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| Clause |  | What it says | Additional info |
| 4 Quality management system | | | |
| 4.1 | General requirements | | |
| 4.1.1 | The organization shall document a quality management system and maintain its effectiveness in  accordance with the requirements of this International Standard and applicable regulatory requirements.  The organization shall establish, implement and maintain any requirement, procedure, activity or  arrangement required to be documented by this International Standard or applicable regulatory  requirements.  The organization shall document the role(s) undertaken by the organization under the applicable  regulatory requirements.  NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer  or distributor | * QMS document   + With requirments from this standard * Cater to region wise regulatory requirements * Procedure,requirement,activity to be maintained as by the standard * Roles undertaken by organisation to be documented   + Manufacture   + Authorise representative   + Importer   + Distributor |  |
| 4.1.2 | The organization shall:  a) determine the processes needed for the quality manage2ment system and the application of  these processes throughout the organization taking into account the roles undertaken by the  organization;  b) apply a risk based approach to the control of the appropriate processes needed for the quality  management system;  c) determine the sequence and interaction of these processes. | * Processes required to be identified, and apply it * Risk based approach for the processes * Establish sequence and interaction of the processes |  |
| 4.1.3 | For each quality management system process, the organization shall:  a) determine criteria and methods needed to ensure that both the operation and control of these  processes are effective;  b) ensure the availability of resources and information necessary to support the operation and  monitoring of these processes;  c) implement actions necessary to achieve planned results and maintain the effectiveness of these  processes;  d) monitor, measure as appropriate, and analyse these processes;  e) establish and maintain records needed to demonstrate conformance to this International Standard  and compliance with applicable regulatory requirements (see 4.2.5). | * QMS Process   + Criteria for operation and control   + Availability of resource and information   + Actions to implement   + Monitor and measure   + Record –maintain |  |
| 4.1.4 | The organization shall manage these quality management system processes in accordance with  the requirements of this International Standard and applicable regulatory requirements. Changes to be  made to these processes shall be:  a) evaluated for their impact on the quality management system;  b) evaluated for their impact on the medical devices produced under this quality management system  c) controlled in accordance with the requirements of this International Standard and applicable  regulatory requirements. | * Changes evaluated   + impact on QMS   + Impact on medical device produced   + controled |  |
| 4.1.5 | When the organization chooses to outsource any process that affects product conformity to  requirements, it shall monitor and ensure control over such processes. The organization shall retain  responsibility of conformity to this International Standard and to customer and applicable regulatory  requirements for outsourced processes. The controls shall be proportionate to the risk involved and the  ability of the external party to meet the requirements in accordance with 7.4. The controls shall include  written quality agreements. | * Outsourced process   + Monitor   + Control   + Requirements complied * Organisation responsible for conformity * Risk based controls * Ability of external party to meet requirements * Written quality agreement |  |
| 4.1.6 | The organization shall document procedures for the validation of the application of computer  software used in the quality management system. Such software applications shall be validated prior to  initial use and, as appropriate, after changes to such software or its application.  The specific approach and activities associated with software validation and revalidation shall be  proportionate to the risk associated with the use of the software.  Records of such activities shall be maintained (see 4.2.5). | * Validation of computer software documented for QMS use * Risk based approach * Records maintained |  |
| Summary 4.1 | 1. Create a QMS which complies to the requirements of the standard 2. Procedures for the activities of the organisation, with a risk based approach 3. Operation of processes, controlling them, monitoring and creating records 4. Changes made and their impact on QMS and medical device in a risk based approach 5. Monitor and control outsourced process 6. Validate QMS computer software | | |
| 4.2 | Documentation requirements | | |
| 4.2.1 | General  The quality management system documentation (see 4.2.4) shall include:  a) documented statements of a quality policy and quality objectives;  b) a quality manual;  c) documented procedures and records required by this International Standard;  d) documents, including records, determined by the organization to be necessary to ensure the  effective planning, operation, and control of its processes;  e) other documentation specified by applicable regulatory requirements. | * Quality policy * Quality objectives * Quality manual * Planning, operation , and control   + Procedures   + Records |  |
| 4.2.2 | **Quality manual**  The organization shall document a quality manual that includes:  a) the scope of the quality management system, including details of and justification for any exclusion  or non-application;  b) the documented procedures for the quality management system, or reference to them;  c) a description of the interaction between the processes of the quality management system.  The quality manual shall outline the structure of the documentation used in the quality management  system. | * Exlusions to be justified * Reference to QMS linked procedures * Interaction of processes * Outline structure of the documentation |  |
| 4.2.3 | Medical device file  For each medical device type or medical device family, the 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:  a) general description of the medical device, intended use/purpose, and labelling, including any  instructions for use;  b) specifications for product;  c) specifications or procedures for manufacturing, packaging, storage, handling and distribution;  d) procedures for measuring and monitoring;  e) as appropriate, requirements for installation;  f) as appropriate, procedures for servicing. | * Medical device file   + Demonstrate conformity to requiremnts of standard   + Description   + Intended use   + Labelling   + Specifications   + Specifications for manufacturing   + Packaging   + Storage   + Handling   + Distribution   + Measuring and monitoring   + Installation   + servicing | DMR,DHF |
| 4.2.4 | Control of documents  Documents required by the quality management system shall be controlled. Records are a special type  of document and shall be controlled according to the requirements given in 4.2.5.  A documented procedure shall define the controls needed to:  a) review and approve documents for adequacy prior to issue;  b) review, update as necessary and re-approve documents;  c) ensure that the current revision status of and changes to documents are identified;  d) ensure that relevant versions of applicable documents are available at points of use;  e) ensure that documents remain legible and readily identifiable;  f) ensure that documents of external origin, determined by the organization to be necessary for the  planning and operation of the quality management system, are identified and their distribution  controlled;  g) prevent deterioration or loss of documents;  h) prevent the unintended use of obsolete documents and apply suitable identification to them.  The organization shall ensure that changes to documents are reviewed and approved either by the  original approving function or another designated function that has access to pertinent background  information upon which to base its decisions.  The organization shall define the period for which at least one copy of obsolete documents shall be  retained. This period shall ensure that documents to which medical devices have been manufactured  and tested are available for at least the lifetime of the medical device as defined by the organization,  but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable  regulatory requirements. | * Document and records * Review and approve documents * Reapprove documents * Revision control * Point of use- relevant docs are available (document distribution format) * Legible and identifiable * Documents of external origin * Prevent   + loss of documents   + Use of obsolete documents * Decide retention period of docs, least the lifetime of the device |  |
