QCI – AIMED Voluntary Initiative on Medical Devices

Indian Certification of Medical Devices

Technical Criteria for Certification of Medical Devices – ICMED 13485
COMMITTEE COMPOSITION

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0. Introduction

0.1 Quality Council of India (QCI), India's apex quality facilitation and national accreditation body, and the Association of Indian Medical Device Industry (AIMED) have signed an MoU on 30 October 2014 to develop and operate voluntary certification programmes for Medical Devices in order to enable medical device industry to demonstrate adherence to the best international standards and enhance its credibility in the world market.

While **QCI and AIMED are the joint Scheme owners**, the governing structure of the initiative is under a multi stakeholder Steering Committee and the initiative would be operated on a non-profit but self-sustaining basis. It would have a defined consensus based technical criteria laid down for the medical devices which would be evaluated by competent third party certification bodies. To identify the competence of certification bodies’ auditors for evaluation of technical criteria as devised and certification process, a multi stakeholders Certification committee is being formed. Certification bodies in turn would be accredited by the National Accreditation Board for Certification Bodies (NABCB), which is part of the international system of equivalence of accreditations and certifications, as per appropriate international standards.

The medical devices manufacturer requiring certification against this scheme is required to be certified ultimately by NABCB accredited Certification Bodies duly approved by the Quality Council of India, as the Scheme owner, and complying with the requirements as specified under this Scheme. The requirements that the Certification bodies need to comply with for getting approved by QCI under this Scheme are detailed in this document.

This ICMED Standard specifies requirements for quality management system that can be used by an organization for the design and development, installation and servicing of medical devices and related services.

The Standard can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements.

This is emphasized that the quality management system requirements specified in this ICMED standard are complementary to technical requirements for products.

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs particularly objectives, the products and/or services it provides, processes employed and size and structure of the organization. It is not the intent of this ICMED Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.
There is a wide variety of medical devices and some of the particular requirements if this ICMED standard only apply to the named groups of medical devices. These groups are defined in Clause 3.

0.2 Process approach

This ICMED Standard is based on a process approach to quality management.

Any activity that receives inputs and converts them to outputs can be considered as a process.

For an organization to function effectively, it has to identify and manage numerous linked processes.

Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the “process approach”.

0.3 Relationship with other standards

0.3.1 Relationship with ISO 9001

0.3.2 Relationship with ISO/TR 14969
ISO/TR 14969 is a Technical Report intended to provide guidance for the application of ISO 13485.

0.4 Compatibility with other management systems

This ICMED Standard follows the format of ISO 9001 for the convenience of users in the medical device community.

This ICMED Standard does not include requirements to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management.

However, this ICMED Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this Standard.

The quality management system requirements specified in this ICMED Standard are complementary to requirements for products. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.
1. Scope

1.1 General

In order to promote quality in the Indian Medical Devices industry and to build its credibility, its brand internationally and enhance the user confidence, it is necessary to have an institutional mechanism for operating Voluntary Certification Scheme(s) based on International Best Practices and sound technical Standards and using competent Certifiers, which can promote Medical Devices manufactured in India as high quality products and bring esteem to the Indian Industry.

Considering this a Steering Committee with a diverse representation was formed which deliberated the need for the following activities:

- Setting up of an independent, multistakeholder governing structure for the Scheme – Two Committees, one Technical and one Certification under the Steering Committee.

- Criteria for Certification and any other technical document necessary for the scheme will be decided by the Technical Committee.

- Certification systems including certification process and requirements for Certification bodies etc. will be decided by the Certification Committee.

The Technical Committee has prepared the Technical Criteria for Certification and initially defined 2 Levels of Voluntary Compliance, the Labeling Requirements and Essential Requirements for Safety & Performance. At a future stage a 3rd Level is envisaged for Compliance to specific Product specifications.

This ICMED Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

The primary objective of this ICMED Standard is to facilitate harmonized medical device regulatory requirements for quality management systems. Organizations whose quality management systems conform to this ICMED Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001.
1.2 Application

All requirements of this ICMED Standard are specific to organizations providing medical devices, regardless of the type or size of the organization.

If regulatory requirements permit exclusions of design and development controls (see 7.1.4.d), this can be used as a justification for their exclusion from the quality management system. These regulations can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with this ICMED Standard reflect exclusion of design and development controls.

