant l'incident,

(ii) par l'importateur, ses nom et adresse et ceux du fabricant, ainsi que les nom, titre et numéros de téléphone et de télécopieur d'un représentant de l'importateur avec lequel communiquer pour tout renseignement concernant l'incident;

c) la date à laquelle le fabricant ou l'importateur a eu connaissance de l'incident;

d) les détails connus de l'incident, y compris la date où il s'est produit et ses répercussions sur la personne en cause;

e) s'ils sont connus, les nom, adresse et numéro de téléphone de la personne qui a signalé l'incident au fabricant ou à l'importateur;

f) s'ils sont connus, le nom de tout autre instrument médical ou accessoire en cause dans l'incident;

g) les observations préliminaires du fabricant ou de l'importateur sur l'incident;

out any proposed action and for submitting a final report; and

(i) a statement indicating whether a previous report has been made to the Minister with respect to the device and, if so, the date of the report.

**61 (1)** After the preliminary report is made in accordance with section 60, a final report shall be submitted to the Minister in accordance with the timetable established under paragraph 60(2)(h).

**(2)** The final report shall contain the following information:

(a) a description of the incident, including the number of persons who have experienced a serious deterioration in the state of their health or who have died;

(b) a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident; and

(c) any actions taken as a result of the investigation referred to in paragraph 60(2)(h), which may include

(i) increased post-market surveillance of the device,

(ii) corrective and preventive action respecting the design and manufacture of the device, and

(iii) recall of the device.

SOR/2002-190, s. 5; SOR/2023-247, s. 9.

**61.1 (1)** Despite subsection 59(1) or (1.1), the manufacturer of a medical device may permit the importer of the device to prepare and submit the preliminary and final reports on the manufacturer's behalf if the information that the manufacturer and the importer must include is identical.

**(2)** The manufacturer shall advise the Minister in writing if the manufacturer has permitted the importer to prepare and submit the reports on the manufacturer's behalf.

SOR/2002-190, s. 5; SOR/2020-262, s. 15.

## Serious Risk of Injury to Human Health

**61.2 (1)** This section applies to a holder of one of the following therapeutic product authorizations:

h) les mesures, notamment l'enquête, qu'entend prendre le fabricant ou l'importateur à l'égard de l'incident, ainsi que le calendrier de celles-ci, lequel comporte la date de présentation du rapport final;

i) une déclaration indiquant si l'instrument a fait l'objet ou non d'un rapport précédent au ministre et, le cas échéant, la date de celui-ci.

**61 (1)** À la suite de la présentation du rapport préliminaire conformément à l'article 60, le rapport final doit être présenté au ministre selon le calendrier visé à l'alinéa 60(2)h).

**(2)** Le rapport final doit contenir les renseignements suivants :

a) une description de l'incident, y compris le nombre de personnes qui sont décédées ou dont l'état de santé s'est gravement détérioré;

b) une explication détaillée des causes de l'incident et une justification des mesures prises à l'égard de celui-ci;

c) le cas échéant, les mesures qui ont été prises à la suite de l'enquête visée à l'alinéa 60(2)h), notamment :

(i) une surveillance accrue après la mise en marché de l'instrument,

(ii) les mesures correctives ou préventives relatives à la conception et à la fabrication de l'instrument,

(iii) le rappel de l'instrument.

DORS/2002-190, art. 5; DORS/2023-247, art. 9.

**61.1 (1)** Malgré les paragraphes 59(1) ou (1.1), le fabricant d'un instrument médical peut permettre à l'importateur de l'instrument de préparer et de soumettre, en son nom, le rapport préliminaire et le rapport final si les renseignements que chacun d'eux doit y inclure sont identiques.

**(2)** S'il confie à l'importateur le soin d'établir et de soumettre les rapports en son nom, le fabricant en avise par écrit le ministre.

DORS/2002-190, art. 5; DORS/2020-262, art. 15.

## Risque grave de préjudice à la santé humaine

**61.2 (1)** Le présent article s'applique au titulaire de l'une des autorisations relatives à un produit thérapeutique suivantes :

- (a)** a medical device licence; and
- (b)** an establishment licence to import Class II, III or IV medical devices.
- (2)** The holder of a therapeutic product authorization issued in respect of a medical device shall submit to the Minister information in respect of any serious risk of injury to human health that the holder receives or becomes aware of and that is relevant to the safety of the device, regarding
- (a)** risks that have been communicated by any regulatory agency that is set out in the *List of Regulatory Agencies for the Purposes of Sections 61.2 and 68.3 of the Medical Devices Regulations*, published by the Government of Canada on its website, as amended from time to time, or by any person who is authorized to manufacture or sell a medical device within the jurisdiction of such a regulatory agency, and the manner of the communication;
- (b)** changes that have been made to the labelling of any medical device and that have been communicated to or requested by any regulatory agency that is set out in the list referred to in paragraph (a); and
- (c)** recalls, reassessments and suspensions or revocations of authorizations, including licences, in respect of any medical device, that have taken place within the jurisdiction of any regulatory agency that is set out in the list referred to in paragraph (a).
- (3)** The information shall be submitted to the Minister within 72 hours after the holder receives or becomes aware of it, whichever occurs first.

SOR/2020-262, s. 16; SOR/2023-19, s. 2.

**61.3 (1)** Despite subsection 61.2(2), if the holder of a therapeutic product authorization issued in respect of a medical device is the manufacturer, they may permit the importer of the device to submit the information required under that subsection on the manufacturer's behalf if the information that the manufacturer and the importer must submit is identical.

**(2)** The manufacturer shall advise the Minister in writing if the manufacturer has permitted the importer to submit the information on the manufacturer's behalf.

SOR/2020-262, s. 16.

- a)** l'homologation d'un instrument médical;
- b)** la licence d'établissement autorisant l'importation d'instruments médicaux de classe II, III ou IV.
- (2)** Le titulaire d'une autorisation relative à un produit thérapeutique délivrée à l'égard d'un instrument médical fournit au ministre les renseignements dont il a reçu communication ou a connaissance concernant tout risque grave de préjudice à la santé humaine et se rapportant à la sécurité de l'instrument en ce qui concerne :
- a)** les risques communiqués, et la façon dont ils l'ont été, par tout organisme de réglementation mentionné dans la *Liste des organismes de réglementation pour l'application des articles 61.2 et 68.3 du Règlement sur les instruments médicaux*, publiée par le gouvernement du Canada sur son site Web, avec ses modifications successives, ou par toute personne autorisée à fabriquer ou à vendre un instrument médical sur le territoire relevant de la compétence d'un tel organisme;
- b)** les changements apportés à l'étiquetage de tout instrument médical à la demande de tout organisme de réglementation mentionné dans la liste visée à l'alinéa a) ou communiqués à un tel organisme;
- c)** les rappels, les réévaluations et les suspensions ou revocations d'autorisations, notamment de licences, relativement à tout instrument médical sur le territoire relevant de la compétence de tout organisme de réglementation mentionné dans la liste visée à l'alinéa a).

**(3)** Il fournit ces renseignements au ministre au plus tard soixante-douze heures après en avoir reçu communication ou en avoir eu connaissance, selon la première des deux éventualités à survenir.

DORS/2020-262, art. 16; DORS/2023-19, art. 2.

**61.3 (1)** Malgré le paragraphe 61.2(2), le titulaire d'une autorisation relative à un produit thérapeutique délivrée à l'égard d'un instrument médical dont il est le fabricant peut permettre à l'importateur de fournir, en son nom, les renseignements visés à ce paragraphe, si les renseignements que chacun d'eux doit fournir sont identiques.

**(2)** S'il permet à l'importateur de fournir les renseignements en son nom, le fabricant en avise par écrit le ministre.

DORS/2020-262, art. 16.

## Summary Report

**61.4 (1)** The holder of a medical device licence shall prepare

- (a) in the case of a Class II medical device, on a biennial basis, a summary report of the information referred to in subsection (2) that the holder received or became aware of during the previous 24 months; and
- (b) in the case of a Class III or IV medical device, on an annual basis, a summary report of the information referred to in subsection (2) that the holder received or became aware of during the previous 12 months.

**(2)** The information to be covered by the summary report is that in respect of

- (a) adverse effects;
- (b) problems referred to in paragraph 57(1)(a);
- (c) incidents referred to in subsection 59(1); and
- (d) serious risks of injury to human health that are relevant to the safety of the medical device and are referred to in subsection 61.2(2).

**(3)** The summary report shall contain a concise critical analysis of the information referred to in subsection (2).

**(4)** In preparing the summary report, the holder shall determine, on the basis of the critical analysis, whether what is known about the benefits and risks associated with the medical device has changed in any of the following ways:

- (a) the potential benefits for patients through the use of the device may be less;
- (b) in respect of each of the risks,
  - (i) the harm associated with the risk is more likely to occur, or
  - (ii) if the harm associated with the risk occurs, the consequences for the health or safety of patients, users or other persons could be more serious; and
- (c) a new risk has been identified.

**(5)** The holder shall include the conclusions they reach under subsection (4) in the summary report.

## Rapport de synthèse

**61.4 (1)** Le titulaire de l'homologation d'un instrument médical prépare :

- a) s'agissant d'un instrument médical de classe II, un rapport de synthèse biennal qui porte sur les renseignements visés au paragraphe (2) dont il a reçu communication ou a pris connaissance au cours des vingt-quatre derniers mois;
- b) s'agissant d'un instrument médical de classe III ou IV, un rapport de synthèse annuel qui porte sur les renseignements visés au paragraphe (2) dont il a reçu communication ou a pris connaissance au cours des douze derniers mois.

**(2)** Les renseignements précisés dans le rapport de synthèse sont les suivants :

- a) les effets nocifs;
- b) les problèmes visés à l'alinéa 57(1)a);
- c) les incidents visés au paragraphe 59(1);
- d) les risques graves de préjudice à la santé humaine se rapportant à la sécurité de l'instrument qui sont visés au paragraphe 61.2(2).

**(3)** Le rapport de synthèse comprend une analyse critique et concise des renseignements visés au paragraphe (2).

**(4)** En préparant le rapport, le titulaire évalue, à partir de son analyse critique, si ce qui est connu à propos des avantages et des risques liés à l'instrument médical a changé de l'une des manières suivantes :

- a) les avantages éventuels pour les patients de l'utilisation de l'instrument pourraient être moindres;
- b) pour chacun des risques, selon le cas :
  - (i) la probabilité que le préjudice lié au risque survienne est plus élevée,
  - (ii) si le préjudice lié au risque survenait, les répercussions sur la santé ou la sûreté des patients, des utilisateurs ou d'autres personnes pourraient être plus élevées;
- c) un nouveau risque a été identifié.

**(5)** Le titulaire fait état, dans le rapport de synthèse, des conclusions qu'il a tirées en application du paragraphe (4).

**(6)** If, in preparing the summary report, the holder concludes that what is known about the benefits and risks associated with the medical device has changed in any of the ways referred to in paragraphs (4)(a) to (c), they shall notify the Minister, in writing, within 72 hours after having reached the conclusion, unless that has already been done.

SOR/2020-262, s. 16; SOR/2023-19, s. 3.

**61.5 (1)** The Minister may, for the purposes of determining whether a medical device meets the applicable requirements of sections 10 to 20, request that the holder of a medical device licence issued in respect of the device submit, within a specified time limit, any of the following:

- (a)** summary reports; or
- (b)** information on the basis of which summary reports were prepared.

**(2)** The holder shall submit to the Minister the summary reports or information, or both, that the Minister requests within the time limit specified in the request.

SOR/2020-262, s. 16; SOR/2023-19, s. 4.

**61.6 (1)** The holder of a medical device licence shall maintain records of the summary reports and the information on the basis of which those reports were prepared.

**(2)** The holder shall retain the records for seven years after the day on which they were created.

SOR/2020-262, s. 16; SOR/2023-19, s. 5.

## Provision of Information Under Section 21.8 of Act

**62 (1)** For the purposes of section 21.8 of the Act, hospitals are the prescribed health care institutions that shall provide information that is in their control to the Minister about a medical device incident.

**(2)** The following prescribed information about a medical device incident that is in a hospital's control shall be provided to the Minister in writing within 30 days after the day on which the medical device incident is first documented within the hospital:

- (a)** the name of the hospital and the contact information of a representative of that hospital;
- (b)** the name or identifier of the medical device;

**(6)** Si le titulaire conclut, en préparant le rapport, que ce qui est connu à propos des avantages et des risques liés à l'instrument médical a changé de l'une des manières visées aux alinéas (4)a) à c), il en informe le ministre par écrit dans les soixante-douze heures après être arrivé à cette conclusion, si ce n'est pas déjà fait.

DORS/2020-262, art. 16; DORS/2023-19, art. 3.

**61.5 (1)** Pour évaluer si l'instrument médical satisfait aux exigences applicables prévues aux articles 10 à 20, le ministre peut demander au titulaire de l'homologation délivrée à l'égard de l'instrument de lui présenter, dans le délai fixé, ce qui suit :

- a)** ses rapports de synthèse;
- b)** les renseignements sur lesquels sont fondés les rapports de synthèse.

**(2)** Le titulaire fournit au ministre, sur demande, ses rapports de synthèse ou les renseignements, ou les deux, dans le délai précisé.

DORS/2020-262, art. 16; DORS/2023-19, art. 4.

**61.6 (1)** Le titulaire de l'homologation d'un instrument médical tient des dossiers contenant ses rapports de synthèse et les renseignements sur lesquels ces rapports sont fondés.

**(2)** Il les conserve pendant sept ans après la date de leur création.

DORS/2020-262, art. 16; DORS/2023-19, art. 5.

## Fourniture de renseignements en application de l'article 21.8 de la Loi

**62 (1)** Pour l'application de l'article 21.8 de la Loi, les hôpitaux sont les établissements de soins de santé tenus de fournir au ministre les renseignements qui relèvent d'eux concernant les incidents liés à un instrument médical.

**(2)** Les renseignements ci-après qui relèvent d'un hôpital concernant tout incident lié à un instrument médical sont fournis au ministre par écrit dans les trente jours suivant le jour où l'incident lié à un instrument médical est consigné pour la première fois dans l'hôpital :

- a)** le nom de l'hôpital et les coordonnées d'une personne représentant celui-ci;
- b)** le nom ou l'identificateur de l'instrument;

- (c) the date on which the medical device incident was first documented;
- (d) the name of the manufacturer of the medical device;
- (e) a description of the medical device incident;
- (f) the lot number of the device or its serial number;
- (g) any contributing factors to the medical device incident, including any medical condition of the patient that directly relates to the medical device incident; and
- (h) the effect of the medical device incident on the patient's health.

(3) A hospital is exempt from section 21.8 of the Act in respect of the reporting of information referred to in subsection (2) if

- (a) the hospital does not have in its control all of the information referred to in paragraphs (2)(b) and (e) in respect of the medical device incident; or
- (b) the medical device incident involves only a medical device that is the subject of an authorization issued under subsection 72(1) or 83(1).

(4) The following definitions apply in this section.

**hospital** means a facility

- (a) that is licensed, approved or designated as a hospital by a province in accordance with the laws of the province to provide care or treatment to persons suffering from any form of disease or illness; or
- (b) that is operated by the Government of Canada and that provides health services to in-patients. (*hôpital*)

**medical device incident** means an incident related to a failure of a medical device, a deterioration in its effectiveness or any inadequacy in its labelling or in its directions for use that has led to the death or a serious deterioration in the state of health of a patient, user or other person or could do so were it to recur. (*incident lié à un instrument médical*)

- (c) la date de la première consignation de l'incident lié à un instrument médical;
- (d) le nom du fabricant de l'instrument;
- (e) une description de l'incident lié à un instrument médical;
- (f) le numéro de lot ou le numéro de série de l'instrument;
- (g) tout facteur ayant contribué à l'incident lié à un instrument médical, notamment tout état pathologique du patient directement rattaché à l'incident lié à un instrument médical;
- (h) l'effet de l'incident lié à un instrument médical sur la santé du patient.

(3) L'hôpital est exempté de l'application de l'article 21.8 de la Loi à l'égard des renseignements visés au paragraphe (2) dans les cas suivants :

- (a) les renseignements visés aux alinéas (2)b) et e) concernant l'incident lié à un instrument médical ne relèvent pas tous de l'hôpital;
- (b) l'incident lié à un instrument médical met en cause seulement un instrument médical qui fait l'objet d'une autorisation délivrée conformément aux paragraphes 72(1) ou 83(1).

(4) Les définitions ci-après s'appliquent au présent article.

**hôpital** Établissement qui, selon le cas :

- (a) fait l'objet d'un permis délivré par une province ou a été approuvé ou désigné par elle à ce titre, en conformité avec ses lois, en vue d'assurer des soins ou des traitements aux personnes atteintes de toute forme de maladie ou d'affection;
- (b) est exploité par le gouvernement du Canada et assure des soins de santé à des patients hospitalisés. (*hôpital*)

**incident lié à un instrument médical** Incident qui est lié à une défaillance d'un instrument médical, à une dégradation de l'efficacité d'un tel instrument ou à un étiquetage ou un mode d'emploi défectueux et qui soit a entraîné le décès ou une détérioration grave de l'état de santé d'un patient, d'un utilisateur ou de toute autre personne, soit serait susceptible de le faire s'il se reproduisait. (*medical device incident*)

**(5)** For the purposes of the Act, *medical device incident* has the same meaning as in subsection (4).

SOR/2019-191, s. 1.

**(5)** Pour l'application de la Loi, *incident lié à un instrument médical* s'entend au sens du paragraphe (4).

DORS/2019-191, art. 1.

## Assessments Ordered Under Section 21.31 of the Act

**62.1 (1)** The Minister's power to make an order under section 21.31 of the Act in respect of a medical device is subject to the following conditions:

**(a)** the person to whom the order is made shall be the holder of a medical device licence issued in respect of the device; and

**(b)** the Minister shall have reasonable grounds to believe that the benefits — or the risks to the health or safety of patients, users or other persons — that are associated with the device are significantly different than they were when the medical device licence was issued or amended.

**(2)** The Minister shall, after examining the results of an assessment that was ordered under section 21.31 of the Act in respect of a medical device,

**(a)** provide the holder of the medical device licence issued in respect of the device with the results of the examination; and

**(b)** ensure that a summary of the results of the examination, together with a description of any steps that the Minister has taken or may take as a consequence of the examination, is published on the Government of Canada website.

SOR/2020-262, s. 17.

## Activities Ordered Under Section 21.32 of the Act

**62.2** The Minister's power to make an order under section 21.32 of the Act in respect of a medical device is subject to the following conditions:

**(a)** the person to whom the order is made shall be the holder of a medical device licence issued in respect of the device;

**(b)** the Minister shall have reasonable grounds to believe that

**(i)** there are significant uncertainties relating to the benefits or adverse effects associated with the device,

## Évaluations ordonnées en vertu de l'article 21.31 de la Loi

**62.1 (1)** Le pouvoir du ministre de donner un ordre visant un instrument médical en vertu de l'article 21.31 de la Loi est assujetti aux conditions suivantes :

**a)** la personne à qui l'ordre est donné est titulaire de l'homologation délivrée à l'égard de l'instrument;

**b)** le ministre a des motifs raisonnables de croire que les avantages — ou les risques pour la santé ou la sûreté des patients, des utilisateurs ou d'autres personnes — liés à l'instrument sont considérablement différents de ce qu'ils étaient au moment où l'homologation a été délivrée ou modifiée.

**(2)** Au terme de son examen des résultats d'une évaluation visant un instrument médical qu'il a ordonnée en vertu de l'article 21.31 de la Loi, le ministre :

**a)** communique les résultats de l'examen au titulaire de l'homologation délivrée à l'égard de l'instrument;

**b)** veille à ce qu'un résumé des résultats de l'examen ainsi que la description, le cas échéant, des mesures qu'il a prises ou peut prendre à la suite de cet examen soient publiés sur le site Web du gouvernement du Canada.

DORS/2020-262, art. 17.

## Activités ordonnées en vertu de l'article 21.32 de la Loi

**62.2** Le pouvoir du ministre de donner un ordre visant un instrument médical en vertu de l'article 21.32 de la Loi est assujetti aux conditions suivantes :

**a)** la personne à qui l'ordre est donné est titulaire de l'homologation délivrée à l'égard de l'instrument;

**b)** le ministre a des motifs de raisonnables de croire, à la fois :

**(i)** que les avantages ou les effets nocifs liés à l'instrument font l'objet d'incertitudes importantes,

(ii) the licensee is unable to provide the Minister with information that is sufficient to manage those uncertainties, and

(iii) the applicable requirements of these Regulations, together with any terms and conditions that have been imposed on the medical device licence, do not allow for sufficient information to be obtained to manage those uncertainties; and

(c) the Minister shall take into account the following matters:

(i) whether the activities that the licensee will be ordered to undertake are feasible, and

(ii) whether there are less burdensome ways of obtaining additional information about the device's effects on the health or safety of patients, users or other persons.

SOR/2020-262, s. 17.

## Shortages

**62.21** The following definitions apply in this section and in sections 62.22 to 62.26.

**List of Medical Devices – Notification of Shortages** means the *List of Medical Devices – Notification of Shortages* that is published by the Government of Canada on its website, as amended from time to time. (*Liste d'instruments médicaux – avis de pénuries*)

**specified medical device** means a medical device that belongs to a category of medical devices that is set out in the *List of Medical Devices – Notification of Shortages*. (*Instrument médical inscrit*)

SOR/2021-199, s. 7.

**62.22** The Minister may add a category of medical devices to the *List of Medical Devices – Notification of Shortages* only if the Minister has reasonable grounds to believe that a shortage of a device that belongs to the category presents or may present a risk of injury to human health.

SOR/2021-199, s. 7.

**62.23 (1)** Subject to subsections (2), (7) and (9), if a shortage of a specified medical device exists or is likely to occur, the manufacturer of the device and, in the case of a Class I device, the importer of the device shall each provide the following information to the Minister electronically in a format specified by or acceptable to the Minister:

(ii) que le titulaire n'est pas en mesure de fournir au ministre des renseignements suffisants pour gérer ces incertitudes,

(iii) que les exigences applicables du présent règlement ainsi que toute condition dont l'homologation est assortie ne permettent pas de recueillir des renseignements suffisants pour gérer ces incertitudes;

c) le ministre tient compte des éléments suivants :

(i) la faisabilité des activités qu'il ordonnera au titulaire de mener,

(ii) l'existence de moyens moins exigeants de recueillir des renseignements supplémentaires quant aux effets de l'instrument sur la santé ou la sûreté des patients, des utilisateurs ou d'autres personnes.

DORS/2020-262, art. 17.

## Pénuries

**62.21** Les définitions qui suivent s'appliquent au présent article et aux articles 62.22 à 62.26.

**instrument médical inscrit** Instrument médical qui appartient à une catégorie d'instruments médicaux figurant sur la *Liste d'instruments médicaux – avis de pénuries*. (*Specified medical device*)

**Liste d'instruments médicaux – avis de pénuries** La *Liste d'instruments médicaux – avis de pénuries*, avec ses modifications successives, publiée par le gouvernement du Canada sur son site Web. (*List of Medical Devices – Notification of Shortages*)

DORS/2021-199, art. 7.

**62.22** Le ministre ne peut ajouter une catégorie d'instruments médicaux à la *Liste d'instruments médicaux – avis de pénuries* que s'il a des motifs raisonnables de croire que la pénurie visant un instrument appartenant à cette catégorie d'instruments présente ou peut présenter un risque de préjudice à la santé humaine.

DORS/2021-199, art. 7.

**62.23 (1)** Sous réserve des paragraphes (2), (7) et (9), s'il y a pénurie ou probabilité de pénurie d'un instrument médical inscrit, le fabricant de l'instrument et, s'agissant d'un instrument de classe I, l'importateur de l'instrument fournissent chacun les renseignements ci-après au ministre, par voie électronique, en la forme précisée ou jugée acceptable par ce dernier :

- (a)** the name and contact information of the manufacturer and, if the information is provided by the importer, the name and contact information of the importer;
- (b)** in the case of a licensed device, the medical device licence number;
- (b.1)** in the case of a device for which the manufacturer holds an authorization issued under section 68.12, the authorization number;
- (c)** the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (d)** the name of the device, including, if applicable, the model name, in English and French;
- (e)** a description of the device and of its packaging and an indication of whether it is a single-use device;
- (f)** the date when the shortage began or is anticipated to begin;
- (g)** the anticipated date when the manufacturer will be able to meet the demand for the device if that date can be anticipated;
- (h)** the reason for the shortage; and
- (i)** a summary of the information that the manufacturer or importer relied on to determine that a shortage of the device exists or is likely to occur.
- (2)** If the manufacturer of a specified medical device decides to discontinue the sale of the device in Canada, the following rules apply:
- (a)** the manufacturer or importer is required to provide only the information referred to in paragraphs (1)(a) to (f) in respect of the shortage that results from the decision and shall also provide under subsection (1) the reason for the discontinuation; and
- (b)** paragraph 4(a) does not apply to the manufacturer.
- (3)** For greater certainty, subsections (1) and (2) do not remove the requirement for
- (a)** a manufacturer that is the holder of a medical device licence to inform the Minister under subsection 43(3); or
- a)** les nom et coordonnées du fabricant et, si les renseignements sont fournis par l'importateur, les nom et coordonnées de celui-ci;
- b)** s'agissant d'un instrument homologué, son numéro d'homologation;
- b.1)** s'agissant d'un instrument pour lequel le fabricant est titulaire d'une autorisation délivrée au titre de l'article 68.12, le numéro de l'autorisation;
- c)** l'identificateur de l'instrument, y compris celui de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;
- d)** le nom de l'instrument, et, le cas échéant, celui du modèle, en français et en anglais;
- e)** la description de l'instrument et de son emballage ainsi qu'une mention indiquant s'il s'agit ou non d'un instrument à usage unique;
- f)** la date réelle ou prévue du début de la pénurie;
- g)** la date prévue à laquelle le fabricant sera en mesure de répondre à la demande pour l'instrument, si cette date peut être prévue;
- h)** la raison de la pénurie;
- i)** un résumé des renseignements sur lesquels le fabricant ou l'importateur s'est fondé pour conclure qu'il y a pénurie ou probabilité de pénurie de l'instrument.
- (2)** Si le fabricant d'un instrument médical inscrit décide d'en cesser la vente au Canada, les règles ci-après s'appliquent :
- a)** le fabricant ou l'importateur de l'instrument ne fournit que les renseignements visés aux alinéas (1)a) à f) à l'égard de la pénurie qui résulte de cette décision; il fournit toutefois également la raison de la cessation de la vente, en application du paragraphe (1);
- b)** l'alinéa (4)a) ne s'applique pas au fabricant.
- (3)** Il est entendu que les paragraphes (1) et (2) n'ont pas pour effet de soustraire le fabricant des obligations suivantes :
- a)** s'agissant du titulaire d'une homologation d'un instrument médical, informer le ministre conformément au paragraphe 43(3);

- (b)** a manufacturer that is the holder of an authorization issued under section 68.12 to inform the Minister under section 68.25.
- (4)** Subject to subsection (8), the information that is required under subsection (1) shall be provided
- (a)** if the manufacturer or importer did not anticipate the shortage, within five business days after the day on which the manufacturer or importer becomes aware of it; and
  - (b)** if the manufacturer or importer anticipates that there will be a shortage, within five business days after the day on which the manufacturer or importer anticipates it.
- (5)** If any of the information that was provided under subsection (1) changes, the manufacturer or importer shall provide the new information to the Minister electronically in a format specified by or acceptable to the Minister within two business days after the day on which the manufacturer or importer makes or becomes aware of the change.
- (6)** Within two business days after the day on which the manufacturer is again able to meet the demand for the specified medical device, the manufacturer or importer shall notify the Minister electronically in a format specified by or acceptable to the Minister of the manufacturer's ability to do so.
- (7)** The manufacturer or importer need not provide the information that is required under subsection (1) if, within the applicable period referred to in paragraph (4)(a) or (b), the manufacturer or importer anticipates that the manufacturer will be able to meet the demand for the specified medical device within 30 days after the day on which the manufacturer or importer anticipated or became aware of the shortage.
- (8)** Despite subsection (7), if the manufacturer or importer subsequently concludes that the manufacturer will be unable to meet the demand within the 30-day period, the manufacturer or the importer shall provide the information that is required under subsection (1) within five business days after the day on which the manufacturer or importer reaches that conclusion.
- (9)** The manufacturer or importer need not provide the information that is required under subsection (1) if the manufacturer
- (a)** is also the manufacturer of another medical device that can be substituted for the specified medical device in respect of which a shortage exists or is likely to occur; and
- b)** s'agissant du titulaire d'une autorisation délivrée au titre de l'article 68.12, informer le ministre conformément à l'article 68.25.
- (4)** Sous réserve du paragraphe (8), les renseignements visés au paragraphe (1) sont fournis dans les cinq jours ouvrables suivant l'une des dates suivantes :
- a)** si le fabricant ou l'importateur n'a pas prévu la pénurie, la date à laquelle il en constate l'existence;
  - b)** si le fabricant ou l'importateur prévoit la pénurie, la date à laquelle il établit cette prévision.
- (5)** En cas de changement des renseignements fournis en application du paragraphe (1), le fabricant ou l'importateur fournit les nouveaux renseignements au ministre, par voie électronique et en la forme précisée ou jugée acceptable par ce dernier, dans les deux jours ouvrables suivant la date à laquelle il apporte ou constate le changement.
- (6)** Dans les deux jours ouvrables suivant la date à laquelle le fabricant est de nouveau en mesure de répondre à la demande pour l'instrument médical inscrit, le fabricant ou l'importateur en avise le ministre par voie électronique et en la forme précisée ou jugée acceptable par ce dernier.
- (7)** Le fabricant ou l'importateur n'est pas tenu de fournir les renseignements visés au paragraphe (1) si, dans la période applicable visée aux alinéas (4)a ou b), il prévoit que dans un délai de trente jours à compter de la date à laquelle il a prévu la pénurie ou constaté son existence, le fabricant sera en mesure de répondre à la demande pour l'instrument médical inscrit.
- (8)** Malgré le paragraphe (7), s'il conclut par la suite que le fabricant ne sera pas en mesure de répondre à la demande dans cette période de trente jours, le fabricant ou l'importateur fournit les renseignements visés au paragraphe (1) dans les cinq jours ouvrables suivant la date à laquelle il parvient à cette conclusion.
- (9)** Le fabricant ou l'importateur n'est pas tenu de fournir les renseignements visés au paragraphe (1) si les conditions ci-après sont réunies :
- a)** le fabricant est également le fabricant d'un instrument médical pouvant remplacer l'instrument médical inscrit faisant l'objet de la pénurie ou de la probabilité de pénurie;

**(b)** is able to meet the demand for the substitute medical device.

SOR/2021-199, s. 7; SOR/2023-19, s. 6.