| 4.2.5 | Control of records  Records shall be maintained to provide evidence of conformity to requirements and of the effective  operation of the quality management system.  The organization shall document procedures to define the controls needed for the identification,  storage, security and integrity, retrieval, retention time and disposition of records.  The organization shall define and implement methods for protecting confidential health information  contained in records in accordance with the applicable regulatory requirements.  Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain  identifiable.  The organization shall retain the records for at least the lifetime of the medical device as defined by the  organization, or as specified by applicable regulatory requirements, but not less than two years from  the medical device release by the organization. | * Identification storage,security and integrity ,retrival,retention, for records * Methods to protect confidential health information(HIPPA) * Legible,identifiable,retrievable, |  |
| 5 Management responsibility | | | |
| 5.1 | Management commitment |  |  |
|  | Top management shall provide evidence of its commitment to the development and implementation of  the quality management system and maintenance of its effectiveness by:  a) communicating to the organization the importance of meeting customer as well as applicable  regulatory requirements;  b) establishing the quality policy;  c) ensuring that quality objectives are established;  d) conducting management reviews;  e) ensuring the availability of resources. | * Commitment to development and implementation of QMS * Meet customer and regulatory requirements * Establish quality policy * Quality objectives established * Management reviews * Availability of resources |  |
| 5.2 | Customer focus |  |  |
|  | Top management shall ensure that customer requirements and applicable regulatory requirements are  determined and met. | * Customer and regulatory requirements are met |  |
| 5.3 | Quality policy |  |  |
|  | Top management shall ensure that the quality policy:  a) is applicable to the purpose of the organization;  b) includes a commitment to comply with requirements and to maintain the effectiveness of the  quality management system;  c) provides a framework for establishing and reviewing quality objectives;  d) is communicated and understood within the organization;  e) is reviewed for continuing suitability. | * Purpose of organisation * Requirements and effectiveness of QMS * Establish and review quality objectives |  |
| 5.4 | planning | | |
| 5.4.1 | Top management shall ensure that quality objectives, including those needed to meet applicable  regulatory requirements and requirements for product, are established at relevant functions and levels  within the organization. The quality objectives shall be measurable and consistent with the quality policy | * Quality objectives and quality policy |  |
| 5.4.2 | **Quality management system planning**  Top management shall ensure that:  a) the planning of the quality management system is carried out in order to meet the requirements  given in 4.1, as well as the quality objectives;  b) the integrity of the quality management system is maintained when changes to the quality  management system are planned and implemented. | * Planning of qms * Integrity maintained during changes |  |
| 5.5 | Responsibility authority and communication | | |
| 5.5.1 | **Responsibility and authority**  Top management shall ensure that responsibilities and authorities are defined, documented and  communicated within the organization.  Top management shall document the interrelation of all personnel who manage, perform and verify work  affecting quality and shall ensure the independence and authority necessary to perform these tasks. | * Responsibilities and authority defined * Interrelation of personal-manage perform and verify work. | Department manuals,  Approvals matrix  Roles and responsibilities |
| 5.5.2 | **Management representative**  Top management shall appoint a member of management who, irrespective of other responsibilities,  has responsibility and authority that includes:  a) ensuring that processes needed for the quality management system are documented;  b) reporting to top management on the effectiveness of the quality management system and any need  for improvement;  c) ensuring the promotion of awareness of applicable regulatory requirements and quality  management system requirements throughout the organization. | * QMS processes documentes * Report to top management on QMS updates * Awarenenss on applicable regulatory requirments |  |
| 5.5.3 | **Internal communication**  Top management shall ensure that appropriate communication processes are established within  the organization and that communication takes place regarding the effectiveness of the quality  management system. | * Communication established |  |
| 5.6 | **Management review** | | |
| 5.6.1 | **General**  The organization shall document procedures for management review. Top management shall review  the organization’s quality management system at documented planned intervals to ensure its  continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for  improvement and the need for changes to the quality management system, including the quality policy  and quality objectives.  Records from management reviews shall be maintained (see 4.2.5). | * Review at planned intervals   + Stability   + Adequacy   + Effectiveness * Opportunities for improvement * Quality policy * Quality objectives |  |
| 5.6.2 | **Review input**  The input to management review shall include, but is not limited to, information arising from:  a) feedback;  b) complaint handling;  c) reporting to regulatory authorities;  d) audits;  e) monitoring and measurement of processes;  f) monitoring and measurement of product;  g) corrective action;  h) preventive action;  i) follow-up actions from previous management reviews;  j) changes that could affect the quality management system;  k) recommendations for improvement;  l) applicable new or revised regulatory requirements. | * Review inputs:   + Feedback   + Complaint handling   + Reporting to regulatory authorities   + Audits   + Monitoring and measurement or process   + Corrective action   + Preventive action   + Follow up actions from previous management reviews   + Changes that could affect the QMS   + Recommendations for improvements   + Applicable new or revised regulatory requirements |  |
| 5.6.3 | **Review outputs**  The output from management review shall be recorded (see 4.2.5) and include the input reviewed and  any decisions and actions related to:  a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality  management system and its processes;  b) improvement of product related to customer requirements;  c) changes needed to respond to applicable new or revised regulatory requirements;  d) resource needs. | * Recorded * Inputs reviewed and actions * Suitability, adequacy and effectiveness of products * Customer requirements improvement * New or revised regulatory requirments * Resource needs |  |
| 6 Resource management | | | |
| 6.1 | **Provision of resource** |  |  |
|  | The organization shall determine and provide the resources needed to:  a) implement the quality management system and to maintain its effectiveness;  b) meet applicable regulatory and customer requirements. | * Resources to implement and maintain QMS * Regulatory and customer requirments meet |  |
| 6.2 | Human resource |  |  |
|  | Personnel performing work affecting product quality shall be competent on the basis of appropriate  education, training, skills and experience.  The organization shall document the process(es) for establishing competence, providing needed  training, and ensuring awareness of personnel.  The organization shall:  a) determine the necessary competence for personnel performing work affecting product quality;  b) provide training or take other actions to achieve or maintain the necessary competence;  c) evaluate the effectiveness of the actions taken;  d) ensure that its personnel are aware of the relevance and importance of their activities and how  they contribute to the achievement of the quality objectives;  e) maintain appropriate records of education, training, skills and experience (see 4.2.5).  NOTE The methodology used to check effectiveness is proportionate to the risk associated with the work for  which the training or other action is being provided. | * Personel work affecting product quality must be competent enough- education, skill, training and experience. * Document- process for establishing competence providing needed training, and awareness of personnel. * Maintain necessary competence * Evaluate effectiveness of action taken * Aware of relevance and importance of the activities * Records of education training skills and experience * Risk based evaluation | Skill matrix  Training matrix  Records storage |