If any requirement(s) of this iCMED Standard is(are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system and appropriate justification shall be recorded.

The processes required by this ICMED Standard, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system.

2. Normative references

The following referenced documents are indispensable for the application of this document.

ISO 9000 Quality management systems - Fundamentals and vocabulary

3. Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 apply.

Wherever requirements are specified as applying to "medical devices", the requirements apply equally to related services as supplied by the manufacturing facility.

The following definitions should be regarded as generic, as definitions provided in national regulations can differ slightly and take precedence.

3.1 Active implantable medical device

*Active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure*

3.2 Active medical device
medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

3.3 Adverse event:
An “Adverse Event” is either a malfunction or a deterioration in the characteristics or performance of a sold medical device [including accessory(s) and labelling] or use error, which either has caused or could have caused or contributed to death, or serious injury to health of patients or other persons.

3.4 Audit:
Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

3.5 Advisory notice

Notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in

— the use of a medical device,
— the modification of a medical device,
— the return of the medical device to the organization that supplied it, or
— the destruction of a medical device

NOTE Issue of an advisory notice might be required to comply with national or regional regulations.

3.6 Customer complaint

Written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market.

3.7 Clinical evaluation:
The review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation.

3.8 Clinical investigation:
Any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device. (Source – ISO/DIS 14155-1)

3.9 Corrective action:
Action to eliminate the cause of a detected nonconformity or other undesirable situation

3.10 Conformity:
Fulfillment of a requirement

3.11 Customer:
Organization or person that receives a product
3.12 Implantable medical device
Medical device intended
— to be totally or partially introduced into the human body or a natural orifice, or
— to replace an epithelial surface or the surface of the eye,
by surgical intervention, and which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention

NOTE: This definition applies to implantable medical devices other than active implantable medical devices.

3.13 Labelling
written, printed or graphic matter affixed
— to a medical device or any of its containers or wrappers, or
— accompanying a medical device,
related to identification, technical description, and use of the medical device, but excluding shipping documents

NOTE: Some regional and national regulations refer to "labelling" as "information supplied by the manufacturer".

3.14 Medical device
any instrument apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
— investigation, replacement, modification, or support of the anatomy or of a physiological process,
— supporting or sustaining life,
— control of conception,
— disinfection of medical devices,
— providing information for medical purposes by means of in vitro examination of specimens derived from
— the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

NOTE: This definition has been developed by the Global Harmonization Task Force (GHTF). See bibliographic reference [15].

3.15 Sterile medical device
Category of medical device intended to meet the requirements for sterility

NOTE
The requirements for sterility of a medical device might be subject to national or regional regulations or standards.
3.16 **Nonconformity:**
Non-fulfillment of a requirement

3.17 **Organization:**
Group of people and facilities with an arrangement of responsibilities, authorities and relationships

3.18 **Preventive action:**
Action to eliminate the cause of a potential nonconformity or other undesirable potential situation

3.19 **Quality Management System:**
Management system to direct and control an organization with regard to quality.

3.20 **Quality Manual:**
Document specifying the quality management system of an organization

3.21 **Quality Policy:**
Overall intentions and direction of an organization related to quality as formally expressed by top management.

3.22 **Quality Objective:**
Something sought, or aimed for, related to quality.

3.23 **Review:**
Activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives.

3.24 **Record:**
Document stating results achieved or providing evidence of activities performed

3.25 **Risk:**
Combination of the probability of occurrence of harm and the severity of that harm.

3.26 **Traceability:**
Ability to trace the history, application or location of that which is under consideration

3.27 **Validation:**
Confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled

3.29 **Verification:**
Confirmation, through the provision of objective evidence that specified requirements have been fulfilled
4. Quality management systems

4.1 General requirements

a) the medical devices manufacturer shall have an established and documented system for implementation and maintenance of a quality management system;
b) the system includes identification of indicators to measure the effectiveness of the quality management system;
c) the periodicity of measuring of these indicators is defined and documented;
d) the processes required for the implementation of the quality management system are identified and documented.

4.2 Quality Management System processes shall be appropriate to the needs of the organization

a) the organization shall have an established system to identify all the processes, their sequences, results, and interactions;
b) there shall be defined criteria to measure the compliance and effectiveness of all the processes;
c) there shall be a system to measure the adequacy of inputs required for the implementation of all the processes;
d) there shall be a system to evaluate and improve the processes based on measurement of defined indicators.