**62.24 (1)** Despite section 62.23, the manufacturer of a specified medical device may permit the importer of the device to provide the information that is required under that section on the manufacturer's behalf if the information that the manufacturer and importer must provide is identical.

**(2)** The manufacturer shall notify the Minister electronically in a format specified by or acceptable to the Minister if the manufacturer has permitted the importer to provide the information on the manufacturer's behalf.

SOR/2021-199, s. 7.

**62.25 (1)** The Minister shall publish, on the Government of Canada website, the information that the Minister receives under section 62.23, other than the information referred to in subparagraph 62.23(1)(i).

**(2)** Subsection (1) does not apply if the Minister has reasonable grounds to believe that a situation, in respect of which information was provided under section 62.23, does not constitute a shortage.

SOR/2021-199, s. 7.

**62.26 (1)** The Minister may request that the manufacturer of a medical device — or any importer or distributor of a medical device — provide the Minister with information that is in their control if the Minister has reasonable grounds to believe that

**(a)** there is a shortage or risk of shortage of the device;

**(b)** a shortage of the device presents or may present a risk of injury to human health;

**(c)** the information is necessary to establish or assess

**(i)** the existence of a shortage or risk of shortage of the device,

**(ii)** the reason for a shortage or risk of shortage of the device,

**(iii)** the effects or potential effects on human health of a shortage of the device, or

**(iv)** measures that could be taken to prevent or alleviate a shortage of the device; and

**(d)** the manufacturer, importer or distributor will not provide the information without a legal obligation to do so.

**b)** le fabricant est en mesure de répondre à la demande pour l'instrument médical de remplacement.

DORS/2021-199, art. 7; DORS/2023-19, art. 6.

**62.24 (1)** Malgré l'article 62.23, le fabricant d'un instrument médical inscrit peut confier à l'importateur de l'instrument le soin de fournir, en son nom, les renseignements visés à cet article si les renseignements que chacun d'eux doit soumettre sont identiques.

**(2)** S'il confie à l'importateur le soin de fournir les renseignements en son nom, le fabricant en avise le ministre par voie électronique et en la forme précisée ou jugée acceptable par ce dernier.

DORS/2021-199, art. 7.

**62.25 (1)** Le ministre publie les renseignements qu'il reçoit au titre de l'article 62.23, à l'exception des renseignements visés à l'alinéa 62.23(1)i), sur le site Web du gouvernement du Canada.

**(2)** Le paragraphe (1) ne s'applique pas si le ministre a des motifs raisonnables de croire que la situation à l'égard de laquelle les renseignements ont été fournis conformément à l'article 62.23 n'est pas une pénurie.

DORS/2021-199, art. 7.

**62.26 (1)** S'il a des motifs raisonnables de croire que les conditions ci-après sont réunies, le ministre peut demander au fabricant, à tout importateur ou à tout distributeur d'un instrument médical de lui fournir les renseignements qui relèvent du fabricant, de l'importateur ou du distributeur :

**a)** il y a pénurie ou risque de pénurie de l'instrument médical;

**b)** une pénurie de l'instrument médical présente ou peut présenter un risque de préjudice à la santé humaine;

**c)** les renseignements sont nécessaires afin d'établir ou d'évaluer, selon le cas :

**(i)** l'existence d'une pénurie ou d'un risque de pénurie,

**(ii)** la raison d'une pénurie ou d'un risque de pénurie,

**(iii)** les effets réels ou potentiels d'une pénurie sur la santé humaine,

**(iv)** les mesures qui pourraient être prises afin de prévenir ou d'atténuer une pénurie;

**(2)** The manufacturer, importer or distributor shall provide the requested information electronically in a format specified by or acceptable to the Minister within the time limit specified by the Minister.

SOR/2021-199, s. 7.

**62.27** The following definitions apply in this section and in sections 62.28 to 62.32.

**designated medical device** means a medical device that is set out in the *List of Medical Devices for Exceptional Importation and Sale*. (*instrument médical désigné*)

**List of Medical Devices for Exceptional Importation and Sale** means the *List of Medical Devices for Exceptional Importation and Sale* that is published by the Government of Canada on its website, as amended from time to time. (*Liste d'instruments médicaux destinés aux importations et aux ventes exceptionnelles*)

SOR/2021-199, s. 7.

**62.28** The Minister may add a medical device to the *List of Medical Devices for Exceptional Importation and Sale* only if the Minister has reasonable grounds to believe that

- (a)** there is a shortage or risk of shortage of another medical device; and
- (b)** the device to be added to that list can be substituted for the device referred to in paragraph (a).

SOR/2021-199, s. 7.

**62.29** The holder of an establishment licence may import a designated medical device if the following conditions are met:

- (a)** the holder provides the Minister, electronically in a format specified by or acceptable to the Minister and not later than the fifth business day before the day on which the designated medical device is imported, with a notification that contains the following information:

- (i)** the holder's name and contact information,
- (ii)** in respect of the designated medical device,
  - (A)** its name and the name of each of its components, parts and accessories, including, if applicable, the model name,

**d)** le fabricant, l'importateur ou le distributeur ne fournira les renseignements que s'il est légalement tenu de le faire.

**(2)** Le fabricant, l'importateur ou le distributeur transmet les renseignements demandés au ministre par voie électronique, en la forme précisée ou jugée acceptable par ce dernier et dans le délai que celui-ci fixe.

DORS/2021-199, art. 7.

**62.27** Les définitions qui suivent s'appliquent au présent article et aux articles 62.28 à 62.32.

**instrument médical désigné** Instrument médical figurant sur la *Liste d'instruments médicaux destinés aux importations et aux ventes exceptionnelles*. (*designated medical device*)

**Liste d'instruments médicaux destinés aux importations et aux ventes exceptionnelles** La *Liste d'instruments médicaux destinés aux importations et aux ventes exceptionnelles*, avec ses modifications successives, publiée par le gouvernement du Canada sur son site Web. (*List of Medical Devices for Exceptional Importation and Sale*)

DORS/2021-199, art. 7.

**62.28** Le ministre ne peut ajouter un instrument médical à la *Liste d'instruments médicaux destinés aux importations et aux ventes exceptionnelles* que s'il a des motifs raisonnables de croire que les conditions ci-après sont réunies :

- a)** il y a pénurie ou risque de pénurie d'un autre instrument médical;
- b)** l'instrument qu'il envisage d'ajouter à cette liste peut remplacer l'instrument visé à l'alinéa a).

DORS/2021-199, art. 7.

**62.29** Le titulaire d'une licence d'établissement peut importer un instrument médical désigné si les exigences ci-après sont respectées :

- a)** il fournit au ministre, par voie électronique et en la forme précisée ou jugée acceptable par ce dernier, au plus tard le cinquième jour ouvrable précédent la date de l'importation de l'instrument médical désigné, un avis contenant les renseignements suivants :

- (i)** ses nom et coordonnées,
- (ii)** à l'égard de l'instrument médical désigné :

- (A)** son nom et celui de ses composants, parties et accessoires et, le cas échéant, celui du modèle,

(B) its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family,

(C) the name and contact information of the manufacturer of the device as it appears on the device label,

(D) the name and address of the establishment where it is manufactured, if different from the information referred to in clause (C), and

(E) a detailed description of the medical conditions, purposes and uses for which it is manufactured, sold or represented, as well as its performance specifications if those specifications are necessary for proper use,

(iii) the intended port of entry into Canada,

(iv) the estimated date of arrival of the shipment of the designated medical device, and

(v) the total number of units of the designated medical device that are intended to be imported on the date referred to in subparagraph (iv);

(b) the designated medical device is authorized to be sold by a regulatory agency within its jurisdiction or, if the device is not required to be authorized by a regulatory agency within its jurisdiction, the device complies with the applicable legal requirements within its jurisdiction;

(c) the following information is set out in the *List of Medical Devices for Exceptional Importation and Sale* in respect of the designated medical device:

(i) its name,

(ii) its class,

(iii) the name of its manufacturer,

(iv) the establishment licence number of the holder,

(v) the name of the regulatory agency referred to in paragraph (b), and

(vi) the date after which it may no longer be imported;

(d) the total number of units of the designated medical device that the holder imports does not exceed the

(B) son identificateur, y compris celui de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments,

(C) les nom et coordonnées du fabricant qui figurent sur l'étiquette de l'instrument,

(D) les nom et adresse de l'établissement où il est fabriqué, si ces renseignements ne correspondent pas à ceux visés à la division (C),

(E) une description détaillée des états pathologiques, des fins et des utilisations pour lesquels il est fabriqué, vendu ou présenté ainsi que ses spécifications de rendement lorsqu'elles sont nécessaires à sa bonne utilisation,

(iii) le point d'entrée prévu de l'instrument au Canada,

(iv) la date d'arrivée prévue de la cargaison de l'instrument médical désigné,

(v) le nombre total d'unités de l'instrument médical désigné devant être importées à la date visée au sous-alinéa (iv);

b) la vente de l'instrument médical désigné est autorisée par un organisme de réglementation sur le territoire relevant de sa compétence ou, s'agissant d'un instrument dont la vente n'a pas à être autorisée par un organisme de réglementation sur le territoire relevant de sa compétence, l'instrument satisfait aux exigences légales qui s'appliquent sur le territoire d'un tel organisme;

c) les renseignements ci-après concernant l'instrument médical désigné figurent sur la *Liste d'instruments médicaux destinés aux importations et aux ventes exceptionnelles* :

(i) son nom,

(ii) sa classe,

(iii) le nom de son fabricant,

(iv) le numéro de la licence d'établissement détenue par le titulaire,

(v) le nom de l'organisme de réglementation visé à l'alinéa b),

(vi) la date après laquelle elle ne peut plus être importée;

maximum limit specified in the list referred to in paragraph (c) in respect of the device, if applicable;

(e) the designated medical device is imported on or before the date referred to in subparagraph (c)(vi); and

(f) the holder has prepared a plan that specifies the measures to be taken in order for the holder to comply with section 62.32.

SOR/2021-199, s. 7.

**62.3** Sections 21 to 21.2 and 26 do not apply to the importation, under section 62.29, of a designated medical device by the holder of an establishment licence.

SOR/2021-199, s. 7.

**62.31 (1)** The provisions of these Regulations — other than this section and sections 44 to 62.2 and 62.32 to 65.6 — do not apply to the sale of a designated medical device that is imported under section 62.29.

**(2)** Subsection (1) ceases to apply to the sale of a designated medical device on the earlier of

(a) the expiry date of the designated medical device, if the device has one, and

(b) the end of the two-year period that begins on the day that follows the date referred to in subparagraph 62.29(c)(vi).

SOR/2021-199, s. 7; SOR/2024-136, s. 11.

**62.32 (1)** The holder of an establishment licence shall not sell a designated medical device that they imported under section 62.29 unless they ensure that the information referred to in clause 62.29(a)(ii)(E) is available in English and French and in a manner that permits the safe use of the device.

**(2)** Subject to subsection (3), the holder shall ensure that the information is available in accordance with subsection (1) until at least the end of the day on the latest expiry date of the designated medical devices that they imported.

**(3)** If the designated medical device does not have an expiry date, the holder shall ensure that the information is available in accordance with subsection (1) until at least the expiration of the period that corresponds to the projected useful life of whichever of the devices that they imported has the latest projected useful life.

SOR/2021-199, s. 7.

d) le nombre total d'unités de l'instrument médical désigné que le titulaire importe n'excède pas la limite maximale figurant sur la liste visée à l'alinéa c) à l'égard de cet instrument, le cas échéant;

e) l'instrument médical désigné est importé à la date visée au sous-alinéa c)(vi) ou avant cette date;

f) le titulaire a établi un plan qui prévoit les mesures envisagées pour se conformer aux exigences de l'article 62.32.

DORS/2021-199, art. 7.

**62.3** Les articles 21 à 21.2 et 26 ne s'appliquent pas à l'importation par le titulaire d'une licence d'établissement, en vertu de l'article 62.29, d'un instrument médical désigné.

DORS/2021-199, art. 7.

**62.31 (1)** Le présent règlement, à l'exception du présent article et des articles 44 à 62.2 et 62.32 à 65.6, ne s'applique pas à la vente d'un instrument médical désigné qui est importé en vertu de l'article 62.29.

**(2)** Le paragraphe (1) cesse de s'appliquer à la vente d'un instrument médical désigné au premier des moments suivants à survenir :

a) la date de péremption de l'instrument médical désigné, si l'instrument en a une;

b) à l'expiration de la période de deux ans commençant le lendemain de la date visée au sous-alinéa 62.29(c)(vi).

DORS/2021-199, art. 7; DORS/2024-136, art. 11.

**62.32 (1)** Le titulaire d'une licence d'établissement ne peut vendre un instrument médical désigné qu'il a importé en vertu de l'article 62.29, à moins de veiller à ce que les renseignements visés à la division 62.29a)(ii)(E) soient disponibles en français et en anglais de façon à permettre l'utilisation sécuritaire de l'instrument.

**(2)** Sous réserve du paragraphe (3), le titulaire veille à ce que les renseignements soient disponibles conformément au paragraphe (1) au moins jusqu'à la fin de la journée à la date de péremption la plus tardive attribuée aux instruments médicaux désignés qu'il a importés.

**(3)** S'agissant d'un instrument médical désigné qui n'a pas de date de péremption, le titulaire veille à ce que les renseignements soient disponibles conformément au paragraphe (1) au moins jusqu'à l'expiration de la durée de vie utile projetée de celui des instruments qu'il a importés dont l'expiration de la durée de vie utile projetée est la plus tardive.

DORS/2021-199, art. 7.

## Recalls

[SOR/2024-136, s. 12(E)]

### Recall Reporting

[SOR/2024-136, s. 13]

**63** Sections 63.2, 64 and 65 do not apply to

- (a)** a retailer; or
- (b)** a health care facility in respect of a medical device that is distributed for use within that facility.

SOR/2024-136, s. 14.

**63.1** Sections 63.2, 64 and 65 do not apply to a manufacturer or importer of a medical device unless the device is likely to cause injury to the health of a patient, user or other person, or could cause serious injury to the health of a patient, user or other person.

SOR/2024-136, s. 15.

**63.2** A manufacturer or importer of a medical device who decides to recall the device without being ordered to do so by the Minister shall provide the Minister with the following information, in writing, within 24 hours after making the decision:

- (a)** the name of the device;
- (b)** the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (c)** in the case of a licensed device, the medical device licence number;
- (d)** in the case of a device for which the manufacturer holds an authorization issued under section 68.12, the authorization number;
- (e)** the name and address of
  - (i)** the manufacturer,
  - (ii)** the establishment where the device was manufactured, if different from that of the manufacturer, and
  - (iii)** the importer;
- (f)** the reason for the recall, the nature of the defectiveness or potential defectiveness of the device and the date on which and the circumstances under which

## Rappels

[DORS/2024-136, art. 12(A)]

### Rapports sur les rappels

[DORS/2024-136, art. 13]

**63** Les articles 63.2, 64 et 65 ne s'appliquent :

- a)** ni aux détaillants;
- b)** ni aux établissements de santé, en ce qui concerne les instruments médicaux distribués pour utilisation interne.

DORS/2024-136, art. 14.

**63.1** Les articles 63.2, 64 et 65 ne s'appliquent au fabricant et à l'importateur d'un instrument médical que si ce dernier causera probablement un préjudice à la santé d'un patient, d'un utilisateur ou d'une autre personne ou pouvait causer un préjudice grave à leur santé.

DORS/2024-136, art. 15.

**63.2** Le fabricant ou l'importateur d'un instrument médical qui décide d'en effectuer le rappel sans que le ministre le lui ait ordonné fournit par écrit à ce dernier les renseignements ci-après dans les vingt-quatre heures après avoir pris cette décision :

- a)** le nom de l'instrument;
- b)** l'identificateur de l'instrument, y compris celui de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;
- c)** s'agissant d'un instrument homologué, son numéro d'homologation;
- d)** s'agissant d'un instrument pour lequel le fabricant est titulaire d'une autorisation délivrée au titre de l'article 68.12, le numéro de l'autorisation;
- e)** les nom et adresse :
  - (i)** du fabricant,
  - (ii)** de l'établissement où l'instrument a été fabriqué, s'ils diffèrent de ceux du fabricant,
  - (iii)** de l'importateur;
- f)** les motifs du rappel, la nature de la défectuosité — réelle ou potentielle — de l'instrument, ainsi que la date et les circonstances de sa découverte;

the defectiveness or potential defectiveness was discovered; and

**(g)** a preliminary evaluation of the risk associated with the defectiveness or potential defectiveness of the device.

SOR/2024-136, s. 15.

**64** A manufacturer or importer of a medical device shall, on or before the day on which the manufacturer or importer begins a recall of the device that has not been ordered by the Minister, provide the Minister with the following information and documents in writing:

**(a)** the name of the device;

**(b)** the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;

**(c)** in the case of a licensed device, the medical device licence number;

**(d)** in the case of a device for which the manufacturer holds an authorization issued under section 68.12, the authorization number;

**(e)** the name and address of

**(i)** the manufacturer,

**(ii)** the establishment where the device was manufactured, if different from that of the manufacturer, and

**(iii)** the importer;

**(f)** the reason for the recall, the nature of the defectiveness or potential defectiveness of the device and the date on which and the circumstances under which the defectiveness or potential defectiveness was discovered;

**(g)** an evaluation of the risk associated with the defectiveness or potential defectiveness of the device;

**(h)** the number of affected units of the device that the manufacturer or importer

**(i)** manufactured in Canada,

**(ii)** imported into Canada, and

**(iii)** sold in Canada;

**g)** une évaluation préliminaire du risque lié à la défectuosité réelle ou potentielle de l'instrument.

DORS/2024-136, art. 15.

**64** Le fabricant ou l'importateur d'un instrument médical fournit par écrit au ministre les renseignements et documents ci-après à la date du lancement du rappel de l'instrument n'ayant pas été ordonné par le ministre ou avant cette date :

**a)** le nom de l'instrument;

**b)** l'identificateur de l'instrument, y compris celui de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;

**c)** s'agissant d'un instrument homologué, son numéro d'homologation;

**d)** s'agissant d'un instrument pour lequel le fabricant est titulaire d'une autorisation délivrée au titre de l'article 68.12, le numéro de l'autorisation;

**e)** les nom et adresse :

**(i)** du fabricant,

**(ii)** de l'établissement où l'instrument a été fabriqué, s'ils diffèrent de ceux du fabricant,

**(iii)** de l'importateur;

**f)** les motifs du rappel, la nature de la défectuosité — réelle ou potentielle — de l'instrument, ainsi que la date et les circonstances de sa découverte;

**g)** l'évaluation du risque lié à la défectuosité réelle ou potentielle de l'instrument;

**h)** le nombre d'unités en cause que le fabricant ou l'importateur a :

**(i)** fabriquées au Canada,

**(ii)** importées au Canada,

**(iii)** vendues au Canada;

**i)** la période durant laquelle le fabricant ou l'importateur a distribué les unités en cause au Canada;

- (i)** the period during which the affected units of the device were distributed in Canada by the manufacturer or importer;
- (j)** the name of each person to whom the affected device was sold by the manufacturer or importer and the number of units of the device sold to each person;
- (k)** a copy of any communication issued with respect to the recall;
- (l)** the proposed strategy for conducting the recall, including
- (i)** the date for beginning the recall,
  - (ii)** the time and manner in which the Minister will be informed of the progress of the recall, and
  - (iii)** the proposed date of its completion;
- (m)** the proposed action to prevent a recurrence of the problem; and
- (n)** the name, title and contact information of the representative of the manufacturer or importer to contact for information concerning the recall.

SOR/2024-136, s. 16.

**65** A manufacturer or importer of a medical device shall, within 30 days after completing a recall of the device that was not ordered by the Minister, provide the Minister with the following information, in writing:

- (a)** the results of the recall; and
- (b)** the action taken to prevent a recurrence of the problem.

SOR/2024-136, s. 17.

**65.1 (1)** A manufacturer of a medical device who recalls the device without being ordered to do so by the Minister may permit the importer of the device to prepare and submit, on the manufacturer's behalf, the information and documents that are required to be provided under sections 63.2, 64 and 65 if the information and documents that the manufacturer and importer must submit are identical.

**(2)** The manufacturer shall advise the Minister in writing if the manufacturer has permitted the importer to prepare and submit the information and documents referred to in subsection (1) on the manufacturer's behalf.

SOR/2002-190, s. 6; SOR/2024-136, s. 18.

**j)** le nom des personnes à qui le fabricant ou l'importateur a vendu l'instrument en cause, ainsi que le nombre d'unités vendues à chaque personne;

**k)** une copie de tout communiqué diffusé relativement au rappel;

**l)** le plan d'action proposé pour effectuer le rappel, y compris :

**(i)** la date du lancement du rappel,

**(ii)** les modalités — de temps et autres — selon lesquelles le ministre sera informé du déroulement du rappel,

**(iii)** la date proposée de la fin du rappel;

**m)** les mesures proposées pour que le problème ne se reproduise pas;

**n)** les nom, titre et coordonnées du représentant du fabricant ou de l'importateur avec lequel communiquer pour obtenir tout renseignement concernant le rappel.

DORS/2024-136, art. 16.

**65** Le fabricant ou l'importateur d'un instrument médical fournit par écrit au ministre les renseignements ci-après dans un délai de trente jours après avoir mis fin au rappel de l'instrument n'ayant pas été ordonné par ce dernier :

**a)** les résultats du rappel;

**b)** les mesures qui ont été prises pour que le problème ne se reproduise pas.

DORS/2024-136, art. 17.

**65.1 (1)** Le fabricant d'un instrument médical qui en effectue le rappel sans que le ministre le lui ait ordonné peut confier à l'importateur de l'instrument le soin de préparer et de soumettre, en son nom, les renseignements et documents que le fabricant est tenu de fournir en vertu des articles 63.2, 64 et 65, si les renseignements et documents que chacun d'eux est tenu de soumettre sont identiques.

**(2)** S'il confie à l'importateur le soin de préparer et de soumettre, en son nom, les renseignements et documents visés au paragraphe (1), le fabricant en avise par écrit le ministre.

DORS/2002-190, art. 6; DORS/2024-136, art. 18.

**65.2 (1)** A person who is ordered by the Minister to recall a medical device shall provide the Minister with the following information in the time and manner specified by the Minister:

- (a)** the name and address of
- (i)** the manufacturer of the device,
  - (ii)** the establishment where the device was manufactured, if different from that of the manufacturer,
  - (iii)** the importer of the device, and
  - (iv)** the person who sold them the device, if the person who is conducting the recall is not the manufacturer;
- (b)** the nature of the defectiveness or potential defectiveness of the device and the date on which and the circumstances under which the defectiveness or potential defectiveness was discovered;
- (c)** the number of affected units of the device that the person
- (i)** manufactured in Canada,
  - (ii)** imported into Canada, and
  - (iii)** sold in Canada;
- (d)** the number of affected units of the device in Canada that are in the possession or control of the person;
- (e)** the period during which the affected units of the device were distributed in Canada by the person;
- (f)** the number of affected units of the device that have been sold by the person at the retail level to consumers in Canada;
- (g)** if the person has sold the affected device to persons in Canada other than consumers referred to in paragraph (f), the names of those persons and the number of units of the device sold to each of them;
- (h)** the proposed strategy for conducting the recall, including
- (i)** the date for beginning the recall,
  - (ii)** the time and manner in which the Minister will be informed of the progress of the recall, and
  - (iii)** the proposed date of its completion;
- 65.2 (1)** La personne à qui le ministre ordonne d'effectuer le rappel d'un instrument médical lui fournit les renseignements ci-après selon les modalités — de temps ou autres — qu'il précise :
- a)** les nom et adresse :
  - (i)** du fabricant de l'instrument,
  - (ii)** de l'établissement où l'instrument a été fabriqué, s'ils diffèrent de ceux du fabricant,
  - (iii)** de l'importateur de l'instrument,
  - (iv)** de la personne qui lui a vendu l'instrument, si la personne effectuant le rappel n'est pas le fabricant;
  - b)** la nature de la défectuosité — réelle ou potentielle — de l'instrument, ainsi que la date et les circonstances de sa découverte;
  - c)** le nombre d'unités en cause que la personne a :
    - (i)** fabriquées au Canada,
    - (ii)** importées au Canada,
    - (iii)** vendues au Canada;
  - d)** le nombre d'unités en cause se trouvant au Canada qu'elle a en sa possession ou dont elle a la charge;
  - e)** la période durant laquelle elle a distribué les unités en cause au Canada;
  - f)** le nombre d'unités en cause qu'elle a vendues au détail à des consommateurs au Canada;
  - g)** dans le cas où elle a vendu l'instrument en cause à des personnes au Canada autres que les consommateurs visés à l'alinéa f), le nom de ces personnes et le nombre d'unités vendues à chacune d'elles;
  - h)** le plan d'action proposé pour effectuer le rappel, y compris :
    - (i)** la date du lancement du rappel,
    - (ii)** les modalités — de temps et autres — selon lesquelles le ministre sera informé du déroulement du rappel,
    - (iii)** la date proposée de la fin du rappel;
  - i)** les mesures proposées pour que le problème ne se reproduise pas;

- (i)** the proposed action to prevent a recurrence of the problem;
- (j)** the name, title and contact information of the representative of the person to contact for information concerning the recall; and
- (k)** any other information that the Minister has reasonable grounds to believe is necessary to reduce the risk of injury to health.
- (2)** The person shall notify the Minister without delay of any change to the information referred to in paragraph (1)(j).
- (3)** The person shall
- (a)** before beginning the recall, provide the Minister with a copy of any communications that the person intends to use in connection with beginning the recall; and
- (b)** after beginning the recall, provide the Minister with, on request and within the time specified by the Minister, a copy of any additional communications that the person uses, or intends to use in connection with the recall.
- (4)** The person shall notify the Minister in writing, within 24 hours, of the beginning and completion of the recall.
- (5)** The person shall, within 30 days after completing the recall, provide the Minister with the following information in writing:
- (a)** the results of the recall; and
- (b)** the action taken to prevent a recurrence of the problem.
- SOR/2024-136, s. 18.
- ## Record Keeping
- 65.3** A manufacturer or importer of a medical device who recalls the device without being ordered to do so by the Minister shall keep a record of the following:
- (a)** a document that sets out the decision to conduct the recall, including
- (i)** the name and title of the individual who made the decision, and
- (ii)** the date the decision was made;
- (b)** the date the recall was completed;
- j)** les nom, titre et coordonnées du représentant de la personne avec lequel communiquer pour obtenir tout renseignement concernant le rappel;
- k)** tout autre renseignement que le ministre a des motifs raisonnables de croire nécessaire pour réduire le risque de préjudice à la santé.
- (2)** La personne avise sans délai le ministre de tout changement apporté aux renseignements visés à l'alinéa (1)j).
- (3)** La personne fournit au ministre :
- a)** avant de lancer le rappel, une copie de tout communiqué qu'elle entend utiliser relativement au lancement du rappel;
- b)** après avoir lancé le rappel, sur demande et dans le délai précisé par le ministre, une copie de tout communiqué additionnel qu'elle utilise ou qu'elle entend utiliser relativement au rappel.
- (4)** La personne informe au ministre, par écrit, dans les vingt-quatre heures, le lancement du rappel ainsi que la fin de ce dernier.
- (5)** La personne fournit au ministre, par écrit, dans un délai de trente jours après avoir mis fin au rappel, les renseignements suivants :
- a)** les résultats du rappel;
- b)** les mesures qui ont été prises pour que le problème ne se reproduise pas.
- DORS/2024-136, art. 18.
- ## Tenue de dossiers
- 65.3** Le fabricant ou l'importateur d'un instrument médical qui en effectue le rappel sans que le ministre le lui ait ordonné tient des dossiers contenant les renseignements et documents suivants :
- a)** un document faisant état de la décision d'effectuer le rappel, y compris :
- (i)** les nom et titre des individus ayant pris la décision,
- (ii)** la date à laquelle elle a été prise;

- (c)** the information and documents referred to in sections 63.2, 64 and 65; and
- (d)** the document provided to the Minister under subsection 65.1(2), if applicable.