| 6.3 | infrastructure |  |  |
|  | The organization shall document the requirements for the infrastructure needed to achieve  conformity to product requirements, prevent product mix-up and ensure orderly handling of product.  Infrastructure includes, as appropriate:  a) buildings, workspace and associated utilities;  b) process equipment (both hardware and software);  c) supporting services (such as transport, communication, or information systems).  The organization shall document requirements for the maintenance activities, including the interval  of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect  product quality. As appropriate, the requirements shall apply to equipment used in production, the  control of the work environment and monitoring and measurement.  Records of such maintenance shall be maintained (see 4.2.5). | * Infrastructure needed to achieve conformity to the product * Prevent product mixup and ensure orderly handling of product * Buildings * Workspace * Associated utilities * Process equipment * Supporting services   + Transportation   + Comminciation   + Information system * Maintenance activities * Equipments used in production * Control of work environment monitoring and measurement | Plant layout  CLRI  Pest control  Infrastructure  Production planning |
| 6.4 | **Work environment and contamination control** | | |
| 6.4.1 | **Work environment**  The organization shall document the requirements for the work environment needed to achieve  conformity to product requirements.  If the conditions for the work environment can have an adverse effect on product quality, the  organization shall document the requirements for the work environment and the procedures to monitor  and control the work environment.  The organization shall:  a) document requirements for health, cleanliness and clothing of personnel if contact between such  personnel and the product or work environment could affect medical device safety or performance;  b) ensure that all personnel who are required to work temporarily under special environmental  conditions within the work environment are competent or supervised by a competent person.  NOTE Further information can be found in ISO 14644 and ISO 14698. | * Requirements for environment needed * Adverse effect on product quality * Work environment and the procedures to monitor and control * Requirments for health, cleanliness and clothing |  |
| 6.4.2 | **Contamination control**  As appropriate, the organization shall plan and document arrangements for the control of contaminated  or potentially contaminated product in order to prevent contamination of the work environment,  personnel, or product.  For sterile medical devices, the organization shall document requirements for control of contamination  with microorganisms or particulate matter and maintain the required cleanliness during assembly or  packaging processes. | * Plan and document controls for contaminated or potentially contaminated product * Prevent contamination of work environment * Sterile medical devices, requirements for control by microorganisms or particulate matter and maintaining the required cleanliness during assembly or packaging process |  |
| 7 product realisation | | | |
| 7.1 | **Planning of product realisation**  The organization shall plan and develop the processes needed for product realization. Planning of  product realization shall be consistent with the requirements of the other processes of the quality  management system.  The organization shall document one or more processes for risk management in product realization.  Records of risk management activities shall be maintained (see 4.2.5)  In planning product realization, the organization shall determine the following, as appropriate:  a) quality objectives and requirements for the product;  b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the  product, including infrastructure and work environment;  c) required verification, validation, monitoring, measurement, inspection and test, handling, storage,  distribution and traceability activities specific to the product together with the criteria for product  acceptance;  d) records needed to provide evidence that the realization processes and resulting product meet  requirements (see 4.2.5).  The output of this planning shall be documented in a form suitable for the organization’s method of  operations.  NOTE Further information can be found in ISO 14971. | * Process needed for product realisation- plan and develop * Consistent with requirements of other process * Risk management in product realisation * Records of risk management activities maintained * Quality objectives and requirements for the product * Establish processes and documents * Resources specific to product development including infrastructure * Verification validation, monitoring measurement and inspection and test ,handling and storage * Distribution and traceability activities * Acceptance criteria * Product realisation meets requirements |  |
| 7.2 | **Customer related process** | | |
| 7.2.1 | **Determination of requirements related to product**  The organization shall determine:  a) requirements specified by the customer, including the requirements for delivery and post-delivery  activities;  b) requirements not stated by the customer but necessary for specified or intended use, as known;  c) applicable regulatory requirements related to the product;  d) any user training needed to ensure specified performance and safe use of the medical device;  e) any additional requirements determined by the organization. | * Customer requirements * Delivery and post delivery requirements * Requirements necessary for intended use * Regulatory requirements * Specified performance and safe use of device * Additional requirements of the organisation |  |
| 7.2.2 | **Review of requirements related to product**  The organization shall review the requirements related to product. This review shall be conducted  prior to the organization’s commitment to supply product to the customer (e.g. submission of tenders,  acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:  a) product requirements are defined and documented;  b) contract or order requirements differing from those previously expressed are resolved;  c) applicable regulatory requirements are met;  d) any user training identified in accordance with 7.2.1 is available or planned to be available;  e) the organization has the ability to meet the defined requirements.  Records of the results of the review and actions arising from the review shall be maintained (see 4.2.5).  When the customer provides no documented statement of requirement, the customer requirements  shall be confirmed by the organization before acceptance.  When product requirements are changed, the organization shall ensure that relevant documents are  amended and that relevant personnel are made aware of the changed requirements. | * Review requirments related to product * Product requirments are defined and documented * Contract or order requirements differing from those previously expressed are resolved * User training * Records of results of review and actions from review maintained * Change in product requirements made sure that the relevant documents are changed |  |
| 7.2.3 | **Communication**  The organization shall plan and document arrangements for communicating with customers in  relation to:  a) product information;  b) enquiries, contracts or order handling, including amendments;  c) customer feedback, including complaints;  d) advisory notices.  The organization shall communicate with regulatory authorities in accordance with applicable  regulatory requirements. | * How to communicate with the customers * Product information * Enquires * Contracts * Order handling * Customer feedback * Complaints * Advisory notices * Communication with regulatory authorities |  |
| 7.3 Design and development | | | |
| 7.3.1 | **General**  The organization shall document procedures for design and development. | * Make procedure |  |