4.2.1 The organization shall determine the process components

a) the organization shall determine the time line for completion of each process;
b) there shall be a system to track any delay of time period in the completion of processes;
c) there shall be a system within the organization to measure the correctness of those processes of sub-parts of a process that the organization outsources from agencies external to the organization;
d) the various components of all processes with the organization shall be defined and documented;
e) the organization shall identify individuals responsible for all the processes including management representative (M.R.);
f) all the processes required for manufacturing, identification, storing, pre-market authorization, sale, installation, maintenance, repair and disposal shall be documented for every product.

4.3 Documentation requirements

4.3.1 The organization shall have following minimum documents

a) a quality manual which has defined scope, exclusions (if any) and procedures covering all operations of the organization;
b) defined quality policy and quality objectives;
c) documents required for planning, implementation and control of all operations of the organization;

d) documented product specifications for each category, type and model of medical device manufactured in the facility;

e) there exists a procedure to test, review, improve and approve, periodically, the quality management system for adequacy;

f) a system is established to check the compliance of the quality management system with the national/state regulations on manufacture of medical devices;

g) a process to prevent the use of out-dated QMS procedures and documents by having an established system of updating the records.

4.3.2 Control of records

4.3.2.1 Organization shall maintain a robust records management system

a) all records pertaining to the quality management system shall be maintained adequately and appropriately;

b) the records shall be maintained for the time period as prescribed by national/state regulations or in absence of such a regulation, in accordance to a defined and documented policy;

c) responsibility for record maintenance shall be given to identified personnel;

d) records shall be preserved and maintained in environmentally safe conditions;

e) management shall document and establish a procedures to,  
   (i) access, issue and obtain copy of records;
   (ii) address theft of records or conducting investigation for missing records.

4.3.2.2 Record management policy shall support the quality policy of the organization

a) records which establish the conformity of the products to product specifications and standards shall be maintained including batch/sample testing and product verification results;

b) records that do not establish the conformity of the products to product specifications and standards shall be maintained;

c) records of audits, management reviews and observations of compliance/non-compliance shall be kept under the supervision of responsible and identified authorised personnel;

d) records of compliance to regulatory requirements shall be maintained, including certificates required for establishing and running a medical device manufacturing site;

e) records of improvisation or change in manufacturing technique, infrastructure, and training of staff shall be maintained;

f) records of safety management systems and adverse incidents shall be maintained;

g) records of all preventive and corrective actions performed shall be maintained;

h) records of all verifications, validations and calibrations shall be maintained;

i) records of all user/customer feedback and complaints shall be maintained;
j) records of components used for verification of product quality shall be maintained;

k) records of all sale, installation and product commissioning shall be maintained.

5. Management responsibility and commitment

a) the management shall provide evidence of its resolution to develop, implement and improve the quality management system within the organization by communicating to the organisation the importance of meeting customer as well as statutory and regulatory requirements;

b) management reviews of the organization include assessment of the performance of quality Management System and this assessment is documented. Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness and maintain records;

c) top Management shall establish a procedure to identify customer requirements and to measure the capability of the organization to meet those requirements;

d) there shall be a system to ensure that quality objectives and quality management system is communicated to all the divisions of the organization;

e) the management shall identify indicators to measure the performance of quality management system in all the divisions of the organization, which includes collection of suitable data for performance measurement.

6. Resource management

6.1 Organization shall have appropriate and adequate human resources

a) the organization shall have documented information about the minimum number of personnel required for each phase of production;

b) the organization shall have documented information on the skills, trainings and experience required by each category of personnel required in the production process;

c) the organization shall have a documented procedure for selection, induction, training and performance monitoring and appraisal of each category of personnel;

d) the organisation shall comply with statutorily required qualifications and competence levels for performing specific tasks;

e) the organisation shall ensure that personnel hired on temporary basis/daily wages/short term contract are competent for product manufacturing process and this is measured before their involvement with the manufacturing process;

f) the personnel shall be made aware of duties, responsibilities and expectations so as to promote product quality;

g) there shall be defined and documented procedures to take appropriate action for negligence of duty, especially when such negligence adversely affects product quality;

h) there shall be defined procedures to address personnel grievances.
6.2. Organization shall have defined & documented policy and procedure for training the personnel

a) there shall be a procedures to identify training requirements and a documented training schedule/calendar for various categories of personnel;
b) records of trainings shall be maintained for a specified time period;
c) there shall be procedures to monitor and measure the performance of personnel after the training programs;
d) training required for performing special tasks or tasks critical to product quality shall be identified. Records of adequately trained personnel and their competence level measured shall be maintained.