SOR/2024-136, s. 18.

**65.4 (1)** Subject to subsection (2), a distributor of a medical device who conducts a recall of the device that was not ordered by the Minister shall keep a record of the following:

- (a)** the name of the device;
- (b)** the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (c)** in the case of a licensed device, the medical device licence number;
- (d)** in the case of a device for which the manufacturer holds an authorization issued under section 68.12, the authorization number;
- (e)** the name and address of
- (i)** the manufacturer,
  - (ii)** the establishment where the device was manufactured, if different from that of the manufacturer,
  - (iii)** the importer, and
  - (iv)** the person who sold them the device;
- (f)** the reason for the recall, the nature of the defectiveness or potential defectiveness of the device and the date on which and circumstances under which the defectiveness or potential defectiveness was discovered;
- (g)** the number of affected units of the device that the distributor sold in Canada;
- (h)** the period during which the affected units of the device were distributed in Canada by the distributor;
- (i)** the name of each person to whom the affected device was sold by the distributor and the number of units of the device sold to each person;
- (j)** a copy of any communication issued with respect to the recall;

- b)** la date à laquelle le rappel a pris fin;
- c)** les renseignements et documents visés aux articles 63.2, 64 et 65;
- d)** le cas échéant, le document fourni au ministre en vertu du paragraphe 65.1(2).

DORS/2024-136, art. 18.

**65.4 (1)** Sous réserve du paragraphe (2), le distributeur d'un instrument médical qui en effectue le rappel sans que le ministre le lui ait ordonné tient des dossiers contenant les renseignements et documents suivants :

- a)** le nom de l'instrument;
- b)** l'identificateur de l'instrument, y compris celui de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;
- c)** s'agissant d'un instrument homologué, son numéro d'homologation;
- d)** s'agissant d'un instrument pour lequel le fabricant est titulaire d'une autorisation délivrée au titre de l'article 68.12, le numéro de l'autorisation;
- e)** les nom et adresse :
- (i)** du fabricant,
  - (ii)** de l'établissement où l'instrument a été fabriqué, s'ils diffèrent de ceux du fabricant,
  - (iii)** de l'importateur,
  - (iv)** de la personne qui lui a vendu l'instrument;
- f)** les motifs du rappel, la nature de la défectuosité — réelle ou potentielle — de l'instrument, ainsi que la date et les circonstances de sa découverte;
- g)** le nombre d'unités en cause que le distributeur a vendues au Canada;
- h)** la période durant laquelle il a distribué les unités en cause au Canada;
- i)** le nom des personnes à qui il a vendu l'instrument en cause, ainsi que le nombre d'unités qu'il a vendues à chacune d'elles;
- j)** une copie de tout communiqué diffusé relativement au rappel;
- k)** les résultats du rappel;

**(k)** the results of the recall; and

**(l)** the date the recall was completed.

**(2)** A distributor who initiates the recall shall keep a record of the following:

**(a)** the information and documents referred to in subsection (1);

**(b)** an evaluation of the risk associated with the defectiveness or potential defectiveness of the medical device to which the recall relates; and

**(c)** the actions that were proposed and actions taken to prevent a recurrence of the problem.

SOR/2024-136, s. 18.

**65.5** A person who is ordered by the Minister to recall a medical device shall keep a record of the information and documents provided to the Minister under section 65.2.

SOR/2024-136, s. 18.

**65.6 (1)** A manufacturer who is required to keep a record under section 65.3 or 65.5 shall keep it for at least the longer of the following periods:

**(a)** the period that is equivalent to the projected useful life of the medical device to which the recall relates plus two years; and

**(b)** the period during which the device is sold in Canada.

**(2)** Any other person who is required to keep a record under section 65.3, 65.4 or 65.5 shall keep it for at least a period equivalent to the projected useful life of the device to which the recall relates plus two years.

**(3)** For the purpose of paragraph (1)(a) and subsection (2), the retention period begins on the day on which the recall is completed.

SOR/2024-136, s. 18.

## Implant Registration

**66 (1)** Subject to section 68, the manufacturer of an implant shall provide, with the implant, two implant registration cards that contain

**(a)** the name and address of the manufacturer;

**(b)** the name and address of any person designated by the manufacturer for the collection of implant registration information;

**I)** la date à laquelle le rappel a pris fin.

**(2)** Le distributeur qui amorce un tel rappel tient des dossiers contenant les renseignements et documents suivants :

**a)** ceux visés au paragraphe (1);

**b)** l'évaluation du risque lié à la défectuosité réelle ou potentielle de l'instrument médical visé par le rappel;

**c)** les mesures qui avaient été proposées et celles qui ont été prises pour que le problème ne se reproduise pas.

DORS/2024-136, art. 18.

**65.5** La personne à qui le ministre ordonne d'effectuer le rappel d'un instrument médical tient des dossiers contenant les renseignements et documents qu'elle lui a fournis en vertu de l'article 65.2.

DORS/2024-136, art. 18.

**65.6 (1)** Le fabricant qui doit tenir des dossiers en application des articles 65.3 ou 65.5 les conserve durant au moins la plus longue des périodes ci-après :

**a)** la période correspondant à la somme de la durée de vie utile projetée de l'instrument médical visé par le rappel et de deux années;

**b)** celle durant laquelle l'instrument est vendu au Canada.

**(2)** Toute autre personne qui doit tenir des dossiers en application des articles 65.3, 65.4 ou 65.5 les conserve pendant une période correspondant au moins à la somme de la durée de vie utile projetée de l'instrument médical visé par le rappel et de deux années.

**(3)** Pour l'application de l'alinéa (1)a) et du paragraphe (2), la période de conservation commence à partir de la date à laquelle le rappel prend fin.

DORS/2024-136, art. 18.

## Enregistrement des implants

**66 (1)** Sous réserve de l'article 68, le fabricant d'un implant doit fournir avec celui-ci deux fiches d'enregistrement sur lesquelles figurent :

**a)** ses nom et adresse;

**b)** les nom et adresse de toute personne désignée par lui pour recueillir les renseignements concernant l'enregistrement de l'implant;

- (c) a notice advising the patient that the purpose of the cards is to enable the manufacturer to notify the patient of new information concerning the safety, effectiveness or performance of the implant, and any required corrective action; and
- (d) a statement advising the patient to notify the manufacturer of any change of address.

(2) An implant registration card shall be designed for the recording of the following information:

- (a) the name of the device, its control number and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (b) the name and address of the health care professional who carried out the implant procedure;
- (c) the date on which the device was implanted;
- (d) the name and address of the health care facility at which the implant procedure took place; and
- (e) the patient's name and address or the identification number used by the health care facility to identify the patient.

(3) The two implant registration cards referred to in subsection (1) shall be printed in both official languages; however, the manufacturer may choose to provide four cards, two in English and two in French.

**67 (1)** Subject to subsection (2), a member of the staff of the health care facility where an implant procedure takes place shall, as soon as possible after the completion of the procedure, enter the information required by subsection 66(2) on each implant registration card, give one card to the implant patient and forward one card to the manufacturer of the implant or the person designated pursuant to paragraph 66(1)(b).

**(2)** The patient's name and address shall not be entered on the implant registration card forwarded to the manufacturer or person designated pursuant to paragraph 66(1)(b) except with the patient's written consent.

**(3)** The health care facility, the manufacturer or the person designated pursuant to paragraph 66(1)(b) shall not disclose the patient's name or address, or any information that might identify the patient, unless the disclosure is required by law.

c) un avis informant le patient que le but des fiches est de lui permettre de communiquer au patient tout nouveau renseignement ayant trait à la sûreté, à l'efficacité ou au rendement de l'implant et de l'aviser des mesures correctives que l'implant nécessite, le cas échéant;

d) une mention demandant au patient de l'aviser de tout changement d'adresse.

(2) Les fiches d'enregistrement doivent être conçues de façon à permettre l'inscription des renseignements suivants :

- a) les nom, numéro de contrôle et identificateur de l'instrument, y compris l'identificateur de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;
- b) les nom et adresse du professionnel de la santé qui a effectué l'implantation;
- c) la date de l'implantation;
- d) les nom et adresse de l'établissement de santé où l'implantation a été effectuée;
- e) les nom et adresse du patient ou le numéro utilisé par l'établissement de santé pour l'identifier.

(3) Les deux fiches d'enregistrement doivent être imprimées dans les deux langues officielles. Le fabricant peut toutefois choisir de fournir quatre fiches, deux en français et deux en anglais.

**67 (1)** Sous réserve du paragraphe (2), dans les plus brefs délais après l'implantation, un membre du personnel de l'établissement de santé où celle-ci a été effectuée doit remplir les deux fiches d'enregistrement et en transmettre une au patient et l'autre au fabricant ou à la personne visée à l'alinéa 66(1)b.

**(2)** Les nom et adresse du patient ne peuvent figurer sur la fiche d'enregistrement transmise au fabricant ou à la personne visée à l'alinéa 66(1)b que si le patient a donné son consentement par écrit.

**(3)** L'établissement de santé, le fabricant et la personne visée à l'alinéa 66(1)b ne peuvent divulguer ni les noms et adresse du patient ni les renseignements pouvant servir à l'identifier, sauf s'ils y sont tenus par la loi.

**68 (1)** The manufacturer of an implant may apply in writing to the Minister for authorization to use an implant registration method other than the implant registration cards described in section 66.

**(2)** The Minister shall authorize the use of the implant registration method proposed in the application referred to in subsection (1) if the Minister determines that the method will enable the manufacturer to achieve the purpose set out in paragraph 66(1)(c) as effectively as the use of implant registration cards.

**(3)** Where an authorization has been granted pursuant to subsection (2), the manufacturer shall implement the alternative implant registration method, and sections 66 and 67 shall apply with such modifications as are necessary.

## PART 1.1

# Medical Devices for an Urgent Public Health Need

[SOR/2023-277, s. 1]

## Definitions and Interpretation

[SOR/2023-277, s. 2]

**68.01** The following definitions apply in this Part.

**authorization** means, unless the context requires otherwise, an authorization that is issued under section 68.12. (*autorisation*)

**COVID-19** [Repealed, SOR/2023-277, s. 3]

**COVID-19 medical device** [Repealed, SOR/2023-277, s. 3]

**List of Medical Devices for an Urgent Public Health Need** means the *List of Medical Devices for an Urgent Public Health Need* that is published by the Government of Canada on its website, as amended from time to time. (*Liste d'instruments médicaux pour des besoins urgents en matière de santé publique*)

**List of Medical Devices for Expanded Use** means the *List of Medical Devices for Expanded Use* that is published by the Government of Canada on its website, as amended from time to time. (*Liste d'instruments médicaux destinés à un usage élargi*)

**68 (1)** Le fabricant d'un implant peut, par écrit, demander au ministre l'autorisation d'utiliser une méthode d'enregistrement des implants autre que celle des fiches d'enregistrement.

**(2)** Le ministre autorise l'utilisation de la méthode proposée s'il détermine qu'elle permettra au fabricant d'atteindre le but mentionné à l'alinéa 66(1)c) aussi efficacement qu'avec les fiches d'enregistrement.

**(3)** Le fabricant doit mettre en œuvre la méthode d'enregistrement autorisée, et les articles 66 et 67 s'appliquent avec les adaptations nécessaires.

## PARTIE 1.1

# Instruments médicaux pour des besoins urgents en matière de santé publique

[DORS/2023-277, art. 1]

## Définitions et interprétation

[DORS/2023-277, art. 2]

**68.01** Les définitions qui suivent s'appliquent à la présente partie.

**autorisation** Autorisation délivrée au titre de l'article 68.12, sauf indication contraire du contexte. (*authorisation*)

**COVID-19** [Abrogée, DORS/2023-277, art. 3]

**instrument médical BUSP** Instrument médical pour des besoins urgents en matière de santé publique parmi les suivants :

**a)** celui qui figure à la colonne 2 de la partie 1 de la *Liste d'instruments médicaux pour des besoins urgents en matière de santé publique* et qui est fabriqué, vendu ou présenté en vue d'être utilisé à l'égard de l'état pathologique correspondant qui figure à la colonne 1;

**b)** celui qui appartient à une catégorie d'instruments médicaux figurant à la colonne 2 de la partie 2 de cette liste et qui est fabriqué, vendu ou présenté en vue

**UPHN medical device** means any of the following medical devices for an urgent public health need:

- (a) a medical device that is set out in column 2 of Part 1 of the *List of Medical Devices for an Urgent Public Health Need* and that is manufactured, sold or represented for use in relation to the corresponding medical condition that is set out in column 1;
- (b) a medical device that belongs to a category of medical devices that is set out in column 2 of Part 2 of that list and that is manufactured, sold or represented for use in relation to the corresponding medical condition that is set out in column 1. (*instrument médical BUSP*)

SOR/2023-19, s. 7; SOR/2023-277, s. 3.

d'être utilisé à l'égard de l'état pathologique correspondant qui figure à la colonne 1. (*UPHN medical device*)

**instrument médical contre la COVID-19** [Abrogée, DORS/2023-277, art. 3]

**Liste d'instruments médicaux destinés à un usage élargi** La *Liste d'instruments médicaux destinés à un usage élargi*, publiée par le gouvernement du Canada sur son site Web, avec ses modifications successives. (*List of Medical Devices for Expanded Use*)

**Liste d'instruments médicaux pour des besoins urgents en matière de santé publique** La *Liste d'instruments médicaux pour des besoins urgents en matière de santé publique*, publiée par le gouvernement du Canada sur son site Web, avec ses modifications successives. (*List of Medical Devices for an Urgent Public Health Need*)

DORS/2023-19, art. 7; DORS/2023-277, art. 3.

**68.011** For the purposes of paragraphs 68.21(1)(h), (i) and (j), and sections 68.24, 68.3, 68.31 and 68.34, a medical device for which the manufacturer holds an authorization is considered not to be a UPHN medical device if

- (a) the device is not set out in column 2 of Part 1 of the *List of Medical Devices for an Urgent Public Health Need* and does not belong to a category of medical devices that is set out in column 2 of Part 2 of that list; or
- (b) the device is set out in column 2 of Part 1 of that list or belongs to a category of medical devices that is set out in column 2 of Part 2 of that list but is not authorized in relation to a corresponding medical condition that is set out, as the case may be, in column 1 of Part 1 or column 1 of Part 2.

SOR/2023-277, s. 4.

**68.011** Pour l'application des alinéas 68.21(1)h), i) et j) et des articles 68.24, 68.3, 68.31 et 68.34, l'instrument médical pour lequel le fabricant est titulaire d'une autorisation est considéré ne pas être un instrument médical BUSP dans les cas suivants :

a) il ne figure pas à la colonne 2 de la partie 1 de la *Liste d'instruments médicaux pour des besoins urgents en matière de santé publique* et n'appartient pas à une catégorie d'instruments médicaux figurant à la colonne 2 de la partie 2 de cette liste;

b) il figure à la colonne 2 de la partie 1 de cette liste ou appartient à une catégorie d'instruments médicaux figurant à la colonne 2 de la partie 2 de cette liste, mais n'est pas autorisé en lien avec un état pathologique correspondant qui figure à la colonne 1 de la partie 1 ou à la colonne 1 de la partie 2 de cette liste, selon le cas.

DORS/2023-277, art. 4.

## Application

**68.02 (1)** This Part applies to medical devices that are not subject to Part 2 or 3.

**(2)** [Repealed, SOR/2023-277, s. 5]

SOR/2023-19, s. 7; SOR/2023-277, s. 5.

## Application

**68.02 (1)** La présente partie s'applique aux instruments médicaux qui ne sont pas visés par les parties 2 ou 3.

**(2)** [Abrogé, DORS/2023-277, art. 5]

DORS/2023-19, art. 7; DORS/2023-277, art. 5.

## Authorization

### Non-application of Part 1 — Importation and Sale

**68.03 (1)** Despite section 8, Part 1 does not apply in respect of the importation or sale of a medical device if the manufacturer holds an authorization for the device.

**(2)** However, the following provisions of Part 1 apply in respect of the importation or sale of the medical device:

- (a)** in the case of an importer, sections 59 to 61;
- (b)** in the case of an importer or distributor, sections 44 to 51.1; and
- (c)** sections 21, 23, 27, 52 to 58, 62 and 62.21 to 65.6.

**(3)** Despite paragraph (2)(b), subsection 44(3) does not apply if the medical device that is imported is a Class I device and the person from whom the device is imported is the manufacturer.

SOR/2023-19, s. 7; SOR/2023-277, s. 6; SOR/2023-277, s. 25; SOR/2024-136, s. 19.

### Advertising — Authorized Class I Medical Device

**68.031** No person shall advertise for the purpose of sale a Class I medical device for which the manufacturer holds an authorization if the device has been subjected to a change described in section 68.13 unless

- (a)** the manufacturer holds an amended authorization; or
- (b)** the advertisement is placed only in a catalogue that includes a clear and visible warning that the devices advertised in the catalogue may not have been authorized in accordance with Canadian law.

SOR/2023-277, s. 7.

### Deemed Authorization

**68.04** [Repealed, SOR/2023-277, s. 8]

**68.05** In sections 68.06 to 68.09, **authorized**, in relation to a medical device, means that the device is the subject of an authorization.

SOR/2023-19, s. 7.

## Autorisation

### Non-application de la Partie 1 — importation et vente

**68.03 (1)** Malgré l'article 8, la partie 1 ne s'applique pas à l'importation et à la vente d'un instrument médical si le fabricant est titulaire d'une autorisation pour celui-ci.

**(2)** Toutefois, les dispositions ci-après de la partie 1 s'appliquent à l'importation et à la vente de l'instrument médical :

- a)** les articles 59 à 61, en ce qui concerne l'importateur;
- b)** les articles 44 à 51.1, en ce qui concerne l'importateur ou le distributeur;
- c)** les articles 21, 23, 27, 52 à 58, 62 et 62.21 à 65.6.

**(3)** Malgré l'alinéa (2)b), le paragraphe 44(3) ne s'applique pas si l'instrument médical qui est importé est un instrument de classe I et si le fabricant est la personne de qui il est importé.

DORS/2023-19, art. 7; DORS/2023-277, art. 6; DORS/2023-277, art. 25; DORS/2024-136, art. 19.

### Publicité — instrument médical de classe I autorisé

**68.031** Il est interdit de faire la publicité en vue de la vente d'un instrument médical de classe I pour lequel le fabricant est titulaire d'une autorisation dans le cas où l'instrument a fait l'objet d'une modification visée à l'article 68.13, sauf dans les cas suivants :

- a)** le fabricant est titulaire d'une autorisation modifiée;
- b)** la publicité ne se fait que par catalogue et celui-ci comporte, lisiblement et bien en vue, un avertissement portant que les instruments qui y sont annoncés peuvent ne pas avoir été autorisés conformément à la législation canadienne.

DORS/2023-277, art. 7.

### Présomption d'autorisation

**68.04** [Abrogé, DORS/2023-277, art. 8]

**68.05** Aux articles 68.06 à 68.09, **autorisé** se dit d'un instrument médical qui fait l'objet d'une autorisation.

DORS/2023-19, art. 7.

**68.06** If a system is authorized, all of its components or parts that are manufactured by the manufacturer of the system are deemed, for the purposes of its importation, sale or advertisement, to be authorized.

SOR/2023-19, s. 7.

**68.07** If a test kit is authorized, all of its reagents or articles that are manufactured by the manufacturer of the test kit are deemed, for the purposes of its importation, sale or advertisement, to be authorized.

SOR/2023-19, s. 7.

**68.08** If a medical device or medical device group is authorized and forms part of a medical device family or medical device group family, as the case may be, all other medical devices or medical device groups in the family are deemed to be authorized.

SOR/2023-19, s. 7.

**68.09 (1)** If all the medical devices that form part of a medical device group are authorized, that medical device group is deemed to be authorized.

**(2)** If a medical device group is authorized, all the medical devices that form part of the medical device group are deemed, for the purposes of its importation, sale or advertisement, to be authorized.

SOR/2023-19, s. 7.

## Application for an Authorization

**68.1 (1)** The Minister may add a medical condition to column 1 of Part 1 or Part 2 of the *List of Medical Devices for an Urgent Public Health Need* only if the Minister has reasonable grounds to believe that

- (a)** the medical condition presents, or is the result of, a significant risk to public health in Canada; and
- (b)** immediate action is required to deal with the risk.

**(2)** The Minister may add a medical device to column 2 of Part 1 of the *List of Medical Devices for an Urgent Public Health Need* only if the Minister has reasonable grounds to believe that there is an urgent public health need for the device that is related to the corresponding medical condition that is set out in column 1.

**(3)** The Minister may add a category of medical devices to column 2 of Part 2 of the *List of Medical Devices for an Urgent Public Health Need* only if the Minister has reasonable grounds to believe that there is an urgent

**68.06** Si un système est autorisé, tous ses composants ou parties qui sont fabriqués par le fabricant du système sont réputés, aux fins de l'importation, de la vente ou de la publicité de celui-ci, être autorisés.

DORS/2023-19, art. 7.

**68.07** Si une trousse d'essai est autorisée, tous ses réactifs ou articles qui sont fabriqués par le fabricant de la trousse sont réputés, aux fins de l'importation, de la vente ou de la publicité de celle-ci, être autorisés.

DORS/2023-19, art. 7.

**68.08** Si un instrument médical ou un ensemble d'instruments est autorisé et qu'il fait partie, selon le cas, d'une famille d'instruments ou d'une famille d'ensembles d'instruments, les autres instruments médicaux ou ensembles d'instruments de cette famille sont réputés être autorisés.

DORS/2023-19, art. 7.

**68.09 (1)** L'ensemble d'instruments dont tous les instruments médicaux sont autorisés est réputé être autorisé.

**(2)** Si un ensemble d'instruments est autorisé, tous les instruments médicaux qui en font partie sont réputés, aux fins de l'importation, de la vente ou de la publicité, être autorisés.

DORS/2023-19, art. 7.

## Demande d'autorisation

**68.1 (1)** Le ministre ne peut ajouter un état pathologique à la colonne 1 des parties 1 ou 2 de la *Liste d'instruments médicaux pour des besoins urgents en matière de santé publique* que s'il a des motifs raisonnables de croire que les conditions ci-après sont réunies :

- a)** l'état pathologique présente un risque appréciable pour la santé publique au Canada ou résulte d'un tel risque;
- b)** une intervention immédiate est nécessaire pour parer au risque.

**(2)** Le ministre ne peut ajouter un instrument médical à la colonne 2 de la partie 1 de la *Liste d'instruments médicaux pour des besoins urgents en matière de santé publique* que s'il a des motifs raisonnables de croire que cet instrument est nécessaire pour combler un besoin urgent en matière de santé publique en lien avec l'état pathologique correspondant qui figure à la colonne 1.

**(3)** Le ministre ne peut ajouter une catégorie d'instruments médicaux à la colonne 2 de la partie 2 de la *Liste d'instruments médicaux pour des besoins urgents en matière de santé publique* que s'il a des motifs

public health need for the devices that belong to that category that is related to the corresponding medical condition set out in column 1.

SOR/2023-19, s. 7; SOR/2023-277, s. 9.

raisonnables de croire que cette catégorie comporte des instruments nécessaires pour combler un besoin urgent en matière de santé publique en lien avec l'état pathologique correspondant qui figure à la colonne 1.

DORS/2023-19, art. 7; DORS/2023-277, art. 9.

**68.11 (1)** A manufacturer of a medical device may submit to the Minister an application for an authorization for the device if it is a UPHN medical device.

**(2)** The application shall be submitted in a form established by the Minister. The application shall contain sufficient information and documents to enable the Minister to determine whether to issue the authorization, including

**(a)** the name of the device;

**(b)** the class of the device;

**(c)** the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;

**(d)** the name and address of the manufacturer as it appears on the device label;

**(e)** the name and address of the establishment where the device is manufactured, if different from those referred to in paragraph (d);

**(f)** a description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented;

**(g)** information respecting the safety and effectiveness of the device;

**(h)** evidence that establishes that the manufacturer has a quality management system in place in respect of the device;

**(i)** the directions for use, unless directions are not required for the device to be used safely and effectively;

**(j)** an attestation by the manufacturer that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls; and

**(k)** a copy of the device label.

**(3)** An application in respect of a Class III or IV medical device shall contain, in addition to the information and documents referred to in subsection (2),

**68.11 (1)** Le fabricant d'un instrument médical peut présenter au ministre une demande d'autorisation pour l'instrument si celui-ci est un instrument médical BUSP.

**(2)** La demande d'autorisation est présentée, en la forme fixée par le ministre et elle contient des renseignements et documents suffisants pour lui permettre d'évaluer s'il convient de délivrer l'autorisation, notamment :

**a)** le nom de l'instrument;

**b)** la classe de l'instrument;

**c)** l'identificateur de l'instrument, y compris celui de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;

**d)** les nom et adresse du fabricant qui figurent sur l'étiquette de l'instrument;

**e)** les nom et adresse de l'établissement où l'instrument est fabriqué, s'ils diffèrent de ceux visés à l'alinéa d);

**f)** la description des états pathologiques, des fins et des utilisations pour lesquels l'instrument est fabriqué, vendu ou présenté;

**g)** les renseignements concernant la sécurité et l'efficacité de l'instrument;

**h)** les preuves établissant que le fabricant a mis en place un système de gestion de la qualité à l'égard de l'instrument;

**i)** le mode d'emploi, sauf lorsque l'instrument peut être utilisé de façon efficace et en toute sécurité sans mode d'emploi;

**j)** une attestation du fabricant portant que celui-ci a mis en place une procédure écrite concernant les registres de distribution, les plaintes, les rapports d'incident et les rappels;

**k)** une copie de l'étiquette de l'instrument.

**(3)** S'agissant d'un instrument médical de classe III ou IV, la demande contient, en plus des renseignements et des documents visés au paragraphe (2) :

- (a)** a description of the materials used in the manufacture and packaging of the device; and
- (b)** a list of the countries, other than Canada, where the device has been sold, the total number of units sold in those countries and a summary of any reported problems with the device and any recalls of the device in those countries.