| 7.3.2 | **Design and development planning**  The organization shall plan and control the design and development of product. As appropriate, design  and development planning documents shall be maintained and updated as the design and development  progresses.  During design and development planning, the organization shall document:  a) the design and development stages;  b) the review(s) needed at each design and development stage;  c) the verification, validation, and design transfer activities that are appropriate at each design and  development stage;  d) the responsibilities and authorities for design and development;  e) the methods to ensure traceability of design and development outputs to design and  development inputs;  f) the resources needed, including necessary competence of personnel. | * Plan and control the design and development * Design and development planning documents to be maintained and updated * Design and development stages * Reviews at each stages * Verification and validation * Design transfer activities * Responsibilities and authorities for D&D activities * Traceability of outputs to inputs * Resources and competence |  |
| 7.3.3 | **Design and development inputs**  Inputs relating to product requirements shall be determined and records maintained (see 4.2.5). These  inputs shall include:  a) functional, performance, usability and safety requirements, according to the intended use;  b) applicable regulatory requirements and standards;  c) applicable output(s) of risk management;  d) as appropriate, information derived from previous similar designs;  e) other requirements essential for design and development of the product and processes.  These inputs shall be reviewed for adequacy and approved.  Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with  each other.  NOTE Further information can be found in IEC 62366–1. | * Determine product requirements and record it * Functional * Performance * Usability * Safety * Regulatory requirements * Outputs of risk management file * Previous design information * Other requirements essential for design * Reviewed and approved * Unambiguous, verifiable, validatable, not in conflict |  |
| 7.3.4 | **Design and development outputs**  Design and development outputs shall:  a) meet the input requirements for design and development;  b) provide appropriate information for purchasing, production and service provision;  c) contain or reference product acceptance criteria;  d) specify the characteristics of the product that are essential for its safe and proper use.  The outputs of design and development shall be in a form suitable for verification against the design  and development inputs and shall be approved prior to release.  Records of the design and development outputs shall be maintained (see 4.2.5). | * Meet the input requirements * Information for purchasing, production and service provision * Product acceptance criteria * Safe and proper use essential characters specified * Records maintained * Verified against inputs | Traceability matrix of inputs to outputs  Product specificatinos, sop-qls  fqc |
| 7.3.5 | **Design and development review**  At suitable stages, systematic reviews of design and development shall be performed in accordance  with planned and documented arrangements to:  a) evaluate the ability of the results of design and development to meet requirements;  b) identify and propose necessary actions.  Participants in such reviews shall include representatives of functions concerned with the design and  development stage being reviewed, as well as other specialist personnel.  Records of the results of the reviews and any necessary actions shall be maintained and include the  identification of the design under review, the participants involved and the date of the review (see 4.2.5). | * Results meet requirements? * Identify and propose actions * Records of results of review * Action plan * Identification of design under review |  |
| 7.3.6 | **Design and development verification**  Design and development verification shall be performed in accordance with planned and documented  arrangements to ensure that the design and development outputs have met the design and development  input requirements.  The organization shall document verification plans that include methods, acceptance criteria and, as  appropriate, statistical techniques with rationale for sample size.  If the intended use requires that the medical device be connected to, or have an interface with, other  medical device(s), verification shall include confirmation that the design outputs meet design inputs  when so connected or interfaced.  Records of the results and conclusions of the verification and necessary actions shall be maintained  (see 4.2.4 and 4.2.5). | * Design and development outputs meet the design and development inputs * Verification plans   + Methods   + Acceptance criteria   + Statistical techniques   + Rationale   + Records of results and conclusions |  |
| 7.3.7 | **Design and development validation**  Design and development validation shall be performed in accordance with planned and documented  arrangements to ensure that the resulting product is capable of meeting the requirements for the  specified application or intended use.  The organization shall document validation plans that include methods, acceptance criteria and, as  appropriate, statistical techniques with rationale for sample size.  Design validation shall be conducted on representative product. Representative product includes  initial production units, batches or their equivalents. The rationale for the choice of product used for  validation shall be recorded (see 4.2.5).  As part of design and development validation, the organization shall perform clinical evaluations or  performance evaluations of the medical device in accordance with applicable regulatory requirements.  A medical device used for clinical evaluation or performance evaluation is not considered to be released  for use to the customer.  If the intended use requires that the medical device be connected to, or have an interface with, other  medical device(s), validation shall include confirmation that the requirements for the specified  application or intended use have been met when so connected or interfaced.  Validation shall be completed prior to release for use of the product to the customer.  Records of the results and conclusion of validation and necessary actions shall be maintained (see 4.2.4  and 4.2.5). | * Planned and documented arrangements * Meets requirements for the specified application or intended use * Document validation plans, include methods and acceptance criteria * Appropriate statistical techniques and rationale for sample size * Validation on initial production units * Batches or equivalents * Rationale for the choice of products used * Clinical evaluations * Performance evaluation * Device used for validation is not considered to be relased for customer * Interfaces and connections to other medical devices to be validated * Records maintained |  |
| 7.3.8 | **Design and development transfer**  The organization shall document procedures for transfer of design and development outputs to  manufacturing. These procedures shall ensure that design and development outputs are verified  as suitable for manufacturing before becoming final production specifications and that production  capability can meet product requirements.  Results and conclusions of the transfer shall be recorded (see 4.2.5). | * Transfer of design outputs to manufacturing * Production capability meets product requirements. |  |
| 7.3.9 | **Control of design and development changes**  The organization shall document procedures to control design and development changes. The  organization shall determine the significance of the change to function, performance, usability, safety  and applicable regulatory requirements for the medical device and its intended use.  Design and development changes shall be identified. Before implementation, the changes shall be:  a) reviewed;  b) verified;  c) validated, as appropriate;  d) approved.  The review of design and development changes shall include evaluation of the effect of the changes on  constituent parts and product in process or already delivered, inputs or outputs of risk management  and product realization processes.  Records of changes, their review and any necessary actions shall be maintained (see 4.2.5). | * Procedure to control design and development changes * Significance of the change to   + Function   + Performance   + Usability   + Safety   + Regulatory requirements * Changes shall be   + Reviewed   + Verified   + Validated as appropriate   + Approved * Evaluation of the effect of the change on risk of device and product realisation process * Records of change and review to be maintained |  |