6.2.1 Organization ensures good health of staff against occupational hazards

a) there shall be defined and documented procedures to protect and promote health of the personnel;
b) the procedures shall include a documented schedule and plan for screening of adverse health effects of work on the personnel;
c) there shall be procedures to provide compensation to the personnel in case of any adverse effects on health or life of the personnel due to nature of work.

6.3. Infrastructure

6.3.1 The organization has appropriate infrastructure to achieve quality product

a) appropriate building, fencing, shelter and environment controlling devices shall be installed and operational in the manufacturing facility, as per the requirement of the products and manufacturing processes;
b) appropriate energy storage and transmission equipment shall be in operational state and national/state certifications of these installations are valid as on date;
c) appropriate and adequate fire prevention and firefighting installations shall be in functional state in the manufacturing facility;
d) the equipment existing in the manufacturing facility shall be assessed for their appropriateness for the manufacturing process and is documented;
e) all such equipment shall comply with national/state/manufacturer’s guidelines for installation, commissioning and functioning;
f) the appropriate equipment/ facilities shall be adequately installed in the manufacturing facility for effective communication within the different sections of the facility.

6.3.1.1 Specific area requirements shall be met adequately

a) the manufacturing area shall be identified into sections of appropriate size so as to prevent mix-up of conforming & non-conforming products;
b) the area size and area environment of each section of the manufacturing site dedicated to a specific process/processes shall be conducive for integration of quality components in the product;

c) material receipt areas, Storage areas, cleaning and processing areas shall be segregated to avoid mix up of products that may exist during different stages of production;

d) areas where products of biological origin are being used shall be segregated physically & environmentally.

6.3.2 The organization shall maintain an environment that supports product quality

a) there shall be documented information on the environmental requirements of the facility;

b) there shall be a documented process planning to monitor, control and maintain the required environment;

c) areas that need special environment conditions due to nature of products at specific stages of production shall be monitored;

d) there shall be devices installed to track the trend and regulate the environment conditions (like temperature, pressure, light, humidity, air velocity, particle size etc.) in areas that have special requirement;

e) adequate precautions shall be taken by means of appropriate infrastructure to control and prevent pollution, dust, dirt and any other form of contamination to the products/production area.

6.3.2.1 The organization shall maintain proper waste management & disposal system

a) the waste management regulations as per national/state regulations shall be complied with;

b) the infrastructure for waste management & disposal systems shall be checked by an appropriate authority and records maintained;

c) the waste management & disposal system shall not endanger the quality or conformity of the product;

d) the personnel shall be adequately trained to follow a documented waste management & disposal system;

e) any rejected or non-conforming product when disposed, the record of the identity of such a product shall be maintained to avoid it’s re-use.

6.3.2.2 The organization has a plan for the cleanliness of the facility

a) there shall be a documented procedures for cleaning, fumigation, disinfection of various parts of the manufacturing facility as per requirements of the production process;

b) the reagents, chemicals or other items used for cleaning, fumigation or disinfection and the procedure for their use shall be available;

c) the schedule for cleaning, fumigation, disinfection of various sections of the manufacturing facility shall be documented and compliance recorded;
d) there shall be a documented procedure(s) to monitor the indicators suggestive of appropriately clean environment (cultures) at specified places in the manufacturing site;

e) there shall be a documented procedure(s) to protect specific manufacturing equipment from contamination;

f) there shall be a procedures for restricted entry into clean areas;

g) there shall be a documented procedures for disinfection of personnel, items and clothing before their entry into clean/aseptic areas;

h) there shall be a documented procedures for disposal of contaminated items;

i) there shall be a documented procedures to periodically screen the health of the personnel who are required to work in clean/aseptic areas;

j) there shall be a documented code for hand washing, clothing, masking, gowning for personnel who are required to work in clean/aseptic areas.