**(4)** Despite subsection (2) and subsection (3), the application need not include the information and documents referred to in paragraphs (2)(g) and (h) and, if applicable, subsection (3) if

- (a)** the application includes information that demonstrates that an authorization or licence for sale of the medical device has been issued by a regulatory agency and that the authorization or licence has not been suspended or revoked; and
- (b)** the name of the regulatory agency appears in the *List of Regulatory Agencies for the Purposes of Sub-section 68.11(4) of the Medical Devices Regulations*, published by the Government of Canada on its website, as amended from time to time.

SOR/2023-19, s. 7; SOR/2023-277, s. 25.

## Issuance

**68.12** The Minister shall issue an authorization for a medical device if the following requirements are met:

- (a)** the manufacturer has submitted an application to the Minister that meets the requirements set out in section 68.11;
- (b)** [Repealed, SOR/2023-277, s. 10]
- (c)** the Minister has sufficient evidence to support the conclusion that the benefits associated with the device outweigh the risks associated with it, having regard to
- (i)** the uncertainties relating to those benefits and risks, and
  - (ii)** the urgent public health need for the device or the absence of any such need;
- (d)** the Minister has sufficient evidence to support the conclusion that the manufacturer has a quality management system in place that is adequate to

**a)** la description des matériaux de fabrication et d'emballage de l'instrument;

**b)** la liste des pays étrangers où l'instrument a été vendu, le nombre total d'unités vendues dans ces pays et un résumé des problèmes signalés et des rappels effectués dans ces pays.

**(4)** Malgré les paragraphes (2) et (3), il n'est pas nécessaire que la demande contienne les renseignements et les documents visés aux alinéas (2)g) et h) et, s'il y a lieu ceux visés au paragraphe (3), si les conditions ci-après sont réunies :

**a)** la demande contient des renseignements qui démontrent qu'une autorisation ou une licence permettant la vente de l'instrument médical a été délivrée par un organisme de réglementation et que cette autorisation ou cette licence n'a pas été suspendue ni révoquée;

**b)** l'organisme de réglementation figure sur la *Liste des organismes de réglementation pour l'application du paragraphe 68.11(4) du Règlement sur les instruments médicaux*, publiée par le gouvernement du Canada sur son site Web, avec ses modifications successives.

DORS/2023-19, art. 7; DORS/2023-277, art. 25.

## Délivrance

**68.12** Le ministre délivre une autorisation pour un instrument médical si les conditions ci-après sont réunies :

**a)** le fabricant a présenté au ministre une demande d'autorisation qui respecte les exigences visées à l'article 68.11;

**b)** [Abrogé, DORS/2023-277, art. 10]

**c)** le ministre dispose de preuves suffisantes pour conclure que les avantages liés à l'instrument l'emportent sur les risques associés à ce dernier, compte tenu à la fois :

- (i)** des incertitudes à l'égard de ces avantages et de ces risques,

- (ii)** du besoin urgent en matière de santé publique à l'égard de l'instrument ou de l'absence d'un tel besoin;

**d)** le ministre dispose de preuves suffisantes pour conclure que le fabricant a mis en place un système de contrôle de la qualité adéquat qui permet à la fois :

- (i) control the quality and, if applicable, the purity and sterility of the device and the materials used in the manufacture of the device, and
- (ii) ensure that the device meets the specifications of the device; and
- (e) the Minister determines that the health or safety of patients, users or other persons will not be unduly affected by the device.

SOR/2023-19, s. 7; SOR/2023-277, s. 10; SOR/2023-277, s. 25; SOR/2023-277, s. 26.

## Amendment

**68.13** No person shall import or sell a medical device for which the manufacturer holds an authorization if the device has been the subject of any of the following changes unless the manufacturer holds an amended authorization:

- (a) in the case of a Class III or IV device, a significant change;
- (b) a change that would result in a change of the class of the device;
- (c) a change in the name of the manufacturer;
- (d) a change in the name of the device;
- (e) a change in the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (f) in the case of a Class I or II device, a change in the medical conditions, purposes or uses for which the device is manufactured, sold or represented.

SOR/2023-19, s. 7; SOR/2023-277, s. 11; SOR/2023-277, s. 25.

**68.14** An application to amend an authorization shall be submitted to the Minister by the holder of the authorization in a form established by the Minister. The application shall contain sufficient information and documents to enable the Minister to determine whether to amend the authorization, including the information and documents referred to in subsection 68.11(2) and (3) that relate to the change referred to in section 68.13 for which an amendment to the authorization is required.

SOR/2023-19, s. 7.

**68.15** The Minister shall amend an authorization for a medical device if the following requirements are met:

- (i) de contrôler la qualité et, s'il y a lieu, la stérilité ou la pureté de l'instrument et de ses matériaux de fabrication,

- (ii) de s'assurer que l'instrument est conforme aux spécifications de l'instrument;

- (e) le ministre conclut que la santé ou la sûreté des patients, des utilisateurs ou d'autres personnes ne seraient pas indûment compromises par l'instrument.

DORS/2023-19, art. 7; DORS/2023-277, art. 10; DORS/2023-277, art. 25; DORS/2023-277, art. 26.

## Modifications

**68.13** Il est interdit de vendre ou d'importer un instrument médical pour lequel le fabricant est titulaire d'une autorisation si l'instrument a fait l'objet de l'une des modifications ci-après, sauf si le fabricant est titulaire d'une autorisation modifiée :

- (a) s'agissant d'un instrument de classe III ou IV, une modification importante;
- (b) une modification ayant pour effet de changer l'instrument de classe;
- (c) une modification du nom du fabricant;
- (d) une modification du nom de l'instrument;
- (e) une modification de l'identificateur de l'instrument, ou de celui de tout instrument médical qui fait partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;
- (f) s'agissant d'un instrument de classe I ou II, une modification des états pathologiques, des fins ou des utilisations pour lesquels l'instrument est fabriqué, vendu ou présenté.

DORS/2023-19, art. 7; DORS/2023-277, art. 11; DORS/2023-277, art. 25.

**68.14** La demande de modification de l'autorisation est présentée par le titulaire de l'autorisation au ministre en la forme fixée par celui-ci et elle contient les renseignements et documents suffisants pour lui permettre d'évaluer s'il convient de modifier l'autorisation, notamment les renseignements et documents visés aux paragraphes 68.11(2) ou (3) relatifs à la modification de l'instrument médical visée à l'article 68.13 pour laquelle une autorisation modifiée est requise.

DORS/2023-19, art. 7.

**68.15** Le ministre modifie l'autorisation pour un instrument médical si les conditions ci-après sont réunies :

- (a)** the holder of the authorization has submitted an application to the Minister that meets the requirements set out in section 68.14;
- (b)** the Minister has sufficient evidence to support the conclusion that the benefits associated with the device outweigh the risks associated with it, having regard to
- (i)** the uncertainties relating to those benefits and risks, and
  - (ii)** the urgent public health need for the device or the absence of any such need; and
- (c)** the Minister determines that the health or safety of patients, users or other persons will not be unduly affected by the device.

SOR/2023-19, s. 7; SOR/2023-277, s. 25.

- a)** le titulaire de l'autorisation a présenté au ministre une demande de modification de l'autorisation qui respecte les exigences visées à l'article 68.14;
- b)** le ministre dispose de preuves suffisantes pour conclure que les avantages liés à l'instrument l'emportent sur les risques associés à ce dernier, compte tenu à la fois :
- (i)** des incertitudes à l'égard de ces avantages et de ces risques,
  - (ii)** du besoin urgent en matière de santé publique à l'égard de l'instrument ou de l'absence d'un tel besoin;
- c)** le ministre conclut que la santé ou la sûreté des patients, des utilisateurs ou d'autres personnes ne seraient pas indûment compromises par l'instrument.

DORS/2023-19, art. 7; DORS/2023-277, art. 25.

## Refusal

**68.16** The Minister may refuse to issue or amend an authorization for a medical device if

- (a)** the Minister has reasonable grounds to believe that the manufacturer has contravened these Regulations or any provision of the Act relating to medical devices;
- (b)** the Minister has reasonable grounds to believe that the device is not labelled in accordance with sections 21 and 23; or
- (c)** the manufacturer has not submitted to the Minister all information, documents or material that was requested under section 68.23 to enable the Minister to determine whether to issue or amend the authorization, within the time limit specified in the request.

SOR/2023-19, s. 7; SOR/2023-277, s. 25; SOR/2023-277, s. 26.

**68.17** The Minister shall refuse to amend an authorization for a medical device if the effect of the proposed amendment would be that the device would not be authorized in relation to at least one of the following medical conditions:

- (a)** a medical condition that qualified the device as a UPHN medical device when the application for the authorization was submitted under section 68.11;
- (b)** a medical condition in relation to which the device was authorized when the application to amend the authorization was submitted under section 68.14, in the case where

## Refus

**68.16** Le ministre peut refuser de délivrer ou de modifier une autorisation pour un instrument médical dans les cas suivants :

- a)** il a des motifs raisonnables de croire que le fabricant ne s'est pas conformé au présent règlement ou aux dispositions de la Loi relatives aux instruments médicaux;
- b)** il a des motifs raisonnables de croire que l'instrument n'est pas étiqueté conformément aux articles 21 et 23;
- c)** le fabricant ne lui a pas fourni, dans le délai précisé dans la demande formulée au titre de l'article 68.23, les renseignements, les documents ou le matériel demandés pour lui permettre d'évaluer s'il convient de délivrer ou modifier l'autorisation.

DORS/2023-19, art. 7; DORS/2023-277, art. 25; DORS/2023-277, art. 26.

**68.17** Le ministre refuse de modifier une autorisation pour un instrument médical si la modification proposée aurait pour effet que l'instrument médical ne soit pas autorisé en lien avec au moins un des états pathologiques suivants :

- a)** celui qui faisait de l'instrument un instrument médical BUSP au moment où la demande d'autorisation a été présentée au titre de l'article 68.11;
- b)** celui à l'égard duquel l'instrument était autorisé au moment où la demande de modification a été présentée au titre de l'article 68.14, si les conditions suivantes sont réunies :

- (i) the holder of the authorization previously submitted an application to amend the authorization under section 68.14 to have the device authorized in relation to the medical condition;
  - (ii) the medical condition qualified the device as a UPHN medical device when that previous application was submitted, and
  - (iii) the authorization was amended under section 68.15 on the basis of that previous application;
- (c) a medical condition in relation to which the device was not authorized when the application to amend the authorization was submitted under section 68.14, in the case where
- (i) the holder of the authorization submitted the application to have the device authorized in relation to the medical condition, and
  - (ii) the medical condition qualified the device as a UPHN medical device when the application was submitted.

SOR/2023-19, s. 7; SOR/2023-277, s. 12.

**68.18** If the Minister refuses to issue or amend an authorization, the Minister shall notify the manufacturer of the medical device in writing of the reasons for the refusal and give them an opportunity to be heard.

SOR/2023-19, s. 7; SOR/2023-277, s. 25.

## Terms and Conditions

**68.19** The Minister may, at any time, impose terms and conditions on an authorization for a medical device or amend those terms and conditions.

SOR/2023-19, s. 7; SOR/2023-277, s. 25.

## Applications Submitted Under Part 1

**68.2** Despite section 68.03, the holder of an authorization for a medical device may submit

- (a) in the case of a Class I device, an application under section 45 for an establishment licence that would authorize the holder to sell or import the device; or
- (b) in the case of a Class II, III or IV device, an application under section 32 for a licence for the device.

SOR/2023-19, s. 7; SOR/2023-277, s. 25.

(i) le titulaire de l'autorisation avait précédemment présenté une demande de modification au titre de l'article 68.14 pour que l'instrument soit autorisé en lien avec cet état pathologique,

(ii) l'état pathologique faisait de l'instrument un instrument médical BUSP au moment où la demande précédente a été présentée,

(iii) l'autorisation a été modifiée au titre de l'article 68.15 sur la base de la demande précédente;

c) celui à l'égard duquel l'instrument n'était pas autorisé au moment où la demande de modification a été présentée au titre de l'article 68.14, si les conditions suivantes sont réunies :

(i) le titulaire de l'autorisation a présenté la demande pour que l'instrument soit autorisé en lien avec cet état pathologique,

(ii) l'état pathologique faisait de l'instrument un instrument médical BUSP au moment où la demande a été présentée.

DORS/2023-19, art. 7; DORS/2023-277, art. 12.

**68.18** Si le ministre refuse de délivrer ou de modifier l'autorisation, il en avise le fabricant de l'instrument médical par avis écrit motivé et lui donne la possibilité de se faire entendre.

DORS/2023-19, art. 7; DORS/2023-277, art. 25.

## Conditions

**68.19** Le ministre peut, en tout temps, assortir de conditions l'autorisation pour un instrument médical ou modifier ces conditions.

DORS/2023-19, art. 7; DORS/2023-277, art. 25.

## Demandes présentées au titre de la Partie 1

**68.2** Malgré l'article 68.03, le titulaire de l'autorisation pour un instrument médical peut présenter les demandes suivantes :

a) s'agissant d'un instrument de classe I, la demande de licence d'établissement prévue à l'article 45 en vertu de laquelle le titulaire pourrait importer ou vendre l'instrument;

b) s'agissant d'un instrument de classe II, III ou IV, la demande d'homologation prévue à l'article 32 pour l'instrument.

DORS/2023-19, art. 7; DORS/2023-277, art. 25.

## Cancellation

**68.21 (1)** The Minister may cancel an authorization for a medical device by written notice to the holder, giving reasons, if

(a) the Minister has reasonable grounds to believe that the holder has contravened these Regulations or any provision of the Act relating to medical devices;

(b) the Minister has reasonable grounds to believe that the risks associated with the device outweigh the benefits associated with it, having regard to

(i) the uncertainties relating to those benefits and risks, and

(ii) the urgent public health need for the device or the absence of any such need;

(c) the Minister has reasonable grounds to believe that the holder does not have a quality management system in place that is adequate to

(i) control the quality and, if applicable, the purity and sterility of the device and the materials used in the manufacture of the device, and

(ii) ensure that the device meets the specifications of the device;

(d) the Minister has reasonable grounds to believe that the health or safety of patients, users or other persons may be unduly affected by the device;

(e) the Minister has reasonable grounds to believe that the holder has failed to comply with the terms and conditions of the authorization;

(f) in the case of an authorization issued in respect of an application submitted on the basis of subsection 68.11(4), the Minister becomes aware that the authorization or licence for sale of the device that had been issued by the regulatory agency is suspended or revoked;

(g) the holder has not submitted to the Minister all information, documents or material that was requested under section 68.23 to enable the Minister to determine whether to cancel the authorization, within the time limit specified in the request;

(h) in the case of a Class I device that is not a UPHN medical device,

(i) the holder does not, within 120 days after the day on which the device ceases to be a UPHN

## Annulation

**68.21 (1)** Le ministre peut, par avis écrit au titulaire, annuler l'autorisation pour un instrument médical dans les cas suivants :

a) il a des motifs raisonnables de croire que le titulaire ne s'est pas conformé au présent règlement ou aux dispositions de la Loi relatives aux instruments médicaux;

b) il a des motifs raisonnables de croire que les risques liés à l'instrument l'emportent sur les avantages associés à ce dernier, compte tenu à la fois :

(i) des incertitudes à l'égard de ces avantages et de ces risques,

(ii) du besoin urgent en matière de santé publique à l'égard de l'instrument ou de l'absence d'un tel besoin;

c) il dispose de motifs raisonnables de croire que le titulaire n'a pas mis en place de système de contrôle de la qualité adéquat qui permet :

(i) de contrôler la qualité, et, s'il y a lieu, la stérilité ou la pureté de l'instrument et de ses matériaux de fabrication,

(ii) de s'assurer que l'instrument est conforme aux spécifications de l'instrument;

d) il a des motifs raisonnables de croire que la santé ou la sûreté des patients, des utilisateurs ou d'autres personnes peuvent être indûment compromises par l'instrument;

e) il a des motifs raisonnables de croire que le titulaire ne s'est pas conformé aux conditions de l'autorisation;

f) s'agissant d'une autorisation délivrée relativement à une demande présentée au titre du paragraphe 68.11(4), si le ministre apprend que l'autorisation ou la licence permettant la vente de l'instrument délivrée par l'organisme de réglementation est suspendue ou révoquée;

g) le titulaire n'a pas fourni au ministre, dans le délai précisé dans la demande, les renseignements, les documents ou le matériel demandés au titre de l'article 68.23 pour qu'il puisse évaluer s'il convient d'annuler l'autorisation;

h) s'agissant d'un instrument de classe I qui n'est pas un instrument médical BUSP :

medical device, submit an application under section 45 for an establishment licence that would authorize the holder to sell or import the device,

(ii) the Minister refuses to issue an establishment licence to the holder under section 47, or

(iii) the holder withdraws the application referred to in subparagraph (i);

(i) in the case of a Class II device that is not a UPHN medical device,

(i) the holder does not, within 120 days after the day on which the device ceases to be a UPHN medical device, provide the Minister with a copy of a contract, signed by both the holder and a registrar recognized by the Minister under section 32.1, that meets the following conditions:

(A) the contract indicates that the holder has begun the certification process to determine whether they have a quality management system that satisfies the standard referred to in paragraph 32(2)(f), and

(B) the contract is in effect when that period expires, or

(ii) the holder does not, within two years after the day on which the device ceases to be a UPHN medical device, provide the Minister with a copy of the quality management system certificate referred to in paragraph 32(2)(f); or

(j) in the case of a Class III or IV device that is not a UPHN medical device,

(i) the holder does not, within 120 days after the day on which the device ceases to be a UPHN medical device, provide the Minister with a copy of a contract, signed by both the holder and a registrar recognized by the Minister under section 32.1, that meets the following conditions:

(A) the contract indicates that the holder has begun the certification process to determine whether they have a quality management system that satisfies the standard referred to in paragraph 32(3)(j) or (4)(p), as the case may be, and

(B) the contract is in effect when that period expires, or

(ii) the holder does not, within two years after the day on which the device ceases to be a UPHN medical device, provide the Minister with a copy of the

(i) soit le titulaire ne présente pas, dans les cent vingt jours suivant la date à laquelle l'instrument cesse d'être un instrument médical BUSP, une demande pour une licence d'établissement au titre de l'article 45 en vertu de laquelle le titulaire pourrait importer ou vendre l'instrument,

(ii) soit le ministre refuse de délivrer une licence d'établissement au titulaire au titre de l'article 47,

(iii) soit le titulaire retire la demande visée au sousalinéa (i);

i) s'agissant d'un instrument de classe II qui n'est pas un instrument médical BUSP :

(i) soit le titulaire ne fournit pas au ministre, dans les cent vingt jours suivant la date à laquelle l'instrument cesse d'être un instrument médical BUSP, une copie d'un contrat, signé à la fois par le titulaire et par un registraire reconnu par le ministre au titre de l'article 32.1, qui respecte les conditions suivantes :

(A) le contrat indique que le titulaire a entrepris le processus de certification visant à vérifier s'il a mis en place un système de gestion de la qualité satisfaisant aux normes visées à l'alinéa 32(2)f),

(B) le contrat est en vigueur à l'expiration de la période,

(ii) soit le titulaire ne fournit pas au ministre, dans les deux ans suivant la date à laquelle l'instrument cesse d'être un instrument médical BUSP, une copie du certificat de système de gestion de la qualité visé à l'alinéa 32(2)f);

j) s'agissant d'un instrument de classe III ou IV qui n'est pas un instrument médical BUSP :

(i) soit le titulaire ne fournit pas au ministre, dans les cent vingt jours suivant la date à laquelle l'instrument cesse d'être un instrument médical BUSP, une copie d'un contrat, signé à la fois par le titulaire et par un registraire reconnu par le ministre au titre de l'article 32.1, qui respecte les conditions suivantes :

(A) le contrat indique que le titulaire a entrepris le processus de certification visant à vérifier s'il a mis en place un système de gestion de la qualité satisfaisant aux normes visées aux alinéas 32(3)j) ou (4)p), selon le cas,

(B) le contrat est en vigueur à l'expiration de la période,

quality management system certificate referred to in paragraph 32(3)(j) or (4)(p), as the case may be.

**(1.1)** If a medical device ceases to be a UPHN medical device after an application for an authorization is submitted under section 68.11 but before the Minister issues the authorization under section 68.12, the reference to “the device ceases to be a UPHN medical device” in subparagraph (1)(h)(i), (i)(i) or (j)(i), as the case may be, shall be read as “the Minister issued the authorization”.

**(1.2)** Subsection (1.1) ceases to apply in respect of the medical device if the device is authorized in relation to a medical condition that qualifies it as a UPHN medical device.

**(2)** A ground for cancellation specified in subparagraph (1)(i)(i) or (j)(i) does not apply if the holder has already provided the Minister with a copy of the quality management system certificate referred to in paragraph 32(2)(f), (3)(j) or (4)(p), as the case may be, or a copy of the contract referred to in the applicable subparagraph.

**(3)** A ground for cancellation specified in subparagraph (1)(i)(ii) or (j)(ii) does not apply if the holder has already provided the Minister with a copy of the quality management system certificate referred to in paragraph 32(2)(f), (3)(j) or (4)(p), as the case may be.

SOR/2023-19, s. 7; SOR/2023-277, s. 13; SOR/2023-277, s. 25.

**68.22** An authorization for a medical device is cancelled if

**(a)** in the case of a Class I device, the holder of the authorization is issued an establishment licence under section 46 that authorizes the holder to sell or import the device;

**(b)** in the case of a Class II, III or IV device, the holder of the authorization is issued a licence for the device under section 36; or

**(c)** the holder of the authorization informs the Minister under section 68.25 that the holder has discontinued the sale of the device in Canada.

SOR/2023-19, s. 7; SOR/2023-277, s. 14(E); SOR/2023-277, s. 25.

**(ii)** soit le titulaire ne fournit pas au ministre, dans les deux ans suivant la date à laquelle l'instrument cesse d'être un instrument médical BUSP, une copie du certificat de système de gestion de la qualité visé aux alinéas 32(3)(j) ou (4)(p), selon le cas.

**(1.1)** Si un instrument médical cesse d'être un instrument médical BUSP après la présentation d'une demande d'autorisation au titre de l'article 68.11, mais avant la délivrance de l'autorisation par le ministre au titre de l'article 68.12, la mention « l'instrument cesse d'être un instrument médical BUSP », aux sous-alinéas (1)(h)(i), i)(i) et j)(i), selon le cas, vaut mention de « le ministre a délivré l'autorisation ».

**(1.2)** Le paragraphe (1.1) cesse de s'appliquer à l'égard de l'instrument médical qui est autorisé en lien avec un état pathologique qui en fait un instrument médical BUSP.

**(2)** Le motif d'annulation précisé à l'un des sous-alinéas (1)i)(i) ou j)(i) ne s'applique pas si le titulaire a déjà fourni au ministre soit une copie du certificat de gestion de la qualité visé aux alinéas 32(2)f, (3)j) ou (4)p) selon le cas, soit une copie du contrat visé au sous-alinéa applicable.

**(3)** Le motif d'annulation précisé à l'un des sous-alinéas (1)i)(ii) ou j)(ii) ne s'applique pas si le titulaire a déjà fourni au ministre une copie du certificat de gestion de la qualité visé aux alinéas 32(2)f, (3)j) ou (4)p), selon le cas.

DORS/2023-19, art. 7; DORS/2023-277, art. 13; DORS/2023-277, art. 25.

**68.22** L'autorisation pour un instrument médical est annulée dans les cas suivants :

**a)** s'agissant d'un instrument de classe I, le ministre délivre au titulaire, à l'égard de l'instrument, une licence d'établissement au titre de l'article 46 en vertu de laquelle le titulaire peut importer ou vendre l'instrument;

**b)** s'agissant d'un instrument de classe II, III ou IV, le ministre délivre au titulaire, pour l'instrument, une homologation au titre de l'article 36;

**c)** lorsque le titulaire de l'autorisation informe le ministre, en application de l'article 68.25, qu'il a cessé de vendre l'instrument au Canada.

DORS/2023-19, art. 7; DORS/2023-277, art. 14(A); DORS/2023-277, art. 25.

## Additional Information and Material

**68.23** The Minister may request that the manufacturer of a medical device who has submitted an application for an authorization or the holder of an authorization submit to the Minister, within a specified time limit, any additional information or documents or any material, including samples, that is necessary to enable the Minister to determine whether to issue, amend or cancel the authorization.

SOR/2023-19, s. 7; SOR/2023-277, s. 25.

## Annual Review

**68.24** The holder of an authorization for a Class II, III or IV medical device that is not a UPHN medical device shall, annually before November 1 and in a form established by the Minister, provide the Minister with a statement signed by the holder or a person authorized to sign on the holder's behalf

- (a) confirming that all the information and documents submitted by the holder with respect to the device are still correct; or
- (b) describing any change to the information and documents submitted by the holder with respect to the device, other than those to be submitted under section 68.14 or 68.34.

SOR/2023-19, s. 7; SOR/2023-277, s. 25.

## Notification – Suspension or Revocation

**68.241 (1)** This section applies to the holder of an authorization for a medical device that was issued in respect of an application submitted on the basis of subsection 68.11(4).

**(2)** If the holder of an authorization for a medical device receives or becomes aware of information to the effect that the authorization or licence for sale of the device that was issued by the regulatory agency is suspended or revoked, the holder shall notify the Minister within 72 hours after they receive or become aware of the information, whichever occurs first.

**(3)** However, the holder is not required to notify the Minister if they or the holder referred to in paragraph 68.3(1)(b) submits that information under section 68.3.

SOR/2023-277, s. 15.

## Renseignements supplémentaires et matériel

**68.23** Le ministre peut demander au fabricant d'un instrument médical qui a déposé une demande d'autorisation ou qui est titulaire d'une telle autorisation de lui fournir, dans le délai précisé, les renseignements et les documents supplémentaires ou le matériel, notamment les échantillons, qui sont nécessaires pour qu'il puisse évaluer s'il convient de délivrer, de modifier ou d'annuler l'autorisation.

DORS/2023-19, art. 7; DORS/2023-277, art. 25.

## Examen annuel

**68.24** Avant le 1<sup>er</sup> novembre de chaque année, le titulaire d'une autorisation pour un instrument médical de classe II, III ou IV qui n'est pas un instrument médical BUSP fournit au ministre, en la forme fixée par celui-ci, une déclaration signée par lui-même ou en son nom par une personne autorisée qui, selon le cas :

- a) atteste que tous les renseignements et les documents qu'il a présentés au sujet de l'instrument sont toujours exacts;
- b) indique tous les changements apportés à ces renseignements et à ces documents, à l'exclusion de ceux qui doivent être présentés en vertu de l'article 68.14 ou 68.34.

DORS/2023-19, art. 7; DORS/2023-277, art. 25.

## Avis – suspension ou révocation

**68.241 (1)** Le présent article s'applique au titulaire d'une autorisation pour un instrument médical délivrée relativement à une demande présentée au titre du paragraphe 68.11(4).

**(2)** Le titulaire d'une autorisation pour un instrument médical qui a reçu communication ou a pris connaissance de renseignements selon lesquels l'autorisation ou la licence permettant la vente de l'instrument délivrée par l'organisme de réglementation a été suspendue ou révoquée en avise le ministre au plus tard soixante-douze heures après en avoir reçu communication ou en avoir eu connaissance, selon la première des deux éventualités à survenir.

**(3)** Toutefois, le titulaire n'a pas à aviser le ministre si lui ou le titulaire visé à l'alinéa 68.3(1)b) fournit ces renseignements en application de l'article 68.3.

DORS/2023-277, art. 15.

## Discontinuance

**68.25** If the holder of an authorization for a medical device discontinues the sale of the device in Canada, the holder shall inform the Minister within 30 days after the discontinuance.

SOR/2023-19, s. 7; SOR/2023-277, s. 25.