| 7.3.10 | **Design and development files**  The 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 | * Maintain file for each device and type * Records demonstrated to conformity of requirments |  |
| 7.4 | **Purchasing** | | |
| 7.4.1 | **Purchasing process**  The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to  specified purchasing information.  The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:  a) based on the supplier’s ability to provide product that meets the organization’s requirements;  b) based on the performance of the supplier;  c) based on the effect of the purchased product on the quality of the medical device;  d) proportionate to the risk associated with the medical device.  The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in  meeting requirements for the purchased product shall be monitored. The results of the monitoring  shall provide an input into the supplier re-evaluation process.  Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the  risk associated with the purchased product and compliance with applicable regulatory requirements.  Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or  performance and any necessary actions arising from these activities shall be maintained (see 4.2.5). | * Produre for purchasing * Establish criteria for evaluation and selection of suppliers   + Suppliers ability to provide product   + Performance of the supplier   + Effect of purchased product on device   + Proportionate with the risk of device * Monitoring and re-evaluations * Supplier performance * Nonfulfillment shall be addressed with the supplier proportionate to risk and regulatory compliance * Records of results of evaluation,selection,monitoring and reevaluation of supplier capability or performance and any necessary actions maintained |  |
| 7.4.2 | **Purchasing information**  Purchasing information shall describe or reference the product to be purchased, including as  appropriate:  a) product specifications;  b) requirements for product acceptance, procedures, processes and equipment;  c) requirements for qualification of supplier personnel;  d) quality management system requirements.  The organization shall ensure the adequacy of specified purchasing requirements prior to their  communication to the supplier.  Purchasing information shall include, as applicable, a written agreement that the supplier notify the  organization of changes in the purchased product prior to implementation of any changes that affect  the ability of the purchased product to meet specified purchase requirements.  To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing  information in the form of documents (see 4.2.4) and records (see 4.2.5). | * Product specifications * Acceptance criteria * Qualification of supplier personel * QMS requirements * Adequacy of requirements prior tot communication to supplier * Purchasing information maintained in the form of documents and records |  |
| 7.4.3 | **Verification of purchased product**  The organization shall establish and implement the inspection or other activities necessary for ensuring  that purchased product meets specified purchasing requirements. The extent of verification activities  shall be based on the supplier evaluation results and proportionate to the risks associated with the  purchased product.  When the organization becomes aware of any changes to the purchased product, the organization shall  determine whether these changes affect the product realization process or the medical device.  When the organization or its customer intends to perform verification at the supplier’s premises,  the organization shall state the intended verification activities and method of product release in the  purchasing information.  Records of the verification shall be maintained (see 4.2.5). | * Inspection * Other activities ensuring the purchased product meets specs * Based on supplier evaluation results and risk of the product * Changes affect product realisation? * Verification at supplier premises * State intended verification activities and method of product release * Records maintained |  |
| 7.5 | **Production and service provisions** | | |
|  | **Control of production and service provision**  Production and service provision shall be planned, carried out, monitored and controlled to ensure that  product conforms to specification. As appropriate, production controls shall include but are not limited to:  a) documentation of procedures and methods for the control of production (see 4.2.4);  b) qualification of infrastructure;  c) implementation of monitoring and measurement of process parameters and product characteristics;  d) availability and use of monitoring and measuring equipment;  e) implementation of defined operations for labelling and packaging;  f) implementation of product release, delivery and post-delivery activities.  The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of  medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount  manufactured and amount approved for distribution. The record shall be verified and approved. | * Planned carried out and monitored * Product conforms to specifications * Production controls   + Documentation of procedures   + Infrastructure   + Monitoring and measurement of process parameters and product characteristics   + Availability and use of monitoring and measuring equipment   + Labelling and packaging operations   + Product release, delivery and post delivery activities * Maintain records * Traceability to extent specified in 7.5.9 with qty mfg and approved for distribution verified and approved |  |
| 7.5.2 | **Cleanliness of product**  The organization shall document requirements for cleanliness of product or contamination control of  product if:  a) product is cleaned by the organization prior to sterilization or its use;  b) product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or  its use;  c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use;  d) product is supplied to be used non-sterile, and its cleanliness is of significance in use;  e) process agents are to be removed from product during manufacture.  If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply  prior to the cleaning process. | * Requirements for cleanliness of product and contamination control   + Cleaned prior to use   + Supplied non sterile and subjected to cleaning process prior to use   + Cannot be cleaned prior to use   + Process agents removed from product during manufacture |  |
| 7.5.3 | **Installation activities**  The organization shall document requirements for medical device installation and acceptance criteria  for verification of installation, as appropriate.  If the agreed customer requirements allow installation of the medical device to be performed by an  external party other than the organization or its supplier, the organization shall provide documented  requirements for medical device installation and verification of installation.  Records of medical device installation and verification of installation performed by the organization or  its supplier shall be maintained (see 4.2.5). | * Document requirements for medical device installation and acceptance criteria * Verification of installation as appropriate * External party – provide documented evidence of installation and verification * State methods of intende verification activities * Records maintained |  |
| 7.5.4 | **Servicing activities**  If servicing of the medical device is a specified requirement, the organization shall document servicing  procedures, reference materials, and reference measurements, as necessary, for performing servicing  activities and verifying that product requirements are met.  The organization shall analyse records of servicing activities carried out by the organization or its  supplier:  a) to determine if the information is to be handled as a complaint;  b) as appropriate, for input to the improvement process.  Records of servicing activities carried out by the organization or its supplier shall be maintained  (see 4.2.5). | * Document servicing procedure * Reference material * Reference measurements * Servicing activities * Records of servicing activities * Determine information to deem as complaints * Input to improvement process |  |
| 7.5.5 | **Particular requirements for sterile medical devices**  The organization shall maintain records of the sterilization process parameters used for each  sterilization batch (see 4.2.5). Sterilization records shall be traceable to each production batch of  medical devices. | * Records of sterilization process parameters * Traceable to each product batch |  |