6.3.3 Resources (manmade or natural) required to maintain appropriate environment shall be available in proper quality & quantity

a) the quality and quantity of water available in the facility shall be appropriate for the production process and this appropriateness is scientifically established and observations recorded;

b) the quality of air available in the facility shall be appropriate for the production process and this appropriateness is scientifically established and observations recorded;

c) the air velocity and direction shall be appropriate for the production process;

d) records of trends of controlled environment shall be maintained for a specified time period;

e) lighting requirements shall be specified and complied for various stages of production.

6.3.3.1 Organization shall plan for maintenance of all components of infrastructure

a) there shall be documented periodic preventive maintenance plans for building, equipment and energy installations in the facility;

b) the records of preventive maintenance shall be maintained as per specified period;

c) organisation shall identify person(s) who is (are) responsible for carrying out the maintenance;

d) maintained procedure shall be documented, the lapses, delays and/or exclusions in maintenance schedule shall be documented and brought to the notice of identified personnel;

e) the recommendations for conducting major repair that may arise during such maintenance shall be documented along with action taken report.

7. Product realization

7.1 Planning of product realization
7.1.1 Organization shall plan for all the phases of product realization

a) there shall be a system to identify and provide all inputs required for the various phases of product realization;
b) the organisation shall provide resources specific to the product;
c) the organisation shall document verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
d) the objectives of Quality Management System shall be integrated throughout product realization;
e) there shall be a system to identify risks to product quality during the phases of product realization and documented procedures for risk minimization;
f) the organization shall maintain a production schedule;
g) the records of past production schedules shall be maintained as per a defined and documented policy of the organization;
h) the organization shall keep records needed to provide evidence that the realization processes and resulting product meet requirements.

7.1.2 Organization has established criteria for product acceptance

a) there shall be a system to measure conformance of products throughout the product realization process;
b) the product shall be verified and validated against pre-determined standards;
c) there shall be documented acceptance and rejection criteria for all products;
d) there shall be system of monitoring and testing of all processes that can influence product quality, acceptance and rejection.

7.1.3 Product realization meets intended and implied requirements

a) customer requirements related to the products shall be defined, reviewed and documented;
b) the products shall meet the requirements of the customer from the point of completion of the products till the point of final use and is documented;
c) the product shall meet national/state regulations;
d) when product requirements change (by law or by any other reason), the product specifications shall be reassessed for its intended or specified use and documented;
e) changes in product specifications shall be brought to the knowledge of users/Customers.

7.1.4 The manufacturing plan incorporates product quality & safety

a) the various phases of manufacturing shall be identified;
b) defined controls shall exist at various stages to check and ensure product conformity;
c) there shall be a system to monitor and test the accuracy in design and specifications of the products during the various phases of manufacturing;
d) the entire plan for product realization from design to dispatch shall be documented including Design Input Review, Design Output Review, Design Verification, Design Validation and Design Changes, If any;
e) product identification shall be done based on specified criteria;
f) personnel shall be made aware of the manufacturing plan, of their roles and interactions during the various stages of the plan;
g) verification and validation of quality parameters for the product shall be performed as per a documented process;
h) verification and validation of measuring instruments used for product manufacturing shall be performed as per a documented process;
i) verification and validation of computer programs used for product manufacturing shall be performed as per a documented process;
j) records of all calibrations, verification and validations shall be maintained as per a defined policy;
k) validation of processes of production shall be performed as per a documented process.

7.2 Customer-related processes

7.2.1 Customer communication

The organization shall determine and implement effective arrangements for communication within organization and with customers in relation to:

a) there shall be a communication system to exchange information on product quality, within the various divisions of the organization;
b) information crucial to product quality shall be communicated within a specified time period as per a defined and documented policy;
c) communications to the users/customers regarding product quality, precautions, product installation, maintenance and use shall be done under an established procedure;
d) enquiries, contracts or order handling, including amendments, and;
e) customer feedback, including customer complaints.

7.3 Traceability, labelling, cleaning and/or sterilization for products shall be ensured

7.3.1 Traceability

a) there shall be a defined policy to ensure traceability of all input components used for product manufacturing;
b) there shall be a defined policy to ensure traceability of the final products;
c) the traceability shall be ensured to the extent defined for various products;
d) there exists a system to initiate appropriate action whenever traceability is compromised.