## Importation – Copy of Authorization

**68.26** If the manufacturer of a medical device holds an authorization for the device, the importer of a shipment of the device shall ensure that the shipment is accompanied by a copy of the authorization.

SOR/2023-19, s. 7; SOR/2023-277, s. 16.

## Incident Reporting

**68.27 (1)** The holder of an authorization for a medical device shall submit a preliminary report to the Minister in respect of any incident that comes to their attention occurring in Canada that involves the device

**(a)** within 10 days after becoming aware of the incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person; or

**(b)** within 30 days after becoming aware of the incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person but could do so were it to recur.

**(2)** The preliminary report shall contain the following information:

**(a)** the name of the medical device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;

**(b)** the names and addresses of the holder and of any known importer of the medical device as well as the name, title and contact information of a representative of the holder to contact for any information concerning the incident;

**(c)** the date on which the holder became aware of the incident;

## Cessation

**68.25** Le titulaire d'une autorisation pour un instrument médical qui cesse de vendre cet instrument au Canada en informe le ministre dans les trente jours suivant la cessation.

DORS/2023-19, art. 7; DORS/2023-277, art. 25.

## Importation – copie de l'autorisation

**68.26** Lorsque le fabricant d'un instrument médical est titulaire d'une autorisation à l'égard de cet instrument, l'importateur d'une cargaison de cet instrument veille à ce que celle-ci soit accompagnée d'une copie de l'autorisation.

DORS/2023-19, art. 7; DORS/2023-277, art. 16.

## Rapports d'incident

**68.27 (1)** Le titulaire d'une autorisation pour un instrument médical présente au ministre un rapport préliminaire à l'égard de tout incident dont il a pris connaissance qui s'est produit au Canada et qui met en cause l'instrument :

**a)** s'agissant d'un incident qui a entraîné la mort ou une détérioration grave de l'état de santé d'un patient, d'un utilisateur ou d'une autre personne, au plus tard dix jours après en avoir pris connaissance;

**b)** s'agissant d'un incident qui n'a pas entraîné la mort ou une détérioration grave de l'état de santé d'un patient, d'un utilisateur ou d'une autre personne, mais qui serait susceptible de le faire s'il se reproduisait, au plus tard trente jours après en avoir pris connaissance.

**(2)** Le rapport préliminaire contient les renseignements suivants :

**a)** les nom et identificateur de l'instrument médical, y compris l'identificateur de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;

**b)** les nom et adresse du titulaire et ceux de tout importateur connu de l'instrument médical, ainsi que les nom, titre et les coordonnées d'un représentant du titulaire avec lequel communiquer pour tout renseignement concernant l'incident;

**c)** la date à laquelle le titulaire a pris connaissance de l'incident;

- (d) the details known in respect of the incident, including the date on which the incident occurred and the consequences for the patient, user or other person;
- (e) the name and contact information, if known, of the person who reported the incident to the holder;
- (f) the names of any other medical devices involved in the incident, including any accessories, if known;
- (g) the preliminary comments of the holder with respect to the incident;
- (h) the course of action, including an investigation, that the holder proposes to follow in respect of the incident and a timetable for carrying out any proposed action and submitting a final report; and
- (i) a statement indicating whether a previous report has been made to the Minister with respect to the medical device and, if so, the date of the report.

SOR/2023-19, s. 7; SOR/2023-277, s. 25.

**68.28 (1)** The holder of the authorization shall, after making the preliminary report, submit a final report to the Minister in accordance with the timetable established under paragraph 68.27(2)(h).

**(2)** The final report shall contain the following information:

- (a) a description of the incident, including the number of persons who have died or experienced a serious deterioration in the state of their health;
- (b) a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident; and
- (c) any actions taken in respect of the medical device as a result of the investigation referred to in paragraph 68.27(2)(h), which may include
  - (i) increased post-market surveillance of the device,
  - (ii) corrective and preventive action respecting the design and manufacture of the device, and
  - (iii) recall of the device.

SOR/2023-19, s. 7; SOR/2023-277, s. 25.

**68.29** The holder of the authorization is not required to submit the preliminary report referred to in section 68.27 or the final report referred to in section 68.28 if

- (d) les détails connus de l'incident, notamment la date où il s'est produit et ses répercussions sur la personne en cause;
- (e) s'ils sont connus, les nom et les coordonnées de la personne qui a signalé l'incident au titulaire;
- (f) s'ils sont connus, le nom de tout autre instrument médical en cause dans l'incident, incluant tout accessoire;
- (g) les observations préliminaires du titulaire au sujet de l'incident;
- (h) les mesures, notamment l'enquête, qu'entend prendre le titulaire à l'égard de l'incident, ainsi que le calendrier de celles-ci, lequel comporte la date de présentation du rapport final;
- (i) une déclaration indiquant si l'instrument médical a fait l'objet d'un rapport précédent au ministre et, le cas échéant, la date de celui-ci.

DORS/2023-19, art. 7; DORS/2023-277, art. 25.

**68.28 (1)** À la suite de la présentation du rapport préliminaire, le titulaire de l'autorisation présente au ministre un rapport final selon le calendrier visé à l'alinéa 68.27(2)h).

**(2)** Le rapport final contient les renseignements suivants :

- (a) une description de l'incident, notamment le nombre de personnes qui sont décédées ou dont l'état de santé s'est gravement détérioré;
- (b) une explication détaillée des causes de l'incident et une justification des mesures prises à l'égard de celui-ci;
- (c) le cas échéant, les mesures qui ont été prises à l'égard de l'instrument médical à la suite de l'enquête visée à l'alinéa 68.27(2)h), notamment les mesures suivantes :
  - (i) une surveillance accrue après la mise en marché de l'instrument,
  - (ii) les mesures correctives ou préventives relatives à la conception et à la fabrication de l'instrument,
  - (iii) le rappel de l'instrument.

DORS/2023-19, art. 7; DORS/2023-277, art. 25.

**68.29** Le titulaire d'une autorisation n'est pas tenu de présenter le rapport préliminaire visé à l'article 68.27 ni

**(a)** the information that the holder would be required to include in that preliminary report is identical to the information that the importer of the device is required to include in the preliminary report referred to in subsection 59(1);

**(b)** the information that the holder would be required to include in that final report is identical to the information that the importer of the device is required to include in the final report referred to in subsection 59(1); and

**(c)** the holder advises the Minister in writing that the importer of the device is submitting the preliminary report and the final report under subsection 59(1).

SOR/2023-19, s. 7.

le rapport final visé à l'article 68.28 si les conditions suivantes sont réunies :

**a)** les renseignements que le titulaire serait tenu d'inclure dans le rapport préliminaire sont identiques à ceux que l'importateur de l'instrument est tenu d'inclure dans le rapport préliminaire visé au paragraphe 59(1);

**b)** les renseignements que le titulaire serait tenu d'inclure dans le rapport final sont identiques à ceux que l'importateur de l'instrument est tenu d'inclure dans le rapport final visé au paragraphe 59(1);

**c)** le titulaire avise le ministre par écrit que l'importateur de l'instrument soumet le rapport préliminaire et le rapport final à l'égard de l'instrument en vertu du paragraphe 59(1).

DORS/2023-19, art. 7.

## Serious Risk of Injury to Human Health

**68.3 (1)** This section applies to the following holders of therapeutic product authorizations:

**(a)** a holder of an authorization for a Class II, III or IV medical device that is not a UPHN medical device; and

**(b)** a holder of an establishment licence to import Class II, III or IV medical devices that imports a device referred to in paragraph (a).

**(2)** The holder of a therapeutic product authorization shall submit to the Minister information in respect of any serious risk of injury to human health that the holder receives or becomes aware of and that is relevant to the safety of a device referred to in paragraph (1)(a), regarding

**(a)** risks that have been communicated by any regulatory agency that is set out in the *List of Regulatory Agencies for the Purposes of Sections 61.2 and 68.3 of the Medical Devices Regulations*, published by the Government of Canada on its website, as amended from time to time, or by any person who is authorized to manufacture or sell a medical device within the jurisdiction of such a regulatory agency, and the manner of the communication;

**(b)** changes that have been made to the labelling of any medical device and that have been communicated to or requested by any regulatory agency that is set out in that list; and

## Risque grave de préjudice à la santé humaine

**68.3 (1)** Le présent article s'applique aux titulaires d'autorisations relatives à un produit thérapeutique suivants :

**a)** le titulaire d'une autorisation pour un instrument médical de classe II, III ou IV qui n'est pas un instrument médical BUSP;

**b)** le titulaire d'une licence d'établissement autorisant l'importation d'instruments médicaux de classe II, III ou IV qui importe un instrument médical visé à l'alinéa a).

**(2)** Le titulaire d'une autorisation relative à un produit thérapeutique fournit au ministre les renseignements dont il a reçu communication ou a connaissance concernant tout risque grave de préjudice à la santé humaine et se rapportant à la sécurité d'un instrument visé à l'alinéa (1)a) en ce qui concerne :

**a)** les risques communiqués, et la façon dont ils l'ont été, par tout organisme de réglementation mentionné dans la *Liste des organismes de réglementation pour l'application des articles 61.2 et 68.3 du Règlement sur les instruments médicaux*, publiée par le gouvernement du Canada sur son site Web, avec ses modifications successives, ou par toute personne autorisée à fabriquer ou à vendre un instrument médical sur le territoire relevant de la compétence d'un tel organisme;

**b)** les changements apportés à l'étiquetage de tout instrument médical à la demande de tout organisme

**(c)** recalls, reassessments and suspensions or revocations of authorizations, including licences, in respect of any medical device, that have taken place within the jurisdiction of any regulatory agency that is set out in that list.

**(3)** The information shall be submitted to the Minister within 72 hours after the holder receives or becomes aware of it, whichever occurs first.

SOR/2023-19, s. 7; SOR/2023-277, s. 17.

de réglementation mentionné dans cette liste ou communiqués à un tel organisme;

**c)** les rappels, les réévaluations et les suspensions ou révocations d'autorisations, notamment de licences, relativement à tout instrument médical sur le territoire relevant de la compétence de tout organisme de réglementation mentionné dans la liste.

**(3)** Le titulaire fournit ces renseignements au ministre au plus tard soixante-douze heures après en avoir reçu communication ou en avoir eu connaissance, selon la première des deux éventualités à survenir.

DORS/2023-19, art. 7; DORS/2023-277, art. 17.

**68.301 (1)** Despite subsection 68.3(2), if the holder of a therapeutic product authorization issued in respect of a medical device is the manufacturer, they may permit the importer of the device to submit the information required under that subsection on the manufacturer's behalf if the information that the manufacturer and the importer must submit is identical.

**(2)** The manufacturer shall advise the Minister in writing if the manufacturer has permitted the importer to submit the information on the manufacturer's behalf.

SOR/2023-277, s. 17.

**68.301 (1)** Malgré le paragraphe 68.3(2), le titulaire d'une autorisation relative à un produit thérapeutique délivrée à l'égard d'un instrument médical dont il est le fabricant peut permettre à l'importateur de fournir, en son nom, les renseignements visés à ce paragraphe, si les renseignements que chacun d'eux doit fournir sont identiques.

**(2)** S'il permet à l'importateur de fournir les renseignements en son nom, le fabricant en avise par écrit le ministre.

DORS/2023-277, art. 17.

## Summary Report

**68.31 (1)** The holder of an authorization for a Class II, III or IV medical device that is not a UPHN medical device shall prepare

**(a)** in the case of a Class II device, on a biennial basis, a summary report of the information referred to in subsection (2) that the holder received or became aware of during the previous 24 months; and

**(b)** in the case of a Class III or IV device, on an annual basis, a summary report of the information referred to in subsection (2) that the holder received or became aware of during the previous 12 months.

**(2)** The information to be covered by the summary report is that in respect of

**(a)** adverse effects;

**(b)** problems referred to in paragraph 57(1)(a);

**(c)** incidents referred to in subsection 68.27(1); and

## Rapport de synthèse

**68.31 (1)** Le titulaire d'une autorisation pour un instrument médical de classe II, III ou IV qui n'est pas un instrument médical BUSP prépare :

**a)** s'agissant d'un instrument de classe II, un rapport de synthèse biennal qui porte sur les renseignements visés au paragraphe (2) dont il a reçu communication ou a pris connaissance au cours des vingt-quatre derniers mois;

**b)** s'agissant d'un instrument de classe III ou IV, un rapport de synthèse annuel qui porte sur les renseignements visés au paragraphe (2) dont il a reçu communication ou a pris connaissance au cours des douze derniers mois.

**(2)** Les renseignements précisés dans le rapport de synthèse sont les suivants :

**a)** les effets nocifs;

**b)** les problèmes visés à l'alinéa 57(1)a);

**c)** les incidents visés au paragraphe 68.27(1);

**(d)** serious risks of injury to human health that are relevant to the safety of the medical device and are referred to in subsection 68.3(1).

**(3)** The summary report shall contain a concise critical analysis of the information referred to in subsection (2).

**(4)** In preparing the summary report, the holder shall determine, on the basis of the critical analysis, whether what is known about the benefits and risks associated with the medical device has changed in any of the following ways:

**(a)** the potential benefits for patients through the use of the device may be less;

**(b)** in respect of each of the risks,

**(i)** the harm associated with the risk is more likely to occur, or

**(ii)** if the harm associated with the risk occurs, the consequences for the health or safety of patients, users or other persons could be more serious; and

**(c)** a new risk has been identified.

**(5)** The holder shall include the conclusions they reach under subsection (4) in the summary report.

**(6)** If, in preparing the summary report, the holder concludes that what is known about the benefits and risks associated with the medical device has changed in any of the ways referred to in paragraphs (4)(a) to (c), they shall notify the Minister, in writing, within 72 hours after having reached the conclusion, unless that has already been done.

SOR/2023-19, s. 7; SOR/2023-277, s. 18; SOR/2023-277, s. 25.

**68.32 (1)** The Minister may, for the purposes of determining whether there is sufficient evidence to support the conclusion that the benefits associated with a medical device outweigh the risks, request that the holder of an authorization for the device submit, within a specified time limit, any of the following:

**(a)** summary reports; or

**(b)** information on the basis of which summary reports were prepared.

**(2)** The holder shall submit to the Minister the summary reports or information, or both, that the Minister requests within the time limit specified in the request.

SOR/2023-19, s. 7; SOR/2023-277, s. 25.

**d)** les risques graves de préjudice à la santé humaine se rapportant à la sécurité de l'instrument médical qui sont visés au paragraphe 68.3(1).

**(3)** Le rapport de synthèse comprend une analyse critique et concise des renseignements visés au paragraphe (2).

**(4)** En préparant le rapport, le titulaire évalue, à partir de son analyse critique, si ce qui est connu à propos des avantages et des risques liés à l'instrument médical a changé de l'une des manières suivantes :

**a)** les avantages éventuels pour les patients de l'utilisation de l'instrument pourraient être moindres;

**b)** pour chacun des risques, selon le cas :

**(i)** la probabilité que le préjudice lié au risque survienne est plus élevée,

**(ii)** si le préjudice lié au risque survient, les répercussions sur la santé ou la sûreté des patients, des utilisateurs ou d'autres personnes pourraient être plus élevées;

**c)** un nouveau risque a été identifié.

**(5)** Le titulaire fait état, dans le rapport de synthèse, des conclusions qu'il a tirées en application du paragraphe (4).

**(6)** Si le titulaire conclut, en préparant le rapport, que ce qui est connu à propos des avantages et des risques liés à l'instrument médical a changé de l'une des manières visées aux alinéas (4)a à c), il en informe le ministre par écrit dans les soixante-douze heures après être arrivé à cette conclusion, si ce n'est pas déjà fait.

DORS/2023-19, art. 7; DORS/2023-277, art. 18; DORS/2023-277, art. 25.

**68.32 (1)** Pour évaluer s'il existe des preuves suffisantes pour conclure que les avantages liés à l'instrument médical l'emportent sur les risques associés à ce dernier, le ministre peut demander au titulaire d'une autorisation délivrée à l'égard de l'instrument de lui présenter, dans le délai précisé dans la demande, ce qui suit :

**a)** ses rapports de synthèse;

**b)** les renseignements sur lesquels sont fondés les rapports de synthèse.

**(2)** Le titulaire fournit au ministre, sur demande, ses rapports de synthèse ou les renseignements, ou les deux, dans le délai précisé dans la demande.

DORS/2023-19, art. 7; DORS/2023-277, art. 25.

**68.33 (1)** The holder of an authorization for a medical device shall maintain records of the summary reports and the information on the basis of which those reports were prepared.

**(2)** The holder shall retain the records for seven years after the day on which they were created.

SOR/2023-19, s. 7; SOR/2023-277, s. 25.

**68.33 (1)** Le titulaire d'une autorisation pour un instrument médical tient des dossiers contenant ses rapports de synthèse et les renseignements sur lesquels ces rapports sont fondés.

**(2)** Il les conserve pendant sept ans après la date de leur création.

DORS/2023-19, art. 7; DORS/2023-277, art. 25.

## Obligation to Submit Certificate

**68.34 (1)** If a new or modified quality management system certificate is issued in respect of a medical device for which the manufacturer holds an authorization and that is not a UPHN medical device, the manufacturer shall submit a copy of the certificate to the Minister within 30 days after it is issued.

**(2)** Subsection (1) does not apply if the manufacturer includes the new or modified quality management system certificate in an application to amend the authorization that is submitted under section 68.14.

SOR/2023-19, s. 7; SOR/2023-277, s. 19.

## Obligation de présenter un certificat

**68.34 (1)** Si un nouveau certificat de système de gestion de la qualité ou un certificat modifié est délivré relativement à un instrument médical qui n'est pas un instrument médical BUSP, le fabricant qui est titulaire d'une autorisation à l'égard de celui-ci doit en présenter une copie au ministre dans les trente jours suivant sa délivrance.

**(2)** Le paragraphe (1) ne s'applique pas si le fabricant inclut le nouveau certificat de système de gestion de la qualité ou le certificat modifié dans la demande de modification de l'autorisation présentée en application de l'article 68.14.

DORS/2023-19, art. 7; DORS/2023-277, art. 19.

## Sale – Cancellation of Authorization

**68.35** Subject to sections 21, 23 and 44, if an authorization for a medical device is cancelled under paragraph 68.21(1)(h), (i) or (j), a person other than the manufacturer may sell the device, despite any other provision in Part 1, for a period of six months beginning on the day on which the authorization is cancelled.

SOR/2023-19, s. 7; SOR/2023-277, s. 20.

## Vente – annulation de l'autorisation

**68.35** Sous réserve des articles 21, 23 et 44, si une autorisation délivrée pour un instrument médical est annulée en application de l'un des alinéas 68.21(1)h), i) ou j), toute personne autre que le fabricant peut, malgré toute autre disposition de la partie 1, le vendre pour une période de six mois à compter de la date de l'annulation.

DORS/2023-19, art. 7; DORS/2023-277, art. 20.

## Expanded Use

**68.351** The Minister may add a medical condition to column 1 of the *List of Medical Devices for Expanded Use* only if the Minister has reasonable grounds to believe that

**(a)** the medical condition presents, or is the result of, a significant risk to public health in Canada; and

**(b)** immediate action is required to deal with the risk.

SOR/2023-277, s. 21.

## Usage élargi

**68.351** Le ministre ne peut ajouter un état pathologique à la colonne 1 de la *Liste d'instruments médicaux destinés à un usage élargi* que s'il a des motifs raisonnables de croire que les conditions ci-après sont réunies :

**a)** l'état pathologique présente un risque appréciable pour la santé publique au Canada ou résulte d'un tel risque;

**b)** une intervention immédiate est nécessaire pour parer au risque.

DORS/2023-277, art. 21.

**68.36 (1)** Le ministre ne peut ajouter un instrument médical homologué, ou un instrument médical de classe

**68.36 (1)** The Minister may add a licensed medical device, or a Class II, III or IV medical device for which the

manufacturer holds an authorization, to column 2 of the *List of Medical Devices for Expanded Use* and an expanded use to column 3 only if the following conditions are met:

- (a)** the Minister has reasonable grounds to believe that there is an urgent public health need for the expanded use of the device that is related to the corresponding medical condition that is set out in column 1;
- (b)** the Minister has sufficient evidence to support the conclusion that the benefits associated with the expanded use outweigh the risks associated with it, having regard to
  - (i)** the uncertainties relating to those benefits and risks, and
  - (ii)** the urgent public health need for the device; and
- (c)** the Minister determines that the health or safety of patients, users or other persons will not be unduly affected by the expanded use of the device.

**(2)** In the case of a licensed medical device, sections 26 and 27, as they relate to an expanded use of the device, do not apply in respect of the importation, sale or advertisement of the device if

- (a)** the medical condition to which the expanded use relates is set out in column 1 of the *List of Medical Devices for Expanded Use*;
- (b)** the device is set out in column 2 of that list; and
- (c)** the expanded use of the device is set out in column 3 of that list.

**(3)** In the case of a Class II, III or IV medical device for which the manufacturer holds an authorization, sections 27 and 68.13, as they relate to an expanded use of the device, do not apply in respect of the importation, sale or advertisement of the device if

- (a)** the medical condition to which the expanded use relates is set out in column 1 of the *List of Medical Devices for Expanded Use*;
- (b)** the device is set out in column 2 of that list; and
- (c)** the expanded use of the device is set out in column 3 of that list.

SOR/2023-19, s. 7; SOR/2023-277, s. 22.

II, III ou IV pour lequel le fabricant est titulaire d'une autorisation, à la colonne 2 de la *Liste d'instruments médicaux destinés à un usage élargi* ni ajouter un usage élargi à la colonne 3 que si les conditions ci-après sont réunies :

- a)** il a des motifs raisonnables de croire que l'usage élargi de l'instrument est nécessaire pour combler un besoin urgent en matière de santé publique relatif à l'état pathologique correspondant qui figure à la colonne 1;
- b)** il dispose de preuves suffisantes pour conclure que les avantages liés à l'usage élargi l'emportent sur les risques associés à cet usage, compte tenu à la fois :
  - (i)** des incertitudes à l'égard de ces avantages et de ces risques,
  - (ii)** du besoin urgent en matière de santé publique à l'égard de l'instrument;
- c)** il conclut que la santé ou la sûreté des patients, des utilisateurs ou d'autres personnes ne seraient pas indûment compromises par l'usage élargi de l'instrument.

**(2)** S'agissant d'un instrument médical homologué, les articles 26 et 27 ne s'appliquent pas à l'égard de l'importation, la publicité ou la vente de celui-ci, dans la mesure où ils se rapportent à l'usage élargi, si les conditions ci-après sont réunies :

- a)** l'état pathologique en lien avec l'usage élargi figure à la colonne 1 de la *Liste d'instruments médicaux destinés à un usage élargi*;
- b)** l'instrument figure à la colonne 2 de cette liste;
- c)** l'usage élargi de l'instrument figure à la colonne 3 de cette liste.

**(3)** S'agissant d'un instrument médical de classe II, III ou IV pour lequel le fabricant est titulaire d'une autorisation, les articles 27 et 68.13 ne s'appliquent pas à l'égard de l'importation, la publicité ou la vente de celui-ci, dans la mesure où ils se rapportent à l'usage élargi, si les conditions ci-après sont réunies :

- a)** l'état pathologique en lien avec l'usage élargi figure à la colonne 1 de la *Liste d'instruments médicaux destinés à un usage élargi*;
- b)** l'instrument figure à la colonne 2 de cette liste;
- c)** l'usage élargi de l'instrument figure à la colonne 3 de cette liste.

DORS/2023-19, art. 7; DORS/2023-277, art. 22.

**68.37** The Minister shall publish on the Government of Canada website supplementary information pertaining to the expanded use, set out in column 3 of the *List of Medical Devices for Expanded Use*, of a licensed medical device — or a Class II, III or IV medical device for which the manufacturer holds an authorization —, set out in column 2 of that list, including

- (a) a statement of the expanded use;
- (b) a statement of the known and potential benefits and risks; and
- (c) any supplement to the directions for use, unless a supplement is not required for the device to be used safely and effectively.

SOR/2023-19, s. 7; SOR/2023-277, s. 23.

**68.37** Le ministre publie sur le site Web du gouvernement du Canada des renseignements supplémentaires relativement à l'usage élargi, qui figure à la colonne 3 de la *Liste d'instruments médicaux destinés à un usage élargi*, d'un instrument médical homologué — ou d'un instrument médical de classe II, III ou IV pour lequel le fabricant est titulaire d'une autorisation —, qui figure à la colonne 2 de cette liste, notamment les renseignements suivants :

- a) la mention de l'usage élargi;
- b) la mention des avantages et risques connus et possibles;
- c) tout supplément au mode d'emploi, sauf lorsque l'instrument peut être utilisé de façon efficace et en toute sécurité sans un tel supplément.

DORS/2023-19, art. 7; DORS/2023-277, art. 23.

**68.38 (1)** The Minister may request from the holder of a medical device licence, in respect of the medical device that is set out in column 2 of the *List of Medical Devices for Expanded Use* for which the licence was issued, any information in relation to the expanded use that is set out in column 3 of that list that the holder possesses or to which they have reasonable access.

**(2)** The Minister may request from the holder of an authorization, in respect of the Class II, III or IV medical device set out in column 2 of the *List of Medical Devices for Expanded Use* for which the authorization was issued, any information in relation to the expanded use set out in column 3 of that list that the holder possesses or to which they have reasonable access.

**(3)** The holder of the licence or authorization shall submit to the Minister the information that the Minister requests within the time limit specified in the request.

SOR/2023-19, s. 7; SOR/2023-277, s. 24.

**68.38 (1)** Le ministre peut demander au titulaire d'une homologation pour un instrument médical figurant à la colonne 2 de la *Liste d'instruments médicaux destinés à un usage élargi* de lui fournir les renseignements dont il dispose ou auxquels il a un accès raisonnable relativement à l'usage élargi figurant à la colonne 3 de cette liste, s'il s'agit de l'instrument médical à l'égard duquel l'homologation a été délivrée.

**(2)** Le ministre peut demander au titulaire d'une autorisation pour un instrument médical de classe II, III ou IV figurant à la colonne 2 de la *Liste d'instruments médicaux destinés à un usage élargi* de lui fournir les renseignements dont il dispose ou auxquels il a un accès raisonnable relativement à l'usage élargi figurant à la colonne 3 de cette liste, s'il s'agit de l'instrument médical à l'égard duquel l'autorisation a été délivrée.

**(3)** Le titulaire de l'homologation ou de l'autorisation fournit au ministre les renseignements demandés, dans le délai précisé dans la demande.

DORS/2023-19, art. 7; DORS/2023-277, art. 24.

## PART 2

# Custom-Made Devices and Medical Devices to Be Imported or Sold for Special Access

## Application

**69 (1)** This Part applies to custom-made devices and medical devices that are to be imported or sold for special access.

**(2)** In this Part, **special access** means access to a medical device for emergency use or if conventional therapies have failed, are unavailable or are unsuitable.

## General

**70** No person shall import or sell a Class III or IV custom-made device or a medical device for special access unless the Minister has issued an authorization for its sale or importation.

## Authorization

**71 (1)** If a health care professional wishes to obtain a medical device referred to in section 70, the professional shall apply to the Minister for an authorization that would permit the manufacturer or importer of the device to sell, or to import and sell, the device to that professional.

**(2)** The application shall contain the following:

**(a)** the name of the device, its class and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;

**(b)** the number of units required;

**(c)** the name and address of the manufacturer or importer;

**(d)** the name, title and telephone number of the representative of the manufacturer or importer to contact for any information concerning the device;

**(e)** the diagnosis, treatment or prevention for which the device is required;

## PARTIE 2

# Instruments faits sur mesure et instruments médicaux importés ou vendus aux fins d'un accès spécial

## Champ d'application

**69 (1)** La présente partie s'applique aux instruments faits sur mesure et aux instruments médicaux importés ou vendus aux fins d'un accès spécial.

**(2)** Pour l'application de la présente partie, **accès spécial** s'entend de l'accès à un instrument médical en cas d'urgence ou lorsque les traitements classiques ont échoué, ne sont pas disponibles ou ne conviennent pas.

## Dispositions générales

**70** Il est interdit d'importer ou de vendre un instrument fait sur mesure de classe III ou IV ou un instrument médical aux fins d'un accès spécial, à moins d'y être autorisé par le ministre.