| 7.5.6 | **Validation of processes for production and service provision**  The organization shall validate any processes for production and service provision where the resulting  output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence,  deficiencies become apparent only after the product is in use or the service has been delivered.  Validation shall demonstrate the ability of these processes to achieve planned results consistently.  The organization shall document procedures for validation of processes, including:  a) defined criteria for review and approval of the processes;  b) equipment qualification and qualification of personnel;  c) use of specific methods, procedures and acceptance criteria;  d) as appropriate, statistical techniques with rationale for sample sizes;  e) requirements for records (see 4.2.5);  f) revalidation, including criteria for revalidation;  g) approval of changes to the processes.  The organization shall document procedures for the validation of the application of computer software  used in production and service provision. Such software applications shall be validated prior to initial  use and, as appropriate, after changes to such software or its application. The specific approach and  activities associated with software validation and revalidation shall be proportionate to the risk  associated with the use of the software, including the effect on the ability of the product to conform to  specifications.  Records of the results and conclusion of validation and necessary actions from the validation shall be  maintained (see 4.2.4 and 4.2.5). | * Validate all processes where output cannot be verified by monitoring and measurement * As consequence deficiency becomes apparent only when the product is in use. * Validation- demonstrate planned results achieved * Criteria for review and approval of the process * Equipment qualification and qualification of personel * Use of specific methods and acceptance criteria * Statistical techniques * Procedures for validation * Computer software used in production and service provision * Validated prior to initial use * Specific activities and approach to software validation and revalidation are to be proportionate to risk * Records of results and conclusions of validation necessary maintained |  |
| 7.5.7 | **Particular requirements for validation of processes for sterilization and sterile**  **barrier systems**  The organization shall document procedures (see 4.2.4) for the validation of processes for sterilization  and sterile barrier systems  Processes for sterilization and sterile barrier systems shall be validated prior to implementation and  following product or process changes, as appropriate.  Records of the results and, conclusion of validation and necessary actions from the validation shall be  maintained (see 4.2.4 and 4.2.5).  NOTE Further information can be found | * Procedure for validation of sterilization * Validated prior to implementaiton * Following product or process change * Records maintained |  |
| 7.5.8 | **Identification**  The organization shall document procedures for product identification and identify product by suitable  means throughout product realization.  The organization shall identify product status with respect to monitoring and measurement  requirements throughout product realization. Identification of product status shall be maintained  throughout production, storage, installation and servicing of product to ensure that only product that  has passed the required inspections and tests or released under an authorized concession is dispatched,  used or installed.  If required by applicable regulatory requirements, the organization shall document a system to assign  unique device identification to the medical device.  The organization shall document procedures to ensure that medical devices returned to the  organization are identified and distinguished from conforming product. | * Procedure for product identification * Product status with respect to monitoring and measurement * Requiremnts throught product realisatioin and identification shall be maintained * Throught production storage and installation and servicing. Ensuring pass product only dispatched * Assign unique device identification to device * Document procedure to identify return as conforming product |  |
| 7.5.9 | **Traceability** | | |
| 7.5.9.1 | **General**  The organization shall document procedures for traceability. These procedures shall define the extent  of traceability in accordance with applicable regulatory requirements and the records to be maintained  (see 4.2.5). | * Procedure for traceability |  |
| 7.5.9.2 | **Particular requirements for implantable medical devices**  The records required for traceability shall include records of components, materials, and conditions for  the work environment used, if these could cause the medical device not to satisfy its specified safety  and performance requirements.  The organization shall require that suppliers of distribution services or distributors maintain records  of the distribution of medical devices to allow traceability and that these records are available for  inspection.  Records of the name and address of the shipping package consignee shall be maintained (see 4.2.5). | * Records of components * Records of materials * Work environment conditions * Suppliers and distributors to maintain records * Records of shipping maintained |  |
| 7.5.10 | **Customer property** |  |  |
|  | The organization shall identify, verify, protect, and safeguard customer property provided for use  or incorporation into the product while it is under the organization’s control or being used by the  organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the  organization shall report this to the customer and maintain records (see 4.2.5). | * Identify,verify, protect, and safeguard customer property * Maintain records |  |
| 7.5.11 | **Preservation of product**  The organization shall document procedures for preserving the conformity of product to requirements  during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts  of a medical device.  The organization shall protect product from alteration, contamination or damage when exposed to  expected conditions and hazards during processing, storage, handling, and distribution by:  a) designing and constructing suitable packaging and shipping containers;  b) documenting requirements for special conditions needed if packaging alone cannot provide  preservation.  If special conditions are required, they shall be controlled and recorded (see 4.2.5). | * Preservation of conformity of product   + Processing   + Storage   + Handling   + And distribution * Constituent parts preserved * Protect product from alteration * Contamination * Damage when exposed to hazards during processing, storage,handling,and distribution * Design and constructing, packaging and shipping containers * Requirements for special conditions * Special conditions controlled and recorded |  |
| 7.6 | **Control of monitoring and measuring equipment** | | |
|  | The organization shall determine the monitoring and measurement to be undertaken and the  monitoring and measuring equipment needed to provide evidence of conformity of product to  determined requirements.  The organization shall document procedures to ensure that monitoring and measurement can be  carried out and are carried out in a manner that is consistent with the monitoring and measurement  requirements.  As necessary to ensure valid results, measuring equipment shall:  a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement  standards traceable to international or national measurement standards: when no such standards  exist, the basis used for calibration or verification shall be recorded (see 4.2.5);  b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded  (see 4.2.5);  c) have identification in order to determine its calibration status;  d) be safeguarded from adjustments that would invalidate the measurement result;  e) be protected from damage and deterioration during handling, maintenance and storage.  The organization shall perform calibration or verification in accordance with documented procedures.  In addition, the organization shall assess and record the validity of the previous measuring results  when the equipment is found not to conform to requirements. The organization shall take appropriate  action in regard to the equipment and any product affected.  Records of the results of calibration and verification shall be maintained (see 4.2.5).  The organization shall document procedures for the validation of the application of computer software  used for the monitoring and measurement of requirements. Such software applications shall be  validated prior to initial use and, as appropriate, after changes to such software or its application.  