harm cannot be estimated, the possible consequences shall be listed for use in *risk evaluation* and *risk control*. The results of these activities shall be recorded in the *risk management file*.

The system used for qualitative or quantitative categorization of probability of occurrence of *harm* and *severity* of *harm* shall be recorded in the *risk management file*.

NOTE 1 *Risk estimation* incorporates an analysis of the probability of occurrence of *harm* and the *severity* of the *harm*. Depending on the area of application, only certain elements of the *risk estimation process* might need to be considered in detail. For example, when the *harm* is minimal, an initial *hazard* and consequence analysis could be sufficient, or when insufficient information or data are available, a conservative estimate of the probability of occurrence can give some indication of the *risk*. See also ISO/TR 24971[9].

NOTE 2 *Risk estimation* can be qualitative or quantitative. Methods of *risk estimation*, including those resulting from systematic faults, are described in ISO/TR 24971[9], which also gives information useful for estimating *risks* for *in vitro diagnostic medical devices*.

NOTE 3 Information or data for estimating *risks* can be obtained, for example, from:

— published standards;

— scientific or technical investigations;

— field data from similar *medical devices* already in use, including publicly available reports of incidents;

— usability tests employing typical users;

— clinical evidence;

— results of relevant investigations or simulations;

— expert opinion; or

— external quality assessment schemes for *in vitro diagnostic medical devices*.

Compliance is checked by inspection of the *risk management file*.

6 *Risk evaluation*

For each identified *hazardous situation*, the *manufacturer* shall evaluate the estimated *risks* and determine if the *risk* is acceptable or not, using the criteria for *risk* acceptability defined in the *risk management* plan.

If the *risk* is acceptable, it is not required to apply the requirements given in 7.1 to 7.5 to this *hazardous situation* (i.e., proceed to 7.6) and the estimated *risk* shall be treated as *residual risk*.

If the *risk* is not acceptable, then the *manufacturer* shall perform *risk control* activities as described in 7.1 to 7.6.

The results of this *risk evaluation* shall be recorded in the *risk management file*.

Compliance is checked by inspection of the *risk management file*.

7 *Risk control*

7.1 *Risk control* option analysis

The *manufacturer* shall determine *risk control* measures that are appropriate for reducing the *risks* to an acceptable level.

The *manufacturer* shall use one or more of the following *risk control* options in the priority order listed:

a) inherently safe design and manufacture;

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b) protective measures in the *medical device* itself or in the manufacturing *process*;

c) information for *safety* and, where appropriate, training to users.

NOTE 1 The rationale for the priority order in selecting the *risk control* options is given in A.2.7.1.

NOTE 2 *Risk control* measures can reduce the *severity* of the *harm* or reduce the probability of occurrence of the *harm*, or both.

NOTE 3 See ISO/TR 24971[9] for guidance on providing information for *safety*.

Relevant standards should be applied as part of the *risk control* option analysis.

NOTE 4 Many standards address inherent *safety*, protective measures, and information for *safety* for *medical devices*. In addition, some *medical device* standards have integrated elements of the *risk management process* (e.g. electromagnetic compatibility, usability, biological evaluation). See ISO/TR 24971[9] for information on the role of International Standards in *risk management*.

The *risk control* measures selected shall be recorded in the *risk management file*.

If, during *risk control* option analysis, the *manufacturer* determines that *risk* reduction is not practicable, the *manufacturer* shall conduct a *benefit-risk* analysis of the *residual risk* (proceed to 7.4).

Compliance is checked by inspection of the *risk management file*.

7.2 Implementation of *risk control* measures

The *manufacturer* shall implement the *risk control* measures selected in 7.1.

Implementation of each *risk control* measure shall be verified. This *verification* shall be recorded in the *risk management file*.

NOTE 1 *Verification* of implementation can be performed as part of design and development *verification* or *process* qualification within a quality management system.

The effectiveness of the *risk control* measures shall be verified. The results of this *verification* shall be recorded in the *risk management file*.

NOTE 2 *Verification* of effectiveness can be performed as part of design and development validation within a quality management system and can include testing with users. See A.2.7.2.

NOTE 3 *Verification* of effectiveness can also be performed as part of design and development *verification* or *process* qualification, if the relationship between the effectiveness in *risk* reduction and the result of design and development *verification* or *process* qualification is known.

EXAMPLE 1 Design *verification* of a certain performance characteristic, such as dose accuracy of a drug injector, can serve as *verification* of effectiveness of *risk control* measures ensuring safe drug dosing.

EXAMPLE 2 *Process* qualification can serve as *verification* of effectiveness of *risk control* measures related to *risk* caused by variations in production output.

NOTE 4 See ISO 13485[5] for more information on design and development *verification* and validation. See also ISO/TR 24971[9] for more guidance.

Compliance is checked by inspection of the *risk management file*.

7.3 *Residual risk* evaluation

After the *risk control* measures are implemented, the *manufacturer* shall evaluate the *residual risk* using the criteria for *risk* acceptability defined in the *risk management* plan. The results of this evaluation shall be recorded in the *risk management file*.

If a *residual risk* is not judged acceptable using these criteria, further *risk control* measures shall be considered (go back to 7.1).

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Compliance is checked by inspection of the *risk management file*.

7.4 *Benefit-risk* analysis

If a *residual risk* is not judged acceptable using the criteria established in the *risk management* plan and further *risk control* is not practicable, the *manufacturer* may gather and review data and literature to determine if the *benefits* of the *intended use* outweigh this *residual risk*.

If this evidence does not support the conclusion that the *benefits* outweigh this *residual risk*, then the *manufacturer* may consider modifying the *medical device* or its *intended use* (go back to 5.2). Otherwise, this *risk* remains unacceptable.