## Autorisation

**71 (1)** Le professionnel de la santé qui désire obtenir un instrument médical visé à l'article 70 doit présenter au ministre une demande visant à autoriser le fabricant ou l'importateur, selon le cas, à lui vendre l'instrument ou à l'importer et à le lui vendre.

**(2)** La demande contient les renseignements et documents suivants :

**a)** les nom, classe et identificateur de l'instrument, y compris l'identificateur de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;

**b)** le nombre d'unités requises;

**c)** les nom et adresse du fabricant ou de l'importateur;

**d)** les nom, titre et numéro de téléphone d'un représentant du fabricant ou de l'importateur avec lequel communiquer pour tout renseignement concernant l'instrument;

**(f)** a statement that sets out

**(i)** the reasons the device was chosen for the diagnosis, treatment or prevention,

**(ii)** the risks and benefits that are associated with its use, and

**(iii)** the reasons the diagnosis, treatment or prevention could not be accomplished using

**(A)** a licensed medical device that is available for sale in Canada, or

**(B)** a medical device for which the manufacturer of that device holds an authorization issued under section 68.12 and that is available for sale in Canada;

**(g)** the name and address of each health care facility at which the device is to be used by that professional;

**(h)** the known safety and effectiveness information in respect of the device;

**(i)** a written undertaking by the health care professional that the professional will inform the patient for whom the device is intended of the risks and benefits associated with its use;

**(j)** the directions for use, unless directions are not required for the device to be used safely and effectively; and

**(k)** in the case of a custom-made device, a copy of the health care professional's written direction to the manufacturer giving the design characteristics of the device.

SOR/2023-19, s. 8.

**e)** le diagnostic, le traitement ou les mesures prophylactiques pour lesquels l'instrument est requis;

**f)** un exposé faisant état :

**(i)** des raisons pour lesquelles l'instrument a été choisi pour le diagnostic, le traitement ou les mesures prophylactiques,

**(ii)** des risques et des avantages liés à son utilisation,

**(iii)** des raisons pour lesquelles le diagnostic, le traitement ou les mesures prophylactiques ne pourraient être effectués à l'aide :

**(A)** d'un instrument médical homologué qui se trouve dans le commerce au Canada,

**(B)** d'un instrument médical pour lequel le fabricant de cet instrument est titulaire d'une autorisation délivrée au titre de l'article 68.12 et qui se trouve dans le commerce au Canada;

**g)** les nom et adresse de chaque établissement de santé où le professionnel de la santé se propose d'utiliser l'instrument;

**h)** les renseignements connus sur la sûreté et l'efficacité de l'instrument;

**i)** un engagement écrit du professionnel de la santé portant qu'il informera le patient auquel l'instrument est destiné des risques et des avantages liés à son utilisation;

**j)** le mode d'emploi, sauf lorsque l'instrument peut être utilisé de façon efficace et en toute sécurité sans mode d'emploi;

**k)** dans le cas d'un instrument fait sur mesure, une copie des directives écrites du professionnel de la santé au fabricant qui précisent les caractéristiques de conception de l'instrument.

DORS/2023-19, art. 8.

**72 (1)** Le ministre délivre au fabricant ou à l'importateur l'autorisation visée au paragraphe 71(1) s'il détermine que les conditions suivantes sont réunies :

**a)** les avantages dont pourrait tirer le patient de l'utilisation de l'instrument l'emportent sur les risques liés à son utilisation;

**b)** la santé ou la sûreté des patients, utilisateurs ou autres personnes ne seraient pas indûment compromis;

**72 (1)** The Minister shall issue an authorization referred to in subsection 71(1) to a manufacturer or importer if the Minister determines that

**(a)** the benefits that may be obtained by the patient through the use of the device outweigh the risks associated with its use;

**(b)** the health or safety of patients, users or other persons will not be unduly affected;

**(c)** a licensed device that would adequately meet the requirements of the patient is not available in Canada;

**(c.1)** a medical device for which the manufacturer of that device holds an authorization issued under section 68.12 and that would adequately meet the requirements of the patient is not available for sale in Canada; and

**(d)** the authorization is not being used by the manufacturer or importer to circumvent the requirements of Part 1 or 1.1.

**(2)** The authorization issued under subsection (1) shall specify

**(a)** the number of units of the device authorized to be imported;

**(b)** the number of units of the device authorized to be sold; and

**(c)** the name of the health care professional to whom the manufacturer or importer may sell the device.

SOR/2023-19, s. 9.

## Additional Information

**73** If the information and documents submitted in respect of an application made pursuant to section 71 are insufficient to enable the Minister to determine whether the conditions set out in subsection 72(1) have been met, the manufacturer, importer or health care professional shall, at the request of the Minister, submit any further information relevant to the application that the Minister may request.

**74** The Minister may, in respect of an authorization that has been issued,

**(a)** request the manufacturer, importer or health care professional to submit information in respect of the device if the Minister believes on reasonable grounds, after reviewing a report or information brought to the Minister's attention, that the device for which the authorization has been issued no longer meets the conditions set out in subsection 72(1); and

**(b)** issue a written cancellation of the authorization, giving reasons, if

**(i)** the Minister determines that the conditions set out in subsection 72(1) are no longer met, or

**(ii)** the information referred to in paragraph (a) has not been submitted.

**c)** aucun instrument médical homologué répondant adéquatement aux besoins du patient ne se trouve dans le commerce au Canada;

**c.1)** aucun instrument médical pour lequel le fabricant de cet instrument est titulaire d'une autorisation délivrée au titre de l'article 68.12 et qui répond adéquatement aux besoins du patient ne se trouve dans le commerce au Canada;

**d)** l'autorisation n'est pas utilisée par le fabricant ou l'importateur pour se soustraire aux exigences de la partie 1 ou de la partie 1.1.

**(2)** L'autorisation précise :

**a)** le nombre d'unités de l'instrument qui peuvent être importées;

**b)** le nombre d'unités de l'instrument qui peuvent être vendues;

**c)** le nom du professionnel de la santé à qui le fabricant ou l'importateur peut vendre l'instrument.

DORS/2023-19, art. 9.

## Renseignements complémentaires

**73** Lorsque les renseignements et documents contenus dans la demande d'autorisation sont insuffisants pour permettre au ministre de déterminer si les conditions visées au paragraphe 72(1) sont réunies, le fabricant, l'importateur ou le professionnel de la santé doit, à la demande du ministre, fournir des renseignements complémentaires.

**74** Le ministre peut, à l'égard d'une autorisation qui a été délivrée :

**a)** demander au fabricant, à l'importateur ou au professionnel de la santé de lui fournir des renseignements concernant l'instrument, s'il a des motifs raisonnables de croire, à la suite de l'examen de tout rapport ou renseignement portés à sa connaissance, que les conditions visées au paragraphe 72(1) ne sont plus remplies;

**b)** annuler, par avis écrit motivé, l'autorisation dans les cas suivants :

**(i)** il détermine que les conditions visées au paragraphe 72(1) ne sont plus remplies,

**(ii)** la personne en cause n'obtempère pas à la demande de renseignements visée à l'alinéa a).

## Labelling

**75** No person shall import or sell a medical device in respect of which an authorization has been issued pursuant to section 72, or a Class I or II custom-made device, unless the device has a label that

- (a) sets out the name of the manufacturer;
- (b) sets out the name of the device; and
- (c) specifies whether the device is a custom-made device or is being imported or sold for special access.

## Distribution Records

**76** The manufacturer or importer of a medical device in respect of which an authorization has been issued pursuant to section 72 shall maintain a distribution record in respect of the device in accordance with sections 52 to 56.

## Incident Reporting

[SOR/2020-262, s. 18(E)]

**77** The health care professional referred to in subsection 71(1) shall, within 72 hours after becoming aware of an incident that involves the medical device for which an authorization has been issued under section 72 and that meets the following conditions, report the incident to the Minister and to the manufacturer or importer of the device and specify the nature of the incident and the circumstances surrounding it:

- (a) the incident is related to a failure of the device or a deterioration in its effectiveness or any inadequacy in its labelling or in its directions for use; and
- (b) the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person or could do so were the incident to recur.

SOR/2020-262, s. 19.

## Implant Registration

**78** Sections 66 to 68 apply in respect of an implant that is imported or sold for special access.

SOR/2002-190, s. 7.

## Étiquetage

**75** Il est interdit d'importer ou de vendre un instrument médical à l'égard duquel une autorisation a été délivrée en vertu de l'article 72 ou un instrument fait sur mesure de classe I ou II, sauf s'il est accompagné d'une étiquette qui porte les renseignements suivants :

- a) le nom du fabricant;
- b) le nom de l'instrument;
- c) une mention précisant qu'il s'agit d'un instrument fait sur mesure ou d'un instrument destiné à être importé ou vendu aux fins d'un accès spécial.

## Registre de distribution

**76** Le fabricant ou l'importateur d'un instrument médical à l'égard duquel une autorisation a été délivrée en vertu de l'article 72 doit tenir un registre de distribution de l'instrument conformément aux articles 52 à 56.

## Rapports d'incident

[DORS/2020-262, art. 18(A)]

**77** Le professionnel de la santé visé au paragraphe 71(1) signale, dans les soixante-douze heures après en avoir eu connaissance, tout incident qui met en cause l'instrument médical à l'égard duquel une autorisation a été délivrée en application de l'article 72, et il en précise la nature et les circonstances au ministre, ainsi qu'au fabricant ou à l'importateur, lorsque l'incident, à la fois :

- a) est lié à une défaillance de l'instrument, à une dégradation de son efficacité ou à un étiquetage ou à un mode d'emploi défectueux;
- b) a entraîné la mort ou une détérioration grave de l'état de santé d'un patient, d'un utilisateur ou d'une autre personne, ou serait susceptible de le faire s'il se reproduisait.

DORS/2020-262, art. 19.

## Enregistrement des implants

**78** Les articles 66 à 68 s'appliquent aux implants qui sont importés ou vendus aux fins d'un accès spécial.

DORS/2002-190, art. 7.

## **PART 3**

# Medical Devices for Investigational Testing Involving Human Subjects

## Application

**79** This Part applies to medical devices that are to be imported or sold for investigational testing involving human subjects.

## General

**80 (1)** Subject to subsections (2) and (3), no person shall import or sell a medical device for investigational testing.

**(2)** A manufacturer or importer of a Class II, III or IV medical device may sell the device to a qualified investigator for the purpose of conducting investigational testing if the manufacturer or importer holds an authorization issued under subsection 83(1) and possesses records that contain all the information and documents required by section 81.

**(3)** A manufacturer or importer of a Class I medical device may sell the device to a qualified investigator for the purpose of conducting investigational testing if the manufacturer or importer possesses records that contain all the information and documents required by section 81.

## Records

**81** The records referred to in section 80 shall contain the following:

**(a)** the name, address and telephone number of the manufacturer and the importer of the device;

**(b)** the name of the device, its class and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;

**(c)** a description of the device and of the materials used in its manufacture and packaging;

**(d)** a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented;

## **PARTIE 3**

# Instruments médicaux pour essais expérimentaux avec des sujets humains

## Champ d'application

**79** La présente partie s'applique aux instruments médicaux importés ou vendus aux fins d'essais expérimentaux avec des sujets humains.

## Dispositions générales

**80 (1)** Sous réserve des paragraphes (2) et (3), il est interdit d'importer ou de vendre un instrument médical aux fins d'essais expérimentaux.

**(2)** Le fabricant ou l'importateur d'un instrument médical de classe II, III ou IV peut le vendre à un chercheur compétent aux fins d'essais expérimentaux, s'il détient une autorisation délivrée en vertu du paragraphe 83(1) et s'il a en sa possession un registre contenant les renseignements et documents visés à l'article 81.

**(3)** Le fabricant ou l'importateur d'un instrument médical de classe I peut le vendre à un chercheur compétent aux fins d'essais expérimentaux, s'il a en sa possession un registre contenant les renseignements et documents visés à l'article 81.

## Registre

**81** Le registre visé à l'article 80 doit contenir les renseignements et documents suivants :

**a)** les nom, adresse et numéro de téléphone du fabricant et de l'importateur de l'instrument;

**b)** les nom, classe et identificateur de l'instrument, y compris l'identificateur de tout instrument médical faisant partie d'un système, d'une trousse d'essai, d'un ensemble d'instruments, d'une famille d'instruments ou d'une famille d'ensembles d'instruments;

**c)** la description de l'instrument, ainsi que ses matériaux de fabrication et d'emballage;

**d)** l'énoncé des caractéristiques de l'instrument qui permettent de l'utiliser pour les états pathologiques, les fins et les utilisations pour lesquels il est fabriqué, vendu ou présenté;

**(e)** a list of the countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries;

**(f)** a risk assessment comprising an analysis and evaluation of the risks, and the risk reduction measures adopted for the purposes of conducting investigational testing of the device, including, as appropriate,

**(i)** the results of any previous research, testing and studies conducted with respect to the device,

**(ii)** a description of the methods currently used to diagnose or treat the medical condition in respect of which the investigational testing is being proposed, and

**(iii)** information respecting any cautions, warnings, contra-indications and possible adverse effects associated with the use of the device;

**(g)** the names of all the qualified investigators to whom the device is proposed to be sold and their qualifications, including their training and experience;

**(h)** the name and address of each institution at which the investigational testing is proposed to be conducted and, in the case of a Class III or IV device, written approval from the institution indicating that the investigational testing may be carried out there;

**(i)** a protocol of the proposed investigational testing, including the number of units of the device proposed to be used for the testing, the hypothesis for and objective of the testing, the period of time during which the testing will be carried out and a copy of the patient consent form;

**(j)** a copy of the device label; and

**(k)** a written undertaking from each qualified investigator to

**(i)** conduct the investigational testing in accordance with the protocol provided by the manufacturer,

**(ii)** inform a patient who is to be diagnosed or treated using the device of any risks and benefits associated with its use, and obtain the patient's written consent for its use,

**(iii)** not use the device or permit it to be used for any purpose other than the investigational testing specified in the protocol,

**e)** la liste des pays étrangers où il a été vendu, le nombre total d'unités vendues dans ces pays et un sommaire des problèmes signalés et des rappels effectués dans ces pays;

**f)** l'appréciation du risque qui consiste en une analyse et une évaluation des risques, ainsi que les mesures de réduction des risques adoptées aux fins de l'essai expérimental, y compris, le cas échéant :

**(i)** les résultats de toute recherche, de tout essai et de toute étude antérieurs effectués relativement à l'instrument,

**(ii)** une description des méthodes actuelles de diagnostic et de traitement de l'état pathologique à l'égard duquel il est proposé d'effectuer l'essai expérimental,

**(iii)** les données sur les précautions, avertissements, contre-indications et effets nocifs possibles liés à l'utilisation de l'instrument;

**g)** le nom de tous les chercheurs compétents à qui il est proposé de vendre l'instrument et leurs qualifications professionnelles, notamment leur formation et leur expérience;

**h)** les nom et adresse de chaque établissement où il est proposé d'effectuer l'essai expérimental et, dans le cas d'un instrument de classe III ou IV, une autorisation écrite de l'établissement portant que l'essai peut y être effectué;

**i)** un protocole de l'essai expérimental, y compris le nombre d'unités de l'instrument qu'il est proposé d'utiliser, le but de l'essai et l'hypothèse sur laquelle il se fonde, la durée de l'essai, ainsi qu'une copie de la formule de consentement des patients;

**j)** un exemplaire de l'étiquette de l'instrument;

**k)** un engagement écrit de la part de chaque chercheur compétent portant :

**(i)** qu'il effectuera l'essai conformément au protocole d'essai fourni par le fabricant,

**(ii)** qu'il informera le patient qui doit faire l'objet du diagnostic ou du traitement au moyen de l'instrument des risques et des avantages liés à l'utilisation de l'instrument et obtiendra de celui-ci un consentement écrit relatif à son utilisation,

**(iii)** qu'il n'utilisera pas l'instrument ou n'en permettra pas l'utilisation à des fins autres que l'essai expérimental visé par le protocole,

**(iv)** not permit the device to be used by any other person except under the direction of the qualified investigator, and

**(v)** in the event of an incident involving the device and that meets the following conditions, report the incident and the circumstances surrounding it to the Minister and to the manufacturer or importer of the device within 72 hours after the qualified investigator becomes aware of the incident:

**(A)** the incident is related to a failure of the device or a deterioration in its effectiveness or any inadequacy in its labelling or in its directions for use, and

**(B)** the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person or could do so were the incident to recur.

SOR/2020-262, s. 20.

## Authorization

**82** An application for an authorization referred to in subsection 80(2) shall be made in writing to the Minister and shall contain

**(a)** in the case of a Class II medical device or a Class III or IV *in vitro* diagnostic device that is not used for patient management, not including a near-patient *in vitro* diagnostic device, the information set out in paragraphs 81(a), (b) and (h) to (j); and

**(b)** in the case of a Class III or IV medical device that is not covered by paragraph (a), the information and documents set out in section 81.

SOR/2002-190, s. 8.

**83 (1)** The Minister shall issue an authorization referred to in subsection 80(2) to a manufacturer or importer if the Minister determines that

**(a)** the device can be used for investigational testing without seriously endangering the life, health or safety of patients, users or other persons;

**(b)** the investigational testing is not contrary to the best interests of patients on whom the testing will be conducted; and

**(c)** the objective of the testing will be achieved.

**(2)** The authorization referred to subsection (1) shall specify

**(iv)** que l'instrument ne sera utilisé que par lui, ou par une personne sous sa supervision,

**(v)** qu'en cas d'un incident qui met en cause l'instrument, il signalera l'incident et les circonstances l'entourant au ministre, ainsi qu'au fabricant ou à l'importateur, dans les soixante-douze heures après en avoir eu connaissance, lorsque l'incident, à la fois :

**(A)** est lié à une défaillance de l'instrument, à une dégradation de son efficacité ou à un étiquetage ou un mode d'emploi défectueux,

**(B)** a entraîné la mort ou une détérioration grave de l'état de santé d'un patient, d'un utilisateur ou d'une autre personne, ou serait susceptible de le faire s'il se reproduisait.

DORS/2020-262, art. 20.

## Autorisation

**82** La demande relative à l'autorisation prévue au paragraphe 80(2) est présentée par écrit au ministre et contient :

**a)** dans le cas d'un instrument médical de classe II ou d'un instrument diagnostique *in vitro* de classe III ou IV qui n'est pas utilisé pour la gestion du patient, sauf un instrument diagnostique clinique *in vitro*, les renseignements visés aux alinéas 81a), b) et h) à j);

**b)** dans le cas de tout autre instrument de classe III ou IV, tous les renseignements et documents visés à l'article 81.

DORS/2002-190, art. 8.

**83 (1)** Le ministre délivre au fabricant ou à l'importateur l'autorisation visée au paragraphe 80(2) s'il détermine que les conditions suivantes sont réunies :

**a)** l'instrument peut être utilisé aux fins de l'essai expérimental sans présenter un risque grave pour la vie, la santé ou la sûreté des patients, utilisateurs ou autres personnes;

**b)** l'essai expérimental ne va pas à l'encontre de l'intérêt des patients en cause;

**c)** les objectifs de l'essai expérimental seront atteints.

**(2)** L'autorisation précise :

**a)** le nom des chercheurs compétents à qui l'instrument peut être vendu;

- (a)** the name of any qualified investigator to whom the device may be sold;
- (b)** the type of diagnosis or treatment for which the device may be sold;
- (c)** the number of units of the device that are authorized to be sold; and
- (d)** the protocol according to which the investigational testing is to be conducted.

## Additional Information

**84** If the information and documents submitted in respect of an application made pursuant to section 82 are insufficient to enable the Minister to determine whether the conditions set out in subsection 83(1) have been met, the manufacturer or importer shall, at the request of the Minister, submit any further information relevant to the application that the Minister may request.

**85 (1)** The Minister may, in respect of a medical device in relation to which investigational testing is being conducted, request the manufacturer or importer of the device to submit information in respect of the testing if the Minister believes on reasonable grounds, after reviewing a report or information brought to the Minister's attention, that one of the following conditions may exist:

- (a)** the testing seriously endangers the life, health or safety of patients, users or other persons;
- (b)** the testing is contrary to the best interests of patients on whom the testing is being conducted;
- (c)** the objective of the testing will not be achieved;
- (d)** the qualified investigator who is conducting the testing is not respecting the undertaking required by paragraph 81(k); or
- (e)** the information submitted in respect of the testing is false or misleading.

**(2)** If the information requested pursuant to subsection (1) is not submitted, or if it is submitted and the Minister determines after reviewing it that a condition identified in that subsection exists, the Minister may, by written notice giving reasons,

- (a)** in the case of a Class I device, direct the manufacturer or importer of the device to stop selling the device to any qualified investigator named in the notice; or

- b)** le type de diagnostic ou de traitement pour lequel l'instrument peut être vendu;
- c)** le nombre d'unités de l'instrument qui peuvent être vendues;
- d)** le protocole régissant l'essai expérimental.

## Renseignements complémentaires

**84** Lorsque les renseignements et documents contenus dans la demande d'autorisation sont insuffisants pour permettre au ministre de déterminer si les conditions visées au paragraphe 83(1) sont réunies, le fabricant ou l'importateur doit, à la demande du ministre, lui fournir des renseignements complémentaires.

**85 (1)** Le ministre peut demander au fabricant ou à l'importateur de l'instrument médical faisant l'objet d'un essai expérimental de lui fournir des renseignements concernant l'essai s'il a des motifs raisonnables de croire, à la suite de l'examen de tout rapport ou renseignement portés à sa connaissance, que l'une des situations suivantes peut exister :

- a)** l'essai présente un risque grave pour la vie, la santé ou la sûreté des patients, utilisateurs ou autres personnes;
- b)** l'essai va à l'encontre de l'intérêt des patients en cause;
- c)** les objectifs de l'essai ne seront pas atteints;
- d)** le chercheur compétent qui effectue l'essai ne respecte pas l'engagement visé à l'alinéa 81k);
- e)** les renseignements soumis concernant l'essai sont faux ou trompeurs.

**(2)** Si le fabricant ou l'importateur ne fournit pas les renseignements demandés ou, dans le cas où ceux-ci sont fournis, si le ministre détermine, à la suite de leur examen, que l'une des situations visées au paragraphe (1) existe, celui-ci peut, par avis motivé :

- a)** dans le cas d'un instrument médical de classe I, ordonner au fabricant ou à l'importateur d'en cesser la vente aux chercheurs compétents précisés dans l'avis;

**(b)** in the case of a Class II, III or IV device, cancel the authorization referred to in subsection 83(1), in whole or in part.

## Labelling

**86** No person shall import or sell a medical device for investigational testing unless the device has a label that sets out

- (a)** the name of the manufacturer;
- (b)** the name of the device;
- (c)** the statements “Investigational Device” and “Instrument de recherche”, or any other statement, in English and French, that conveys that meaning;
- (d)** the statements “To Be Used by Qualified Investigators Only” and “Réservé uniquement à l’usage de chercheurs compétents”, or any other statement, in English and French, that conveys that meaning; and
- (e)** in the case of an IVDD, the statements “The performance specifications of this device have not been established” and “Les spécifications de rendement de l’instrument n’ont pas été établies”, or any other statement, in English and French, that conveys that meaning.

## Advertising

**87** No person shall advertise a medical device that is the subject of investigational testing unless

- (a)** that person holds an authorization issued under subsection 83(1) to sell or import the device; and
- (b)** the advertisement clearly indicates that the device is the subject of investigational testing, and the purpose of the investigational testing.

## Other Requirements

**88** The requirements set out in the following provisions apply to medical devices to which this Part applies:

- (a)** sections 52 to 56 with respect to distribution records;
- (b)** sections 57 and 58 with respect to complaint handling;

**b)** dans le cas d’un instrument médical de classe II, III ou IV, annuler tout ou partie de l’autorisation délivrée en vertu du paragraphe 83(1).

## Étiquetage

**86** Il est interdit d’importer ou de vendre un instrument médical aux fins d’essais expérimentaux, sauf s’il est accompagné d’une étiquette qui porte les renseignements suivants :

- a)** le nom du fabricant;
- b)** le nom de l’instrument;
- c)** les mentions « Instrument de recherche » et « Investigational Device », ou toute mention équivalente, en français et en anglais;
- d)** les mentions « Réservé uniquement à l’usage de chercheurs compétents » et « To Be Used by Qualified Investigators Only », ou toute mention équivalente, en français et en anglais;
- e)** dans le cas d’un instrument diagnostique in vitro, les mentions « Les spécifications de rendement de l’instrument n’ont pas été établies » et « The performance specifications of this device have not been established », ou toute mention équivalente, en français et en anglais.

## Publicité

**87** Il est interdit à toute personne de faire la publicité d’un instrument médical faisant l’objet d’un essai expérimental, sauf si :

- a)** d’une part, la personne est titulaire d’une autorisation d’importation ou de vente de l’instrument délivrée en vertu du paragraphe 83(1);
- b)** d’autre part, la publicité précise clairement le fait que l’instrument fait l’objet d’un essai expérimental, et le but de celui-ci.

## Exigences supplémentaires

**88** Les exigences prévues aux dispositions ci-après s’appliquent aux instruments médicaux visés par la présente partie :

- a)** les articles 52 à 56 visant les registres de distribution;
- b)** les articles 57 et 58 visant les plaintes;

(c) sections 59 to 61.1 with respect to reports on incidents;

(d) sections 63 to 65.6 with respect to recalls; and

(e) sections 66 to 68 with respect to implant registration.

SOR/2002-190, s. 9; SOR/2020-262, s. 21; SOR/2024-136, s. 20.

**88.1** Subsections 61.2(2) and (3) and section 61.3 apply in respect of medical devices to which this Part applies except that the references to a holder of a therapeutic product authorization in those provisions shall be read as references to a holder of an authorization issued under subsection 83(1).

SOR/2020-262, s. 22.

c) les articles 59 à 61.1 visant les rapports d'incidents;

d) les articles 63 à 65.6 visant les rappels;

e) les articles 66 à 68 visant l'enregistrement des implants.

DORS/2002-190, art. 9; DORS/2020-262, art. 21; DORS/2024-136, art. 20.

## PART 4

# Export Certificates

**89 (1)** For the purposes of section 37 of the Act, Schedule 3 sets out the form to be used for an export certificate for medical devices.

**(2)** The export certificate shall be signed and dated by

(a) where the exporter of the device is a corporation,

(i) the exporter's senior executive officer in Canada,  
(ii) the exporter's senior regulatory officer in Canada, or

(iii) the authorized agent of the person referred to in subparagraph (i) or (ii); or

(b) where the exporter of the device is an individual,

(i) the exporter, or

(ii) the exporter's authorized agent.

**90** No person shall sign an export certificate that is false or misleading or that contains omissions that may affect its accuracy and completeness.

**91** The exporter of a device shall maintain, at their principal place of business in Canada, records that contain the completed export certificates and shall, when requested to do so by an inspector, submit the export certificates for examination.

**88.1** Les paragraphes 61.2(2) et (3) et l'article 61.3 s'appliquent à l'égard des instruments médicaux visés par la présente partie. Toutefois la mention du titulaire d'une autorisation relative à un produit thérapeutique dans ces dispositions vaut mention du titulaire d'une autorisation délivrée en vertu du paragraphe 83(1).

DORS/2020-262, art. 22.

## PARTIE 4

# Certificat d'exportation

**89 (1)** Pour l'application de l'article 37 de la Loi, le certificat d'exportation d'un instrument médical doit être en la forme établie à l'annexe 3.

**(2)** Il doit être signé et daté par l'une des personnes suivantes :

a) si l'exportateur de l'instrument est une personne morale :

(i) son premier dirigeant au Canada,

(ii) son directeur des affaires réglementaires au Canada,

(iii) le mandataire de la personne visée aux sous-alinéas (i) ou (ii);

b) si l'exportateur de l'instrument est une personne physique :

(i) l'exportateur lui-même,

(ii) son mandataire.

**90** Il est interdit de signer un certificat d'exportation qui est faux ou trompeur ou qui comporte des omissions qui peuvent avoir une incidence sur son exactitude et son intégrité.