The specific approach and activities associated with software validation and revalidation shall be  proportionate to the risk associated with the use of the software, including the effect on the ability of  the product to conform to specifications.  Records of the results and conclusion of validation and necessary actions from the validation shall be  maintained (see 4.2.4 and 4.2.5).  NOTE Further information can be found in ISO 10012. | * Procedure for monitoring and measurement * Determine what to monitor and undertake * Calibrated or verified at specific intervals * Or prior to use against standards * Basis used for calibration mentioned * Adjustments and readjustments recorded * Identification inorder to determine calibration status * Safeguard from adjustment that would invalidate the measurement results * Protected from damage and detoriation during handling maintenance and storage * Calibration and verification in accordance with procedures * Record validity of previous measuring results * Appropriate actions when equipment found not to conform to requirements * Records of calibration and verification maintained * Procedure for validation of computer software used for monitoring and measuring requirements |  |
| 8 measurment analysis and improvemetn | | | |
| 8.1 | General | | |
|  | The organization shall plan and implement the monitoring, measurement, analysis and improvement  processes needed to:  a) demonstrate conformity of product;  b) ensure conformity of the quality management system;  c) maintain the effectiveness of the quality management system.  This shall include determination of appropriate methods, including statistical techniques, and the  extent of their use. | * Plan and implement measuremet, monitoring and improvement * Demonstrate conformity * Conformity to QMS * Maintain effectiveness of QMS * Approperiate methods and statistical techniques |  |
| 8.2 | **Monitoring and measurement** |  |  |
| 8.2.1 | **Feedback**  As one of the measurements of the effectiveness of the quality management system, the organization  shall gather and monitor information relating to whether the organization has met customer  requirements. The methods for obtaining and using this information shall be documented.  The organization shall document procedures for the feedback process. This feedback process shall  include provisions to gather data from production as well as post-production activities.  The information gathered in the feedback process shall serve as potential input into risk management  for monitoring and maintaining the product requirements as well as the product realization or  improvement processes.  If applicable regulatory requirements require the organization to gain specific experience from postproduction  activities, the review of this experience shall form part of the feedback process. | * Gather and monitor information relating to requirments met * Procedure for feedback process * Gather data from production and post production activities * Potential inputs for risk management process * Improvement process |  |
| 8.2.2 | The organization shall document procedures for timely complaint handling in accordance with  applicable regulatory requirements.  These procedures shall include at a minimum requirements and responsibilities for:  a) receiving and recording information;  b) evaluating information to determine if the feedback constitutes a complaint;  c) investigating complaints;  d) determining the need to report the information to the appropriate regulatory authorities;  e) handling of complaint-related product;  f) determining the need to initiate corrections or corrective actions.  If any complaint is not investigated, justification shall be documented. Any correction or corrective  action resulting from the complaint handling process shall be documented.  If an investigation determines activities outside the organization contributed to the complaint, relevant  information shall be exchanged between the organization and the external party involved.  Complaint handling records shall be maintained (see 4.2.5). | * Procedure for timely complaint handling * Receiving and recording information * Evaluating information * Investigating complaints * Reporting to regulatory authorities * Handling of complaints related to product * Need to initiate correction, corrective action and preventive actions * Justification for not investigating * Information exchange between organisation and external party * Complaint handling records maintained |  |
| 8.2.3 | **Reporting to regulatory authorities**  If applicable regulatory requirements require notification of complaints that meet specified reporting  criteria of adverse events or issuance of advisory notices, the organization shall document procedures  for providing notification to the appropriate regulatory authorities.  Records of reporting to regulatory authorities shall be maintained (see 4.2.5). | * Reporting of adverse events * Issuance of advisory notice * Procedures documented * Reporting records maintained |  |
| 8.2.4 | **Internal audit**  The organization shall conduct internal audits at planned intervals to determine whether the quality  management system:  a) conforms to planned and documented arrangements, requirements of this International Standard,  quality management system requirements established by the organization, and applicable  regulatory requirements;  b) is effectively implemented and maintained.  The organization shall document a procedure to describe the responsibilities and requirements for  planning and conducting audits and recording and reporting audit results.  An audit program shall be planned, taking into consideration the status and importance of the processes  and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and  methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall  ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.  Records of the audits and their results, including identification of the processes and areas audited and  the conclusions, shall be maintained (see 4.2.5).  The management responsible for the area being audited shall ensure that any necessary corrections  and corrective actions are taken without undue delay to eliminate detected nonconformities and their  causes. Follow-up activities shall include the verification of the actions taken and the reporting of  verification results.  NOTE Further information can be found in ISO 19011. | * Conduct at planned intervals * Requirments of iso 13485 are effective and maintained * Procedure to describe responsibilities and requirements for planning are maintained * Status and importance of process * Results of previous audits * Criteria, scope and methods are defined and recorded * Ensure objectivity and impartiality of process * Shall not audit their own work * Results maintained, identificatins areas audited, processes * Corrections and corrective actions taken according to audit findings * Reporting the verification of the action taken |  |
| 8.2.5 | **Monitoring and measurement of processes**  The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the  quality management system processes. These methods shall demonstrate the ability of the processes to  achieve planned results. When planned results are not achieved, correction and corrective action shall  be taken, as appropriate. | * Monitor and measure QMS processes * Ability to achieve planned results * When results not achieved, correction and corrective action taken |  |
| 8.2.6 | **Monitoring and measurement of product**  The organization shall monitor and measure the characteristics of the product to verify that product  requirements have been met. This shall be carried out at applicable stages of the product realization  process in accordance with the planned and documented arrangements and documented procedures.  Evidence of conformity to the acceptance criteria shall be maintained. The identity of the person  authorizing release of product shall be recorded (see 4.2.5). As appropriate, records shall identify the  test equipment used to perform measurement activities.  Product release and service delivery shall not proceed until the planned and documented arrangements  have been satisfactorily completed.  For implantable medical devices, the organization shall record the identity of personnel performing any  inspection or testing. | * Characteristic of product monitored and measured * Product requirments met * At applicable stages of product relaisation * Planned and documented arrangements and procedures * Evidence of conformity to acceptance criteria * Identity of person authorizing release of product recorded * Test equipment used * Product release and service delivery * Identity of personel performing any inspection or testing(implants) |  |