If the *benefits* outweigh the *residual risk*, then proceed to 7.5.

The results of the *benefit-risk* analysis shall be recorded in the *risk management file*.

NOTE See ISO/TR 24971[9] for guidance on performing a *benefit-risk* analysis.

Compliance is checked by inspection of the *risk management file*.

7.5 *Risks* arising from *risk control* measures

The *manufacturer* shall review the effects of the *risk control* measures with regard to whether:

— new *hazards* or *hazardous situations* are introduced; or

— the estimated *risks* for previously identified *hazardous situations* are affected by the introduction of the *risk control* measures.

Any new or increased *risks* shall be managed in accordance with 5.5 to 7.4.

The results of this review shall be recorded in the *risk management file*.

Compliance is checked by inspection of the *risk management file*.

7.6 Completeness of *risk control*

The *manufacturer* shall review the *risk control* activities to ensure that the *risks* from all identified *hazardous situations* have been considered and all *risk control* activities are completed.

The results of this review shall be recorded in the *risk management file*.

Compliance is checked by inspection of the *risk management file*.

8 Evaluation of overall *residual risk*

After all *risk control* measures have been implemented and verified, the *manufacturer* shall evaluate the overall *residual risk* posed by the *medical device*, taking into account the contributions of all *residual risks*, in relation to the *benefits* of the *intended use*, using the method and the criteria for acceptability of the overall *residual risk* defined in the *risk management* plan [see 4.4 e)].

If the overall *residual risk* is judged acceptable, the *manufacturer* shall inform users of significant *residual risks* and shall include the necessary information in the *accompanying documentation* in order to disclose those *residual risks*.

NOTE 1 The rationale for the disclosure of significant *residual risks* is given in A.2.8.

NOTE 2 See ISO/TR 24971[9] for guidance on the evaluation of overall *residual risk* and the disclosure of *residual risks*.

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If the overall *residual risk* is not judged acceptable in relation to the *benefits* of the *intended use*, the *manufacturer* may consider implementing additional *risk control* measures (go back to 7.1) or modifying the *medical device* or its *intended use* (go back to 5.2). Otherwise, the overall *residual risk* remains unacceptable.

The results of the evaluation of the overall *residual risk* shall be recorded in the *risk management file*.

Compliance is checked by inspection of the *risk management file* and the *accompanying documentation*.

9 *Risk management* review

Prior to release for commercial distribution of the *medical device*, the *manufacturer* shall review the execution of the *risk management* plan. This review shall at least ensure that:

— the *risk management* plan has been appropriately implemented;

— the overall *residual risk* is acceptable; and

— appropriate methods are in place to collect and review information in the production and *post-production* phases.

The results of this review shall be recorded and maintained as the *risk management* report and shall be included in the *risk management file*.

The responsibility for review shall be assigned in the *risk management* plan to persons having the appropriate authority [see 4.4 b)].

Compliance is checked by inspection of the *risk management file*.

10 Production and *post-production* activities

10.1 General

The *manufacturer* shall establish, document and maintain a system to actively collect and review information relevant to the *medical device* in the production and *post-production* phases. When establishing this system, the *manufacturer* shall consider appropriate methods for the collection and processing of information.

NOTE 1 See also 7.3.3, 8.2.1, 8.4 and 8.5 of ISO 13485:2016[5].

NOTE 2 See ISO/TR 24971[9] for guidance on production and *post-production* activities.

Compliance is checked by inspection of the appropriate documents.

10.2 Information collection

The *manufacturer* shall collect, where applicable:

a) information generated during production and monitoring of the production *process*;

b) information generated by the user;

c) information generated by those accountable for the installation, use and maintenance of the *medical device*;

d) information generated by the supply chain;

e) publicly available information; and

f) information related to the generally acknowledged *state of the art*.

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NOTE Information related to the generally acknowledged *state of the art* can include new or revised standards, published validated data specific to the application of the *medical device* under consideration, the availability of alternative *medical devices* and/or therapies, and other information (see also ISO/TR 24971[9]).

The *manufacturer* shall also consider the need to actively collect and review publicly available information about similar *medical devices* and similar other products on the market.

Compliance is checked by inspection of the appropriate documents.

10.3 Information review

The *manufacturer* shall review the information collected for possible relevance to *safety*, especially whether:

— previously unrecognised *hazards* or *hazardous situations* are present;

— an estimated *risk* arising from a *hazardous situation* is no longer acceptable;

— the overall *residual risk* is no longer acceptable in relation to the *benefits* of the *intended use*; or

— the generally acknowledged *state of the art* has changed.

The results of the review shall be recorded in the *risk management file*.

Compliance is checked by inspection of the *risk management file*.

10.4 Actions

If the collected information is determined to be relevant to *safety*, the following actions apply.

1) Concerning the particular *medical device*,

   — the *manufacturer* shall review the *risk management file* and determine if reassessment of *risks* and/or assessment of new *risks* is necessary;

   — if a *residual risk* is no longer acceptable, the impact on previously implemented *risk control* measures shall be evaluated and should be considered as an input for modification of the *medical device*;

   — the *manufacturer* should consider the need for actions regarding *medical devices* on the market; and

   — any decisions and actions shall be recorded in the *risk management file*.

2) Concerning the *risk management process*,

   — the *manufacturer* shall evaluate the impact on previously implemented *risk management* activities; and

   — the results of this evaluation shall be considered as an input for the review of the suitability of the *risk management process* by *top management* (see 4.2).

NOTE Some aspects of *post-production* monitoring are the subject of some national regulations. In such cases, additional measures might be required (e.g. prospective *post-production* evaluations).

Compliance is checked by inspection of the *risk management file* and other appropriate documents.

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