**91** L'exportateur doit tenir, à son principal établissement au Canada, des dossiers où sont versés les certificats d'exportation remplis et, sur demande d'un inspecteur, lui soumettre ces certificats pour examen.

**92** The exporter of a device shall retain the export certificate for a period of not less than five years after the date of export.

## PART 5

# Transitional Provisions, Repeal and Coming into Force

## Transitional Provisions

**93** For the purposes of sections 94 and 95, *old regulations* means the *Medical Devices Regulations*, C.R.C., c. 871, and *Director* has the meaning assigned to it by those regulations.

**94 (1)** Subject to subsection (2), if an application for a notice of compliance has been submitted with respect to a medical device pursuant to Part V of the old regulations but has not been processed by the Director as of June 30, 1998, an application for a medical device licence shall be made pursuant to these Regulations.

**(2)** For the purposes of an application for a medical device licence, the information and documents required by paragraphs 32(2)(a) to (e), (3)(a) to (i) or (4)(a) to (o) are deemed to have been submitted if a notice of compliance with respect to the device had been issued under the old regulations.

**95 (1)** A medical device that, on June 30, 1998, is being sold in Canada pursuant to the old regulations is not required to be licensed until February 1, 1999, if,

**(a) in the case of a device that is subject to Part V of the old regulations, the manufacturer**

**(i) has a notice of compliance in respect of the device that is in effect on June 30, 1998, or**

**(ii) does not have a notice of compliance in respect of the device that is in effect on June 30, 1998, but has met, during the period beginning on October 8, 1982, and ending on March 31, 1983, the requirements for device notification pursuant to Part II of the old regulations in respect of the device; and**

**(b) in the case of a device that is not subject to Part V of the old regulations, the manufacturer has, by June 30, 1998, furnished the Director**

**92** L'exportateur doit conserver les certificats d'exportation pendant au moins cinq ans suivant la date d'exportation.

## PARTIE 5

# Dispositions transitoires, abrogation et entrée en vigueur

## Dispositions transitoires

**93 Pour l'application des articles 94 et 95, *ancien règlement* s'entend du Règlement sur les instruments médicaux, C.R.C., ch. 871, et *Directeur* s'entend au sens de ce règlement.**

**94 (1)** Si une demande d'avis de conformité à l'égard d'un instrument médical a été présentée conformément à la partie V de l'ancien règlement et que le Directeur n'en a pas terminé l'examen le 30 juin 1998, l'instrument doit quand même faire l'objet d'une demande d'homologation aux termes du présent règlement.

**(2)** Toutefois, aux fins de la demande d'homologation, les renseignements et documents exigés aux termes des alinéas 32(2)a) à e), (3)a) à i) ou (4)a) à o) sont réputés avoir été fournis si un avis de conformité à l'égard de l'instrument avait été délivré selon l'ancien règlement.

**95 (1)** Tout instrument médical en vente au Canada le 30 juin 1998 aux termes de l'ancien règlement n'a pas à être homologué avant le 1<sup>er</sup> février 1999 si :

**a) dans le cas d'un instrument visé par la partie V de l'ancien règlement, le fabricant :**

**(i) est titulaire d'un avis de conformité à l'égard de l'instrument qui est valide le 30 juin 1998,**

**(ii) n'est pas titulaire d'un tel avis de conformité, mais s'est conformé à la partie II de l'ancien règlement durant la période du 8 octobre 1982 au 31 mars 1983;**

**b) dans le cas d'un instrument qui n'est pas visé par la partie V de l'ancien règlement, le fabricant a remis au Directeur, au plus tard le**

with the notification required in subsection 24(1) of the old regulations in respect of the device.

(2) If an initial application for licensing of a medical device that is referred to in subsection (1) is submitted before February 1, 1999, the information and documents required by paragraphs 32(2)(a) to (e), (3)(a) to (i) or (4)(a) to (o) are deemed to have been submitted if

(a) in the case of a device that is subject to Part V of the old regulations, the manufacturer

(i) has a notice of compliance in respect of the device that is in effect on June 30, 1998, or

(ii) does not have a notice of compliance that is in effect on June 30, 1998, in respect of the device, but has met, during the period beginning on October 8, 1982, and ending on March 31, 1983, the requirements for device notification pursuant to Part II of the old regulations in respect of the device;

(b) in the case of a device that is not subject to Part V of the old regulations, the manufacturer has, by June 30, 1998, furnished the Director with the notification required in subsection 24(1) of the old regulations in respect of the device.

(3) Subsections (1) and (2) cease to apply in respect of a medical device if a change described in section 34 is made in respect of the device or if the notice of compliance is suspended or cancelled under section 40 of the old regulations.

(4) For the purposes of this section, a notice of compliance may be suspended or cancelled under section 40 of the old regulations as if that section were still in force.

## Repeal

### 96 [Repeal]

## Coming into Force

**97 (1)** Subject to subsections (2) to (5), these Regulations come into force on July 1, 1998.

**(2)** Section 32, except paragraphs (2)(f), (3)(j) and (4)(p), comes into force

30 juin 1998, la déclaration visée au paragraphe 24(1) de l'ancien règlement à l'égard de l'instrument.

(2) Lorsque la première demande d'homologation à l'égard d'un instrument médical visé au paragraphe (1) est présentée avant le 1<sup>er</sup> février 1999, les renseignements et documents exigés aux termes des alinéas 32(2)a) à e), (3)a) à i) ou (4)a) à o) sont réputés avoir été fournis si :

a) dans le cas d'un instrument visé par la partie V de l'ancien règlement, le fabricant :

(i) est titulaire d'un avis de conformité à l'égard de l'instrument qui est valide le 30 juin 1998,

(ii) n'est pas titulaire d'un tel avis de conformité, mais s'est conformé à la partie II de l'ancien règlement durant la période du 8 octobre 1982 au 31 mars 1983;

b) dans le cas d'un instrument qui n'est pas visé par la partie V de l'ancien règlement, le fabricant a remis au Directeur, au plus tard le 30 juin 1998, la déclaration visée au paragraphe 24(1) de l'ancien règlement à l'égard de l'instrument.

(3) Les paragraphes (1) et (2) cessent de s'appliquer à l'égard de l'instrument médical si celui-ci fait l'objet d'une modification visée à l'article 34 ou si l'avis de conformité est suspendu ou annulé en vertu de l'article 40 de l'ancien règlement.

(4) Pour l'application du présent article, tout avis de conformité peut être suspendu ou annulé en vertu de l'article 40 de l'ancien règlement comme si cet article était encore en vigueur.

## Abrogation

### 96 [Abrogation]

## Entrée en vigueur

**97 (1)** Sous réserve des paragraphes (2) à (5), le présent règlement entre en vigueur le 1<sup>er</sup> juillet 1998.

**(2)** L'article 32, à l'exception des alinéas (2)f), (3)j) et (4)p), entre en vigueur :

- (a) in the case of a medical device referred to in section 94 or 95, on September 1, 1998;**
- (b) in the case of any other medical device, on July 1, 1998.**
- (3) Paragraphs 32(2)(f), (3)(j) and (4)(p) come into force on January 1, 2003.**
- (4) Sections 43 and 44 come into force on January 1, 1999.**
- (5) Sections 45 to 51 come into force on November 1, 1998.**

SOR/2001-217, s. 1.

- a) dans le cas des instruments médicaux visés aux articles 94 et 95, le 1<sup>er</sup> septembre 1998;**
- b) dans le cas de tout autre instrument médical, le 1<sup>er</sup> juillet 1998.**
- (3) Les alinéas 32(2)f), (3)j) et (4)p) entrent en vigueur le 1<sup>er</sup> janvier 2003.**
- (4) Les articles 43 et 44 entrent en vigueur le 1<sup>er</sup> janvier 1999.**
- (5) Les articles 45 à 51 entrent en vigueur le 1<sup>er</sup> novembre 1998.**

DORS/2001-217, art. 1.

## SCHEDULE 1

(Section 6)

# Classification Rules for Medical Devices

## PART 1

### Medical Devices other than in Vitro Diagnostic Devices

#### Invasive Devices

*Rule 1:*

**(1)** Subject to subrules (2) and (3), all surgically invasive devices are classified as Class II.

**(2)** A surgically invasive device that is intended to diagnose, monitor, control or correct a defect of the central cardiovascular system or the central nervous system or of a fetus in utero is classified as Class IV.

**(3)** A surgically invasive device that is intended to be absorbed by the body, or that is normally intended to remain in the body for at least 30 consecutive days, is classified as Class III.

*Rule 2:*

**(1)** Subject to subrules (2) to (4), all invasive devices that penetrate the body through a body orifice or that come into contact with the surface of the eye are classified as Class II.

**(2)** A device described in subrule (1) that is intended to be placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the ear drum is classified as Class I.

**(3)** A device described in subrule (1) that is normally intended to remain in the body or in contact with the surface of the eye for at least 30 consecutive days is classified as Class III.

**(4)** A device described in subrule (1) that is intended to be represented as preventing the transmission of infectious agents during sexual activities or reducing the risk thereof is classified as Class III.

## ANNEXE 1

(article 6)

# Règles de classification des instruments médicaux

## PARTIE 1

### Instruments médicaux autres que les instruments diagnostiques in vitro

#### Instruments effractifs

*Règle 1*

**(1)** Sous réserve des paragraphes (2) et (3), les instruments effractifs chirurgicaux sont classés dans la classe II.

**(2)** Ils sont classés dans la classe IV s'ils sont destinés à diagnostiquer, surveiller, contrôler ou corriger un défaut du système cardiovasculaire central, du système nerveux central ou d'un foetus dans l'utérus.

**(3)** Ils sont classés dans la classe III s'ils sont habituellement destinés à demeurer dans le corps pendant au moins 30 jours consécutifs ou s'ils sont absorbés par celui-ci.

*Règle 2*

**(1)** Sous réserve des paragraphes (2) à (4), les instruments effractifs qui pénètrent dans le corps par un de ses orifices ou qui entrent en contact avec la surface de l'œil sont classés dans la classe II.

**(2)** Ils sont classés dans la classe I s'ils sont destinés à être placés dans les cavités buccale ou nasale jusqu'au pharynx ou dans le canal auditif jusqu'au tympan.

**(3)** Ils sont classés dans la classe III s'ils sont habituellement destinés à demeurer dans le corps ou en contact avec la surface de l'œil pendant au moins 30 jours consécutifs.

**(4)** Ils sont classés dans la classe III s'ils sont destinés à être présentés comme prévenant ou réduisant la transmission d'agents infectieux dans le cadre d'activités sexuelles.

*Rule 3:*

Despite rules 1 and 2

- (a)** all denture materials and orthodontic appliances, and their accessories, are classified as Class II;
- (b)** all surgical or dental instruments are classified as Class I; and
- (c)** all latex condoms are classified as Class II.

## Non-invasive Devices

*Rule 4:*

**(1)** Subject to subrule (2), all non-invasive devices that are intended to come into contact with injured skin are classified as Class II.

**(2)** A device described in subrule (1) that is intended to be used as a mechanical barrier, for compression or for absorption of exudations, is classified as Class I.

*Rule 5:*

A non-invasive device intended for channelling or storing gases, liquids, tissues or body fluids for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class II.

*Rule 6:*

**(1)** Subject to subrules (2) and (3), a non-invasive device intended for modifying the biological or chemical composition of blood or other body fluids, or liquids, for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class III.

**(2)** A device described in subrule (1) whose characteristics are such that the modification process may introduce a foreign substance into the body that is potentially hazardous, taking into account the nature and quantity of the substance, is classified as Class IV.

**(3)** A device described in subrule (1) that accomplishes the modification by centrifugation, gravity filtration or the exchange of gas or heat is classified as Class II.

*Rule 7:*

**(1)** Subject to subrule (2), all other non-invasive devices are classified as Class I.

**(2)** A device described in subrule (1) is classified as Class II if it is intended

- (a)** to act as a calibrator, tester or quality control support to another medical device; or
- (b)** to be connected to an active device that is classified as Class II, III or IV.

*Règle 3*

Malgré les règles 1 et 2 :

- a)** les produits dentaires et les appareils orthodontiques, ainsi que leurs accessoires, sont classés dans la classe II;
- b)** les instruments chirurgicaux ou dentaires sont classés dans la classe I;
- c)** les condoms en latex sont classés dans la classe II.

## Instruments non effractifs

*Règle 4*

**(1)** Sous réserve du paragraphe (2), les instruments non effractifs destinés à entrer en contact avec une peau lésée sont classés dans la classe II.

**(2)** Ils sont classés dans la classe I s'ils sont destinés à servir de barrière mécanique ou aux fins d'absorption des exsudats ou de compression.

*Règle 5*

Les instruments non effractifs destinés à acheminer ou à stocker des gaz, liquides ou tissus, ou des fluides de l'organisme, aux fins d'introduction dans le corps par perfusion ou autre administration sont classés dans la classe II.

*Règle 6*

**(1)** Sous réserve des paragraphes (2) et (3), les instruments non effractifs destinés à modifier la composition biologique ou chimique du sang ou de tout autre fluide de l'organisme, ou d'un liquide, aux fins d'introduction dans le corps par perfusion ou autre administration sont classés dans la classe III.

**(2)** Ils sont classés dans la classe IV si leurs caractéristiques sont telles que le processus de modification peut introduire dans le corps une substance étrangère potentiellement dangereuse, compte tenu de sa nature et de sa quantité.

**(3)** Ils sont classés dans la classe II si la modification s'effectue par centrifugation ou filtration par gravité, ou par échange de gaz ou de chaleur.

*Règle 7*

**(1)** Sous réserve du paragraphe (2), les autres instruments non effractifs sont classés dans la classe I.

**(2)** Ils sont classés dans la classe II s'ils sont destinés, selon le cas :

- a)** à servir de dispositifs d'étalonnage, d'essai ou de soutien au contrôle de la qualité d'un autre instrument médical;

## Active Devices

### Rule 8:

**(1)** Subject to subrules (2) and (3), an active device intended to emit ionizing radiation, including any device or software intended to control or monitor such a device or directly influence its performance, is classified as Class III.

**(2)** A device described in subrule (1) that is intended to be used in radiographic mode is classified as Class II.

**(3)** Despite subrule (2), an active device that is intended to be used for mammographies is classified as Class III.

### Rule 9:

**(1)** Subject to subrules (2) and (3), an active therapeutic device, including any dedicated software, intended to be used to administer or withdraw energy to or from the body is classified as Class II.

**(2)** If the administration or withdrawal by a device described in subrule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the intensity of the energy and the part of the body concerned, the device is classified as Class III.

**(3)** A device described in subrule (2) that is intended to control the treatment of a patient's condition through a closed loop system is classified as Class IV.

### Rule 10:

**(1)** Subject to subrule (2), an active diagnostic device, including any dedicated software, that supplies energy for the purpose of imaging or monitoring physiological processes is classified as Class II.

**(2)** A device described in subrule (1) that is intended to be used to monitor, assess or diagnose a disease, a disorder, an abnormal physical state or a pregnancy, if erroneous readings could result in immediate danger, is classified as Class III.

### Rule 11:

**(1)** Subject to subrules (2) and (3), an active device, including any dedicated software, intended to administer drugs, body fluids or other substances to the body or withdraw them from the body is classified as Class II.

**(2)** If the administration or withdrawal by a device described in subrule (1) is potentially hazardous, taking

**b)** à être connectés à un instrument actif de classe II, III ou IV.

## Instruments actifs

### Règle 8

**(1)** Sous réserve des paragraphes (2) et (3), les instruments actifs destinés à émettre des rayonnements ionisants, y compris tout instrument ou logiciel qui est destiné à commander ou à surveiller de tels instruments ou à influer directement sur leur rendement, sont classés dans la classe III.

**(2)** Ils sont classés dans la classe II s'ils sont destinés à effectuer des radiographies.

**(3)** Malgré le paragraphe (2), ils sont classés dans la classe III s'ils sont destinés à effectuer des mammographies.

### Règle 9

**(1)** Sous réserve des paragraphes (2) et (3), les instruments thérapeutiques actifs, y compris leurs logiciels spécialisés, destinés à transmettre de l'énergie au corps ou à en retirer de celui-ci sont classés dans la classe II.

**(2)** Ils sont classés dans la classe III si la transmission ou le retrait est susceptible de présenter un danger, compte tenu de la nature de la transmission ou du retrait, de l'intensité de l'énergie et de la partie du corps en cause.

**(3)** Les instruments visés au paragraphe (2) sont toutefois classés dans la classe IV s'ils sont destinés à contrôler le traitement de l'état du patient à l'aide d'un système à boucle fermée.

### Règle 10

**(1)** Sous réserve du paragraphe (2), les instruments diagnostiques actifs, y compris leurs logiciels spécialisés, qui fournissent de l'énergie aux fins de l'imagerie ou la surveillance de processus physiologiques sont classés dans la classe II.

**(2)** Ils sont classés dans la classe III s'ils sont destinés à surveiller, évaluer ou diagnostiquer une maladie, un désordre, un état physique anormal ou une grossesse et qu'une lecture erronée est susceptible de présenter un danger immédiat.

### Règle 11

**(1)** Sous réserve des paragraphes (2) et (3), les instruments actifs, y compris leurs logiciels spécialisés, destinés à administrer des drogues, des fluides de l'organisme ou toute autre substance au corps ou à les retirer de celui-ci sont classés dans la classe II.

**(2)** Ils sont classés dans la classe III si l'administration ou le retrait est susceptible de présenter un danger,

into account the nature of the administration or withdrawal, the nature of the substance involved and the part of the body concerned, the device is classified as Class III.

**(3)** A device described in subrule (2) that is intended to control the treatment of a patient's condition through a closed loop system is classified as Class IV.

*Rule 12:*

Any other active device is classified as Class I.

## Special Rules

*Rule 13:*

A medical device that is intended to be used for

- (a)** disinfecting or sterilizing blood, tissues or organs that are intended for transfusion or transplantation is classified as Class IV; and
- (b)** disinfecting or sterilizing a medical device is classified as Class II.

*Rule 14:*

**(1)** Subject to subrule (2), the following medical devices are classified as Class IV:

- (a)** a medical device that is manufactured from or that incorporates human or animal cells or tissues or their derivatives; and
- (b)** a medical device that is manufactured from or that incorporates a product produced through the use of recombinant DNA technology.

**(2)** A device described in subrule (1) that is intended to come into contact with intact skin only is classified as Class I.

*Rule 15:*

Any medical device that is a material intended to be sold to a health care professional or dispenser for the specific purpose of configuration or arrangement into a mould or shape to meet the needs of an individual is classified in the class that applies to the finished medical device.

*Rule 16:*

Despite rules 1 to 15, a medical device set out in column 1 of an item of the table to this rule is classified as the class set out in column 2 of that item.

compte tenu de la nature de l'administration ou du retrait, de la nature de la substance et de la partie du corps en cause.

**(3)** Les instruments visés au paragraphe (2) sont toutefois classés dans la classe IV s'ils sont destinés à contrôler le traitement de l'état du patient à l'aide d'un système à boucle fermée.

*Règle 12*

Les autres instruments actifs sont classés dans la classe I.

## Règles particulières

*Règle 13*

Les instruments médicaux qui sont destinés à :

- a)** désinfecter ou stériliser le sang, les tissus ou les organes destinés aux transfusions ou aux implantations sont classés dans la classe IV;
- b)** désinfecter ou stériliser un instrument médical sont classés dans la classe II.

*Règle 14*

**(1)** Sous réserve du paragraphe (2), les instruments médicaux ci-après sont classés dans la classe IV :

- a)** les instruments qui sont fabriqués avec des cellules ou des tissus, humains ou animaux, ou avec leurs dérivés, ou ceux qui contiennent de tels tissus, cellules ou dérivés;
- b)** les instruments qui sont fabriqués avec un produit élaboré au moyen de la technologie de recombinaison de l'ADN, ou ceux qui contiennent un tel produit.

**(2)** Ils sont classés dans la classe I s'ils sont destinés à entrer en contact uniquement avec une peau intacte.

*Règle 15*

L'instrument médical qui est une matière destinée à être vendue à un professionnel de la santé ou à un préparateur pour adaptation ou façonnage au moyen d'un moule ou d'une forme en vue de répondre aux besoins d'une personne est classé dans la même classe que l'instrument médical fini.

*Règle 16*

Malgré les règles 1 à 15, les instruments médicaux visés à la colonne 1 du tableau de la présente règle sont classés dans la classe mentionnée à la colonne 2.

## TABLE

	Column 1	Column 2
Item	Medical device	Class
1	Breast implants	IV
2	Tissue expanders for breast reconstruction and augmentation	IV

## PART 2

# In Vitro Diagnostic Devices

## Use with respect to Transmissible Agents

### Rule 1:

An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, tissues or organs to assess their suitability for transfusion or transplantation is classified as Class IV.

### Rule 2:

An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent is classified as Class II, unless

**(a)** it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease if there is a risk of propagation in the Canadian population, in which case it is classified as Class IV; or

**(b)** it falls into one of the following categories, in which case it is classified as Class III:

**(i)** it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a serious disease where there is a risk of propagation in the Canadian population,

**(ii)** it is intended to be used to detect the presence of, or exposure to, a sexually transmitted agent,

**(iii)** it is intended to be used to detect the presence of an infectious agent in cerebrospinal fluid or blood, or

**(iv)** there is a risk that an erroneous result would cause death or severe disability to the individual being tested, or to the individual's offspring.

## TABLEAU

	Colonne 1	Colonne 2
Article	Instrument médical	Classe
1	Implants mammaires	IV
2	Prothèses utilisées pour la reconstruction ou l'augmentation du sein	IV

## PARTIE 2

# Instruments diagnostiques in vitro (IDIV)

## Usage à l'égard d'agents transmissibles

### Règle 1

L'IDIV destiné à être utilisé pour détecter la présence d'un agent transmissible dans le sang, y compris ses composantes ou ses dérivés, les tissus ou les organes, ou leur exposition à un tel agent, afin de déterminer s'ils se prêtent aux transfusions ou aux transplantations est classé dans la classe IV.

### Règle 2

L'IDIV destiné à être utilisé pour détecter la présence d'un agent transmissible, ou l'exposition à un tel agent, est classé dans la classe II, sauf dans les cas suivants :

**a)** il est destiné à être utilisé pour détecter la présence d'un agent transmissible qui cause une maladie pouvant provoquer la mort, ou l'exposition à un tel agent, lorsqu'il y a risque de propagation dans la population canadienne, auquel cas il est classé dans la classe IV;

**b)** il appartient à l'une ou l'autre des catégories suivantes, auquel cas il est classé dans la classe III :

**(i)** il est destiné à être utilisé pour détecter la présence d'un agent transmissible qui provoque une maladie grave, ou l'exposition à un tel agent, lorsqu'il y a risque de propagation dans la population canadienne,

**(ii)** il est destiné à être utilisé pour détecter la présence d'un agent transmissible sexuellement, ou l'exposition à un tel agent,

**(iii)** il est destiné à être utilisé pour détecter la présence d'un agent infectieux dans le liquide céphalorachidien ou dans le sang,

**(iv)** un résultat erroné risque d'entraîner la mort ou une incapacité grave de la personne en cause, ou de sa progéniture.

#### Rule 3:

An IVDD that is intended to be used for patient management is classified as Class II, unless it falls into one of the following categories, in which case it is classified as Class III:

- (a) it is intended to be used for the management of patients suffering from a life-threatening disease; or
- (b) there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient.

## Other Uses

#### Rule 4:

An IVDD that is not subject to rules 1 to 3 and that is intended to be used in diagnosis or patient management is classified as Class II, unless it falls into one of the following categories, in which case it is classified as Class III:

- (a) it is intended to be used in screening for or in the diagnosis of cancer;
- (b) it is intended to be used for genetic testing;
- (c) it is intended to be used in screening for congenital disorders in the fetus;
- (d) there is a risk that an erroneous diagnostic result would cause death or severe disability to the patient being tested or to that patient's offspring;
- (e) it is intended to be used for disease staging; or
- (f) it is intended to be used to monitor levels of drugs, substances or biological components, if there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient.

#### Rule 5:

An IVDD that is intended to be used for blood grouping or tissue typing to ensure the immunological compatibility of blood, blood components, tissue or organs that are intended for transfusion or transplantation is classified as Class III.

## Special Rules

#### Rule 6:

A near patient IVDD is classified as Class III.

#### Règle 3

L'IDIV destiné à être utilisé aux fins de la conduite du traitement d'un patient est classé dans la classe II, sauf s'il appartient à l'une ou l'autre des catégories suivantes, auquel cas il est classé dans la classe III :

- a) il est destiné à être utilisé pour la conduite du traitement d'un patient qui souffre d'une maladie pouvant causer la mort;
- b) un résultat erroné risque de donner lieu à une décision sur le traitement du patient qui entraîne une situation pouvant causer sa mort imminente.

## Autres utilisations

#### Règle 4

L'IDIV qui n'est pas visé aux règles 1 à 3 et qui est destiné à être utilisé pour le diagnostic ou la conduite du traitement d'un patient est classé dans la classe II, sauf s'il appartient à l'une ou l'autre des catégories suivantes, auquel cas il est classé dans la classe III :

- a) il est destiné à être utilisé pour le dépistage ou le diagnostic du cancer;
- b) il est destiné à être utilisé pour des tests génétiques;
- c) il est destiné à être utilisé pour le dépistage d'affections congénitales du fœtus;
- d) un résultat diagnostique erroné risque d'entraîner la mort ou une incapacité grave du patient ou de sa progéniture;
- e) il est destiné à être utilisé pour la stadiification de la maladie;
- f) il est destiné à être utilisé pour surveiller des concentrations de drogues, de substances ou de composantes biologiques, lorsqu'un résultat erroné risque de donner lieu à une décision sur le traitement du patient qui entraîne une situation pouvant causer sa mort imminente.

#### Règle 5

L'IDIV destiné à être utilisé pour le typage du sang ou des tissus afin d'assurer la compatibilité immunologique du sang, y compris ses composantes, des tissus ou des organes destinés à la transfusion ou à la transplantation est classé dans la classe III.

## Règles particulières

#### Règle 6

L'instrument diagnostique clinique in vitro est classé dans la classe III.

*Rule 7:*

In cases where an IVDD, including its analyzers, reagents and software, is intended to be used with another IVDD, the class of both IVDDs will be that of the IVDD in the class representing the higher risk.

*Rule 8:*

If rules 1 to 7 do not apply, all other IVDDs are classified as Class I.

*Rule 9:*

Despite rules 1 to 8, an IVDD set out in column 1 of an item of the table to this rule is classified as the class set out in column 2 of that item.

**TABLE**

Item	Column 1 IVDD	Column 2 Class
1	Near patient <i>in vitro</i> diagnostic device for the detection of pregnancy or for fertility testing	II
2	Near patient <i>in vitro</i> diagnostic device for determining cholesterol level	II
3	Microbiological media used to identify or infer the identity of a microorganism	I
4	IVDD used to identify or infer the identity of a cultured microorganism	I

SOR/2007-119, s. 1.

*Règle 7*

Si un IDIV d'une classe donnée, y compris ses analyseurs, réactifs et logiciels, est destiné à être utilisé avec un IDIV d'une autre classe, les deux instruments sont classés dans celle des deux classes présentant le risque le plus élevé.

*Règle 8*

Si aucune des règles 1 à 7 ne s'appliquent, l'IDIV est classé dans la classe I.

*Règle 9*

Malgré les règles 1 à 8, les IDIV visés à la colonne 1 du tableau de la présente règle sont classés dans la classe mentionnée à la colonne 2.

**TABLEAU**

Article	Colonne 1 IDIV	Colonne 2 Classe
1	Instrument diagnostique clinique <i>in vitro</i> destiné à la détection des grossesses ou aux tests de fertilité	II
2	Instrument diagnostique clinique <i>in vitro</i> pour déterminer le niveau de cholestérol	II
3	Milieu microbiologique utilisé pour identifier un micro-organisme ou en déduire l'identité	I
4	IDIV destiné à être utilisé pour identifier un micro-organisme cultivé ou en déduire l'identité	I

DORS/2007-119, art. 1.