| 8.3 | **Control of nonconforming product** | | |
| 8.3.1 | **General**  The organization shall ensure that product which does not conform to product requirements is  identified and controlled to prevent its unintended use or delivery. The organization shall document  a procedure to define the controls and related responsibilities and authorities for the identification,  documentation, segregation, evaluation and disposition of nonconforming product.  The evaluation of nonconformity shall include a determination of the need for an investigation and  notification of any external party responsible for the nonconformity.  Records of the nature of the nonconformities and any subsequent action taken, including the evaluation,  any investigation and the rationale for decisions shall be maintained (see 4.2.5) | * Product non conforming is identified * Controlled of unintended use and delivery * Procedure to control to prevent its unintended use or delivery, controls and define related responsibilities authorities for identification, documentation, segregation,evaluation and disposition of NC * Determination of need for investigation * Notification of external party * Records of nature of nonconformity * Subsequent action taken * Evaluation, investigation * Rationale for decisions |  |
| 8.3.2 | **Actions in response to nonconforming product detected before delivery**  The organization shall deal with nonconforming product by one or more of the following ways:  a) taking action to eliminate the detected nonconformity;  b) taking action to preclude its original intended use or application;  c) authorizing its use, release or acceptance under concession.  The organization shall ensure that nonconforming product is accepted by concession only if the  justification is provided, approval is obtained and applicable regulatory requirements are met. Records  of the acceptance by concession and the identity of the person authorizing the concession shall be  maintained (see 4.2.5). | * Eliminate detected nonconformity * Actions to take * Authoriziing its use release or acceptance under concession * Justification * Records of acceptance * Identity of person authorizing the concession |  |
| 8.3.3 | **Actions in response to nonconforming product detected after delivery**  When nonconforming product is detected after delivery or use has started, the organization shall take  action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken  shall be maintained (see 4.2.5).  The organization shall document procedures for issuing advisory notices in accordance with applicable  regulatory requirements. These procedures shall be capable of being put into effect at any time. Records  of actions relating to the issuance of advisory notices shall be maintained (see 4.2.5). | * After delivery, potential effects, records of action taken * Procedure for issueance of advisory notice * Capable of put in effect anytime * Records maintained |  |
| 8.3.4 | **Rework**  The organization shall perform rework in accordance with documented procedures that takes into  account the potential adverse effect of the rework on the product. These procedures shall undergo the  same review and approval as the original procedure.  After the completion of rework, product shall be verified to ensure that it meets applicable acceptance  criteria and regulatory requirements.  Records of rework shall be maintained (see 4.2.5). | * Rework in accordance with documents * Potential adverse effects of rework * Same review and approval as original procedure * Acceptance criteria met * Records maintained |  |
| 8.4 | **Analysis of data** | | |
|  | The organization shall document procedures to determine, collect and analyse appropriate data  to demonstrate the suitability, adequacy and effectiveness of the quality management system. The  procedures shall include determination of appropriate methods, including statistical techniques and  the extent of their use.  The analysis of data shall include data generated as a result of monitoring and measurement and from  other relevant sources and include, at a minimum, input from:  a) feedback;  b) conformity to product requirements;  c) characteristics and trends of processes and product, including opportunities for improvement;  d) suppliers;  e) audits;  f) service reports, as appropriate.  If the analysis of data shows that the quality management system is not suitable, adequate or effective,  the organization shall use this analysis as input for improvement as required in 8.5.  Records of the results of analyses shall be maintained (see 4.2.5). | * Procedure to determine, collect and analyse appropriate data * Suitability, adequacy and effectiveness of quality management system * Methods and statistical techniques * Data from monitoring and measurement * Feedback, * Conformity to product requirements * Characteristics and trends of processes * Opportunities for improvement * Suppliers * Audits * Service reports * Input for improvements * Records maintained |  |
| 8.5 | Improvement | | |
| 8.5.1 | **General**  The organization shall identify and implement any changes necessary to ensure and maintain the  continued suitability, adequacy and effectiveness of the quality management system as well as medical  device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket  surveillance, analysis of data, corrective actions, preventive actions and management review. | * Implement ensure continued suitability, adequacy and effectiveness * Medical safety and performance – * quality policy * quality objectives, * audit results * postmarket surveillance * analysis of data * corrective actions * preventive actions * management reviews |  |
| 8.5.2 | **Corrective action**  The organization shall take action to eliminate the cause of nonconformities in order to prevent  recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions  shall be proportionate to the effects of the nonconformities encountered.  The organization shall document a procedure to define requirements for:  a) reviewing nonconformities (including complaints);  b) determining the causes of nonconformities;  c) evaluating the need for action to ensure that nonconformities do not recur;  d) planning and documenting action needed and implementing such action, including, as appropriate,  updating documentation;  e) verifying that the corrective action does not adversely affect the ability to meet applicable  regulatory requirements or the safety and performance of the medical device;  f) reviewing the effectiveness of corrective action taken.  Records of the results of any investigation and of action taken shall be maintained (see 4.2.5). | * eliminate cause of nonconformity * prevent recurrence * corrective action taken without undue delay * proportionate to effect of nonconformity encountered * procedure to define requiremnts * reviewing non conformities * determining cause of nonconformities * need for action evaluation for non recurrence * documenting actions, changes, * corrective action meets regulatory requirments * safety and performance * effectiveness of corrective action * results of investigations of actions taken |  |
| 8.5.3 | **Preventive action**  The organization shall determine action to eliminate the causes of potential nonconformities in order  to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential  problems.  The organization shall document a procedure to describe requirements for:  a) determining potential nonconformities and their causes;  b) evaluating the need for action to prevent occurrence of nonconformities;  c) planning and documenting action needed and implementing such action, including, as appropriate,  updating documentation;  d) verifying that the action does not adversely affect the ability to meet applicable regulatory  requirements or the safety and performance of the medical device;  e) reviewing the effectiveness of the preventive action taken, as appropriate.  Records of the results of any investigations and of action taken shall be maintained (see 4.2.5). | * eliminate cause of potential non conformity * effects of potential problems * document a procedure * determingin potential non conformities * and causes * evaluating need for action * prevent occurrence of non conformities * planning and documenting action needed * updating documentation * verifying action * adversely affect ability to meet regulatory requirements * requirements of safety and performance of the medical device * reviewing effectiveness of the preventive action * records of the results maintained |  |