## **SCHEDULE 2**

(Section 1)

### **Implants**

- 1** Heart valve
- 2** Annuloplasty ring
- 3** Active implantable device systems
  - (a)** all models of implantable pacemakers and leads;
  - (b)** all models of implantable defibrillators and leads;
  - (c)** artificial heart;
  - (d)** implantable ventricular support system; and
  - (e)** implantable drug infusion system
- 4** Devices of human origin
  - (a)** human dura mater; and
  - (b)** wound covering containing human cells

SOR/2022-197, s. 13(F).

## **ANNEXE 2**

(article 1)

### **Implants**

- 1** Valvule cardiaque.
- 2** Anneau pour annuloplastie.
- 3** Instruments implantables actifs suivants :
  - a)** tous les modèles de stimulateurs cardiaques implantables et d'électrodes;
  - b)** tous les modèles de défibrillateurs implantables et d'électrodes;
  - c)** cœur artificiel;
  - d)** système d'assistance ventriculaire implantable;
  - e)** système implantable pour la perfusion de médicaments.
- 4** Instruments d'origine humaine suivants :
  - a)** dure-mère humaine;
  - b)** pansement contenant des cellules humaines.

DORS/2022-197, art. 13(F).

## SCHEDULE 3

(Section 89)

# Export Certificate for Medical Devices

UNDER THE *Medical Devices Regulations*

I, \_\_\_\_\_, certify that I have knowledge of all matters contained in this certificate and that

**1** I am (*check applicable box*)

**(a)** where the medical device described in this certificate is exported by a corporation

- the exporter's senior executive officer,
  - the exporter's senior regulatory officer,
  - the authorized agent of the exporter's senior executive officer, or
  - the authorized agent of the exporter's senior regulatory officer; and
- (b)** where the medical device described in this certificate is exported by an individual
- the exporter, or
  - the exporter's authorized agent.

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\_\_\_\_\_, (*State name and address of exporter or, if a corporation, name and address of principal place of business in Canada*).

**2** On the \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_, a package containing \_\_\_\_\_ (*description of device, including serial number, model name, lot number and quantity, as applicable; if additional space required, attach as Appendix "A"*) is/will be consigned to \_\_\_\_\_ (*name and address of consignee*).

**3** The package is marked in distinct overprinting with the word "Export" or "Exportation".

**4** The medical device was not manufactured for consumption in Canada.

**5** The medical device is not sold for consumption in Canada.

## ANNEXE 3

(article 89)

# Certificat d'exportation pour instruments médicaux

SOUS LE RÉGIME DU *Règlement sur les instruments médicaux*

Je soussigné, \_\_\_\_\_, atteste ce qui suit :

**1** Je suis (*cocher la case appropriée*) :

**a)** dans le cas où l'instrument médical décrit ci-après est exporté par une personne morale :

- le premier dirigeant de l'exportateur
  - le directeur des affaires réglementaires de l'exportateur
  - le mandataire du premier dirigeant de l'exportateur
  - le mandataire du directeur des affaires réglementaires de l'exportateur
- b)** dans le cas où l'instrument décrit ci-après est exporté par une personne physique :
- l'exportateur
  - le mandataire de l'exportateur

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\_\_\_\_\_, (*indiquer les nom et adresse de l'exportateur; dans le cas d'une personne morale, indiquer les nom et adresse du principal établissement au Canada*) et je connais tous les détails contenus dans le présent certificat.

**2** Le \_\_\_\_\_ (*date : jour, mois, année*), un emballage contenant \_\_\_\_\_ (*description de l'instrument, y compris n° de série, modèle, n° de lot et quantité, selon le cas. Si l'espace est insuffisant, annexer un appendice A*) est/sera expédié à \_\_\_\_\_ (*nom et adresse du destinataire*).

**3** L'emballage porte clairement en surimpression le mot « Exportation » ou « Export ».

**4** L'instrument n'a pas été fabriqué pour la consommation au Canada.

**5** L'instrument n'est pas vendu pour la consommation au Canada.

**6** The package and its contents do not contravene any known requirement of the law of the country of \_\_\_\_\_ (*state country of consignee*).

**7** All relevant information is contained in this certificate and no relevant information has been knowingly withheld.

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Signature

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Position title

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Date

**6** L'emballage et son contenu n'enfreignent aucune règle de droit connue de \_\_\_\_\_ (*inscrire le nom du pays du destinataire*).

**7** Tous les renseignements pertinents sont consignés au présent certificat et aucun renseignement utile n'en a été sciemment omis.

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Signature

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Titre du poste

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Date

## RELATED PROVISIONS

— SOR/2003-173, s. 6

**6** The manufacturer of a medical device for which a medical device licence has been issued before the coming into force of these Regulations shall, before November 1, 2003, submit to the Minister, together with the statement required by subsection 43(1) of the *Medical Devices Regulations*, a copy of the quality system certificate referred to in paragraph 32(2)(f), (3)(j) or (4)(p) of those Regulations, as applicable.]

— SOR/2019-63, s. 2

**2 (1)** Despite subsection 43.12(1) of the *Medical Devices Regulations*, *information in respect of a clinical study or investigational testing*, as defined in section 43.11 of those Regulations, that is confidential business information and that is contained in an application with respect to which one of the following circumstances occurred before the day on which these Regulations come into force ceases to be confidential business information on the day on which these Regulations come into force:

- (a)** the Minister issued a licence under paragraph 36(1)(a) of the *Medical Devices Regulations*;
- (b)** the Minister amended a licence under paragraph 36(1)(b) of the *Medical Devices Regulations*;
- (c)** the Minister refused to issue or amend a licence under section 38 of the *Medical Devices Regulations*.

**(2)** Subsection (1) does not apply to information referred to in subsection 43.12(2) of the *Medical Devices Regulations*.

— SOR/2021-199, s. 10

**10 (1)** In this section and in sections 11 to 15, ***Exceptional Importation and Shortages Interim Order No. 2*** means the *Interim Order No. 2 Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19*, made by the Minister of Health on March 1, 2021 and published in Part I of the *Canada Gazette* on March 20, 2021.

## DISPOSITIONS CONNEXES

— DORS/2003-173, art. 6

**6** Le fabricant qui obtient l'homologation de son instrument médical avant l'entrée en vigueur du présent règlement doit, avant le 1<sup>er</sup> novembre 2003, fournir au ministre, avec sa déclaration faite aux termes du paragraphe 43(1) du *Règlement sur les instruments médicaux*, une copie du certificat de système qualité visé aux alinéas 32(2)f, (3)j ou (4)p) de ce règlement, selon le cas.

— DORS/2019-63, art. 2

**2 (1)** Malgré le paragraphe 43.12(1) du *Règlement sur les instruments médicaux*, les *renseignements relatifs à une étude clinique ou un essai expérimental*, au sens de l'article 43.11 de ce règlement, qui sont des renseignements commerciaux confidentiels et qui sont contenus dans une demande relativement à laquelle l'une des circonstances ci-après est survenue avant la date d'entrée en vigueur du présent règlement cessent d'être des renseignements commerciaux confidentiels à la date d'entrée en vigueur du présent règlement :

- a)** le ministre a délivré une homologation en application de l'alinéa 36(1)a) du *Règlement sur les instruments médicaux*;
- b)** le ministre a modifié une homologation en application de l'alinéa 36(1)b) du *Règlement sur les instruments médicaux*;
- c)** le ministre a refusé de délivrer ou de modifier une homologation en vertu de l'article 38 du *Règlement sur les instruments médicaux*.

**(2)** Le paragraphe (1) ne s'applique pas aux renseignements visés au paragraphe 43.12(2) du *Règlement sur les instruments médicaux*.

— DORS/2021-199, art. 10

**10 (1)** Au présent article et aux articles 11 à 15, ***Arrêté d'urgence n° 2 sur les importations exceptionnelles et les pénuries*** s'entend de l'*Arrêté d'urgence n° 2 concernant les drogues, les instruments médicaux et les aliments à des fins diététiques spéciales dans le cadre de la COVID-19*, pris par la ministre de la Santé le 1<sup>er</sup> mars 2021 et publié dans la Partie I de la *Gazette du Canada* le 20 mars 2021.

**(2)** In sections 11 to 15, *designated biocide*, *designated drug*, *designated food for a special dietary purpose*, *designated hand sanitizer* and *designated medical device* have the same meaning as in the Exceptional Importation and Shortages Interim Order No. 2.

— SOR/2021-199, s. 13

**13 (1)** Section 62.31 of the *Medical Devices Regulations* applies in respect of a designated medical device that was imported under the Exceptional Importation and Shortages Interim Order No. 2.

**(2)** Section 62.32 of those Regulations applies to the holder of an establishment licence in respect of a designated medical device that they imported under that Interim Order.

— SOR/2021-199, s. 15

**15** A person who, immediately before the Exceptional Importation and Shortages Interim Order No. 2 ceased to have effect, was permitted, under subsection 30(2) of that Interim Order, to conduct an activity in respect of a designated hand sanitizer may continue to do so without holding an establishment licence that authorizes them to do so until the earliest of

**(a)** the occurrence of one of the circumstances referred to in paragraphs 30(2)(a) to (c) of that Interim Order, and

**(b)** September 1, 2023.

— SOR/2023-19, s. 10

**10 (1)** In sections 11 to 19, *Interim Order No. 3* means *Interim Order No. 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*, made by the Minister on February 21, 2022 and published in the *Canada Gazette*, Part I, on March 12, 2022.

**(2)** Unless the context requires otherwise, words and expressions used in sections 11 to 19 have the same meaning as in the *Medical Devices Regulations*.

**(3)** For the purposes of sections 11 to 19, a reference to “instrument médical destiné à être utilisé à l’égard de la COVID-19” in the French version of Interim Order No. 3 and the *List of Medical Devices for Expanded Use in Relation to the COVID-19 Pandemic* shall be read as “instrument médical contre la COVID-19”.

**(2)** Aux articles 11 à 15, *aliment à des fins diététiques spéciales* désigné, *biocide* désigné, *désinfectant pour les mains* désigné, *drogue* désignée et *instrument médical* désigné s’entendent au sens de l’Arrêté d’urgence n° 2 sur les importations exceptionnelles et les pénuries.

— DORS/2021-199, art. 13

**13 (1)** L’article 62.31 du *Règlement sur les instruments médicaux* s’applique à l’égard de l’instrument médical désigné importé en vertu de l’Arrêté d’urgence n° 2 sur les importations exceptionnelles et les pénuries.

**(2)** L’article 62.32 du même règlement s’applique au titulaire d’une licence d’établissement à l’égard de l’instrument médical désigné qu’il importe en vertu de cet arrêté d’urgence.

— DORS/2021-199, art. 15

**15** La personne qui, immédiatement avant que l’Arrêté d’urgence n° 2 sur les importations exceptionnelles et les pénuries ne cesse d’avoir effet, était autorisée par le paragraphe 30(2) de cet arrêté d’urgence à poursuivre l’exercice d’une activité à l’égard d’un désinfectant pour les mains désigné peut continuer à exercer l’activité sans être titulaire d’une licence d’établissement l’y autorisant jusqu’au premier des moments suivants à survenir :

**a)** le moment où survient l’un des événements visés aux alinéas 30(2)a) à c) de cet arrêté d’urgence;

**b)** le 1<sup>er</sup> septembre 2023.

— DORS/2023-19, art. 10

**10 (1)** Aux articles 11 à 19, *arrêté d’urgence n° 3* s’entend de l’Arrêté d’urgence n° 3 concernant l’importation et la vente d’instruments médicaux destinés à être utilisés à l’égard de la COVID-19, pris par le ministre le 21 février 2022 et publié dans la Partie I de la *Gazette du Canada* le 12 mars 2022.

**(2)** Sauf indication contraire du contexte, les mots et expressions employés dans les articles 11 à 19 ont la même signification que dans le *Règlement sur les instruments médicaux*.

**(3)** Pour l’application des articles 11 à 19, toute mention de « instrument médical destiné à être utilisé à l’égard de la COVID-19 » dans la version française de l’arrêté d’urgence n° 3 et dans la *Liste d’instruments médicaux destinés à un usage supplémentaire relativement à la pandémie de la COVID-19* vaut mention de « instrument médical contre la COVID-19 ».

— SOR/2023-19, s. 11

**11** Despite subsection 68.11(1) of the *Medical Devices Regulations*, an application for an authorization for importation or sale of a COVID-19 medical device that was submitted to the Minister under Interim Order No. 3 before the day on which these Regulations come into force and in respect of which no decision has been made before that day is deemed to be an application for an authorization submitted under section 68.11 of the *Medical Devices Regulations*.

— SOR/2023-19, s. 12

**12 (1)** An authorization for importation or sale of a COVID-19 medical device that was issued by the Minister under Interim Order No. 3 before the day on which these Regulations come into force and has not been cancelled before that day is deemed to be an authorization issued under section 68.12 of the *Medical Devices Regulations*.

**(2)** Any terms and conditions of an authorization for importation or sale referred to in subsection (1) are deemed to have been imposed by the Minister under section 68.19 of the *Medical Devices Regulations* on the other authorization referred to in that subsection.

— SOR/2023-19, s. 13

**13** A COVID-19 medical device for which the manufacturer of the device holds an authorization and that is not labelled in accordance with subsection 21(2) of the *Medical Devices Regulations* in the six-month period that begins on the day on which these Regulations come into force the device may, despite that subsection, be sold during that period.

— SOR/2023-19, s. 14

**14** Section 68.35 of the *Medical Devices Regulations* shall be read without reference to subsection 21(2) of those Regulations in regard to any portion of the period referred to in that section that falls within the period referred to in section 13.

— SOR/2023-19, s. 15

**15** An application to amend an authorization for importation or sale of a COVID-19 medical device that was submitted to the Minister under Interim Order No. 3 before the day on which these Regulations come into force and in respect of which no decision has been made before

— DORS/2023-19, art. 11

**11** Malgré le paragraphe 68.11(1) du *Règlement sur les instruments médicaux*, toute demande d'autorisation d'importation ou de vente d'un instrument médical contre la COVID-19 présentée auprès du ministre au titre de l'arrêté d'urgence n° 3 avant la date d'entrée en vigueur du présent règlement et à l'égard de laquelle aucune décision n'a été prise avant cette date est réputée être une demande d'autorisation présentée au titre de l'article 68.11 du *Règlement sur les instruments médicaux*.

— DORS/2023-19, art. 12

**12 (1)** Toute autorisation d'importation ou de vente d'un instrument médical contre la COVID-19 délivrée par le ministre au titre de l'arrêté d'urgence n° 3 avant la date d'entrée en vigueur du présent règlement et qui n'a pas été annulée avant cette date est réputée être une autorisation délivrée au titre de l'article 68.12 du *Règlement sur les instruments médicaux*.

**(2)** Toute condition assortie à une autorisation d'importation ou de vente visée au paragraphe (1) est réputée être une condition dont le ministre a assorti, au titre de l'article 68.19 du *Règlement sur les instruments médicaux*, l'autre autorisation visée à ce paragraphe.

— DORS/2023-19, art. 13

**13** S'agissant d'un instrument médical contre la COVID-19 pour lequel le fabricant est titulaire d'une autorisation et qui, dans les six mois suivant la date d'entrée en vigueur du présent règlement, n'est pas étiqueté conformément aux exigences du paragraphe 21(2) du *Règlement sur les instruments médicaux*, l'instrument peut, malgré ce paragraphe, être vendu pendant cette période.

— DORS/2023-19, art. 14

**14** L'article 68.35 du *Règlement sur les instruments médicaux* est interprété sans égard à toute mention du paragraphe 21(2) de ce même règlement concernant toute partie de la période visée à cet article qui est comprise dans la période visée à l'article 13.

— DORS/2023-19, art. 15

**15** Toute demande de modification d'autorisation d'importation ou de vente d'un instrument médical contre la COVID-19 présentée auprès du ministre au titre de l'arrêté d'urgence n° 3 avant la date d'entrée en vigueur du présent règlement et à l'égard de laquelle aucune décision n'a été prise avant cette date est réputée être une demande de modification d'autorisation présentée au titre

that day is deemed to be an application to amend an authorization submitted under section 68.14 of the *Medical Devices Regulations*.

— SOR/2023-19, s. 16

**16** An authorization for importation or sale of a COVID-19 medical device that was amended by the Minister under Interim Order No. 3 before the day on which these Regulations come into force and has not been cancelled before that day is deemed to be an authorization that is amended to the same extent under section 68.15 of the *Medical Devices Regulations*.

— SOR/2023-19, s. 17

**17** A request that was made by the Minister under Interim Order No. 3 before the day on which these Regulations come into force for additional information or material, including samples, is deemed to be a request for additional information or material under section 68.23 of the *Medical Devices Regulations*.

— SOR/2023-19, s. 18

**18 (1)** In the case of a COVID-19 medical device that is not a UPHN medical device on the day on which these Regulations come into force, a reference in subparagraphs 68.21(1)(h)(i), (i)(i) and (ii) and (j)(i) and (ii) of the *Medical Devices Regulations* to “the device ceases to be a UPHN medical device” shall be read as “the *Regulations Amending the Medical Devices Regulations (Interim Order No. 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19)* come into force”.

**(2)** Subsection (1) ceases to apply in respect of a COVID-19 medical device referred to in that subsection if the device becomes a UPHN medical device.

— SOR/2023-19, s. 19

**19** A request that was made by the Minister under Interim Order No. 3 before the day on which these Regulations come into force for information in relation to the expanded use of a COVID-19 medical device or another medical device set out in the *List of Medical Devices for Expanded Use in Relation to the COVID-19 Pandemic*, referred to in the definition *List of Medical Devices for Expanded Use* in subsection 1(1) of the Interim Order, is deemed to be a request for information in relation to the expanded use under subsection 68.38(1) or (2) of the *Medical Devices Regulations*, as the case may be.

de l'article 68.14 du *Règlement sur les instruments médicaux*.

— DORS/2023-19, art. 16

**16** Toute autorisation d'importation ou de vente d'un instrument médical contre la COVID-19 modifiée par le ministre au titre de l'arrêté d'urgence n° 3 avant la date d'entrée en vigueur du présent règlement et qui n'a pas été annulée avant cette date est réputée être une autorisation modifiée dans la même mesure au titre de l'article 68.15 du *Règlement sur les instruments médicaux*.

— DORS/2023-19, art. 17

**17** Toute demande faite par le ministre au titre de l'arrêté d'urgence n° 3 avant la date d'entrée en vigueur du présent règlement en vue d'obtenir des renseignements supplémentaires ou du matériel, notamment des échantillons, est réputée être une demande de renseignements supplémentaires ou de matériel au titre de l'article 68.23 du *Règlement sur les instruments médicaux*.

— DORS/2023-19, art. 18

**18 (1)** S'agissant d'un instrument médical contre la COVID-19 qui n'est pas un instrument médical BUSP à la date d'entrée en vigueur du présent règlement, la mention « l'instrument cesse d'être un instrument médical BUSP » aux sous-alinéas 68.21(1)h)(i), i)(i) et (ii) et j)(i) et (ii) du *Règlement sur les instruments médicaux* vaut mention de « le *Règlement modifiant le Règlement sur les instruments médicaux (Arrêté d'urgence n° 3 concernant l'importation et la vente d'instruments médicaux destinés à être utilisés à l'égard de la COVID-19)* entre en vigueur ».

**(2)** Le paragraphe (1) cesse de s'appliquer à l'égard d'un instrument médical contre la COVID-19 visé à ce paragraphe si l'instrument devient un instrument médical BUSP.

— DORS/2023-19, art. 19

**19** Toute demande faite par le ministre au titre de l'arrêté d'urgence n° 3 avant la date d'entrée en vigueur du présent règlement en vue d'obtenir des renseignements relatifs à l'usage élargi d'un instrument médical contre la COVID-19 ou d'un autre instrument médical figurant sur la *Liste d'instruments médicaux destinés à un usage supplémentaire relativement à la pandémie de la COVID-19* mentionnée dans la définition de *Liste d'instruments médicaux destinés à un usage élargi* au paragraphe 1(1) de l'arrêté d'urgence est réputée être une demande de renseignements relatifs à l'usage élargi au titre des

— SOR/2023-277, s. 27

**27 (1)** In this section, **authorization** has the same meaning as in section 68.01 of the *Medical Devices Regulations*.

**(2)** In respect of an authorization for a medical device that is issued before the day on which these Regulations come into force, paragraph 68.17(a) of the *Medical Devices Regulations* is to be read as follows:

**(a)** COVID-19;

**(3)** Section 68.17 of the *Medical Devices Regulations*, as it read immediately before the day on which these Regulations come into force, applies in respect of an application to amend an authorization that was submitted under section 68.14 of the *Medical Devices Regulations* before the day on which these Regulations come into force and in respect of which no decision has been made before that day.

— SOR/2024-136, s. 21

**21** Unless the context requires otherwise, the words and expressions used in sections 22 and 23 have the same meaning as in the *Medical Devices Regulations*.

— SOR/2024-136, s. 22

**22** A person who has submitted an application for an establishment licence under section 45 of the *Medical Devices Regulations* before the day on which section 7 comes into force and in respect of which no decision has been made before that day must not be issued the licence unless, by that day and in the form established by the Minister, the person provides the Minister with the information referred to in paragraph 45(b) of the *Medical Devices Regulations*, as amended by these Regulations.

— SOR/2024-136, s. 23

**23** The holder of an establishment licence that was issued under section 46 of the *Medical Devices Regulations* before the day on which section 7 comes into force must, by that day and in the form established by the Minister, provide the Minister with the contact information, other than the telephone number, of the representative of the establishment to contact for information concerning the licence.

paragraphes 68.38(1) ou (2) du *Règlement sur les instruments médicaux*.

— DORS/2023-277, art. 27

**27 (1)** Au présent article, **autorisation** s'entend au sens de l'article 68.01 du *Règlement sur les instruments médicaux*.

**(2)** Concernant toute autorisation pour un instrument médical délivrée avant la date d'entrée en vigueur du présent règlement, l'alinéa 68.17a) du *Règlement sur les instruments médicaux* est réputé avoir le libellé suivant :

**a)** la COVID-19;

**(3)** L'article 68.17 du *Règlement sur les instruments médicaux*, dans sa version antérieure à la date d'entrée en vigueur du présent règlement, s'applique à l'égard de toute demande de modification d'une autorisation présentée en vertu de l'article 68.14 de ce règlement avant la date d'entrée en vigueur du présent règlement et à l'égard de laquelle aucune décision n'a été prise avant cette date.

— DORS/2024-136, art. 21

**21** Sauf indication contraire, les termes utilisés aux articles 22 et 23 s'entendent au sens du *Règlement sur les instruments médicaux*.

— DORS/2024-136, art. 22

**22** La personne ayant présenté une demande de licence d'établissement en vertu de l'article 45 du *Règlement sur les instruments médicaux* avant la date d'entrée en vigueur de l'article 7 à l'égard de laquelle aucune décision n'a été prise avant cette date ne peut se voir délivrer la licence, à moins qu'elle ne fournisse au ministre, d'ici cette date et en la forme fixée par ce dernier, les renseignements visés à l'alinéa 45b) du *Règlement sur les instruments médicaux*, dans sa version modifiée par le présent règlement.

— DORS/2024-136, art. 23

**23** Le titulaire d'une licence d'établissement qui a été délivrée en vertu de l'article 46 du *Règlement sur les instruments médicaux* avant la date d'entrée en vigueur de l'article 7 fournit au ministre d'ici cette date et en la forme fixée par ce dernier, les coordonnées — autres que le numéro de téléphone — du représentant de l'établissement avec lequel communiquer pour obtenir tout renseignement concernant la licence.

# AMENDMENTS NOT IN FORCE

— SOR/2024-110, s. 83

**83** The *Medical Devices Regulations*<sup>2</sup> are amended by adding the following after section 2:

**2.1** For greater certainty, these Regulations apply to a medical device that is a drug referred to in paragraph (b) or (c) of the definition *biocide* in subsection 1(1) of the *Biocides Regulations*.

— SOR/2024-238, s. 41

**41** Subsections 36(2) to (4) of the *Medical Devices Regulations*<sup>2</sup> are replaced by the following:

**(2)** The Minister may, at any time, impose terms and conditions on a medical device licence or amend such terms and conditions after considering

- (a)** whether there are uncertainties relating to the benefits or risks associated with the device;
- (b)** whether the requirements under the Act are sufficient for the following objectives to be met:
  - (i)** maintaining the safety and effectiveness of the device,
  - (ii)** optimizing the benefits and managing the risks associated with the device, and
  - (iii)** identifying any changes relating to those benefits and risks and managing uncertainties related to the benefits and risks;
- (c)** whether the proposed terms and conditions may contribute to those objectives being met;
- (d)** whether compliance with the proposed terms and conditions is technically feasible; and
- (e)** whether there are less burdensome ways for those objectives to be met.

— SOR/2024-238, s. 42

**42** Section 37 of the Regulations is replaced by the following:

<sup>2</sup> SOR/98-282

# MODIFICATIONS NON EN VIGUEUR

— DORS/2024-110, art. 83

**83** Le *Règlement sur les instruments médicaux*<sup>2</sup> est modifié par adjonction, après l'article 2, de ce qui suit :

**2.1** Il est entendu que le présent règlement s'applique à un instrument médical qui est une drogue visée aux alinéas b) ou c) de la définition de *biocide* au paragraphe 1(1) du *Règlement sur les biocides*.

— DORS/2024-238, art. 41

**41** Les paragraphes 36(2) à (4) du *Règlement sur les instruments médicaux*<sup>2</sup> sont remplacés par ce qui suit :

**(2)** Le ministre peut, en tout temps, assortir de conditions l'homologation délivrée à l'égard d'un instrument médical ou modifier de telles conditions après avoir pris en considération les questions suivantes :

- a)** celle de savoir si des incertitudes liées aux avantages ou aux risques associés à l'instrument existent;
- b)** celle de savoir si les exigences prévues sous le régime de la Loi sont suffisantes pour atteindre les objectifs suivants :
  - (i)** maintenir la sûreté et l'efficacité de l'instrument,
  - (ii)** optimiser les avantages et gérer les risques associés à l'instrument,
  - (iii)** déceler tout changement lié à ces avantages et à ces risques et gérer les incertitudes à leur égard;
- c)** celle de savoir si les conditions proposées peuvent contribuer à l'atteinte de ces objectifs;
- d)** celle de savoir si le respect des conditions proposées est réalisable sur le plan technique;
- e)** celle de savoir si des moyens moins exigeants existent pour atteindre ces objectifs.

— DORS/2024-238, art. 42

**42** L'article 37 du même règlement est remplacé par ce qui suit :

<sup>2</sup> DORS/98-282

**37** If the terms and conditions of a medical device licence for an *in vitro* diagnostic device require that tests be performed to ensure that the device continues to meet the applicable requirements set out in sections 10 to 20, no person shall sell a device from a lot of the *in vitro* diagnostic device unless

(a) the results and protocols of the tests performed on devices in the lot have been provided to the Minister; and

(b) the Minister determines, on the basis of the results and protocols provided that the devices in the lot continue to meet the applicable requirements set out in sections 10 to 20.

— SOR/2024-238, s. 50

**50** Any terms and conditions that, immediately before the day on which section 41 of these Regulations comes into force, are set out in a medical device licence referred to in subsection 36(1) of the *Medical Devices Regulations* are deemed to be imposed by the Minister under subsection 36(2) of the *Medical Devices Regulations*, as that subsection reads as of that day.

**37** Il est interdit de vendre tout instrument d'un lot d'instruments diagnostiques in vitro qui contient des instruments dont l'homologation est assortie de conditions prévoyant que des essais soient effectués pour veiller à ce qu'ils satisfassent toujours aux exigences applicables prévues aux articles 10 à 20 sauf si, à la fois :

a) le protocole d'essai et les résultats des essais effectués sur des instruments faisant partie du lot ont été fournis au ministre;

b) le ministre conclut, selon le protocole et les résultats fournis, que les instruments faisant partie du lot satisfont toujours aux exigences applicables prévues aux articles 10 à 20.

— DORS/2024-238, art. 50

**50** Les conditions dont toute homologation visée au paragraphe 36(1) du *Règlement sur les instruments médicaux* est assortie avant la date d'entrée en vigueur de l'article 41 du présent règlement sont réputées être imposées par le ministre en vertu du paragraphe 36(2) du *Règlement sur les instruments médicaux*, dans sa version à cette date ou après celle-ci.