7.3.2 Labelling

a) the labelling of medical devices shall follow guidelines prescribed by national/state/scientific recommendations including the mention of shelf life/ expiry date of the product;
b) the extent and type of labelling shall include precautionary material specific to the medical device;
c) there shall be a system to communicate information on packaging and storing;
d) there shall be a procedure to ensure that the appropriate documents are accompanied with products for the necessary instructions about installation and usage of the product;
e) labelling tags for intended use shall be attached according to an appropriate system to each product.

7.3.3 Cleaning and/or sterilization

a) there shall be defined and documented policy specific to the products for performing the cleaning and/or sterilization of the product at appropriate stages of the manufacturing;
b) there shall be defined & documented process based on which cleaning and/or sterilization is performed and validated prior to market release;
c) there shall be a documented criteria based on which the cleaning and/or sterilization completion is evaluated, maintained and records maintained;
d) guidelines shall accompany the products that are to be subjected to cleaning/sterilization before their final use for intended purposes;
e) there shall be procedures to prevent contamination of the products by other potentially contaminated products;
f) the suitability of all input components that could influence the sterility of products shall be assessed.

7.4 Operational Life Cycle Management

7.4.1 Organization shall ensure consistency in product characteristics

a) there shall be a system to confirm that the product specifications match with those specified for the product;
b) any change in product specifications, uses and precautions related to product use shall be incorporated in the relevant documents;
c) there shall be a documented policy that would prescribe procedure for communication of changes in uses and precautions to the existing users.

7.4.2 Installation procedures shall be determined by the organization

a) the installation protocols shall include briefing to the customer and inspection of the site of installation;
b) there shall be a system to maintain the details of transportation of medical devices and record of this is maintained for a defined period;
c) for specific products as per defined policy, the unique identification of product shall be maintained throughout the sales, delivery, installation process and after installation;
d) the requirements for product installation that are expected from the customer’s side shall be specified beforehand giving customer a time period as per the defined policy;
e) the property of the customer that is handled by the organization during the installation shall be conserved against undue damages and this responsibility shall be defined in product installation policy;
f) the instructions for installation of the product shall be communicated with adequate documentation;
g) the shelf life of the product, including its warranty/guarantee period shall be mentioned in the documents supplied to the customer with the product;
h) there shall be a defined policy for the financial responsibility of any damage to the product from the point of dispatch to the point of receipt at the installation site;
i) there shall be a system to ensure that the arrangements (infrastructure/energy/manpower requirements etc.) for installation are completed before the installation phase begins;
j) there shall be a documented system to ensure the compliance of all regulatory requirements necessary for the medical device installation and scheduled operation before the installation begins;
k) there shall be a system to maintain documentation of completion of installation and successful operation of the medical device.

7.4.3 Organization shall maintain after sale documents

a) if defects or non-conformity is detected in the product after receipt of the product at the installation site, there shall be an established and documented procedures to initiate return/repair of the product;
b) products returned to the manufacturer after delivery to the customer shall undergo a process of identification;
c) rejected/ returned products to the manufacturer shall be kept separate from the conforming products;
d) there shall be a system to initiate investigation of the cause of non-conformity and procedures to prevent re-occurrence.

7.4.4 Non-conformity after dispatch and maintenance procedures shall be determined by the organization

a) the maintenance manual shall be included as per a defined policy for every specified category of products;
b) records of servicing activities performed by the manufacturer shall be documented;
c) the unique identification of product shall be maintained after installation – for specific products as per a defined policy;
d) if the investigation for the cause of non-conformity is not performed, the reason for not performing such investigation shall be documented;
e) when the non-conformity is detected after installation or after the product has been operationalized, there shall be a system to detect and document the effects and impacts of such a non-conformity, if any;
f) there shall be a system to preserve the quality of the product during internal processing, transit and delivery to the intended destination;
g) any non-conformity arising during the transit shall be brought to the notice of the manufacturer and the customer based on a specific procedure.
7.4.5 The organization shall arrange for post-production requirements

a) there shall be a system to evaluate the ability of the product to meet intended use;
b) verification of the product shall be performed according to an established procedure and results shall be documented;
c) validation of the product shall be performed according to an established procedure and results shall be documented;
d) there shall be a system to identify non-conformity in final product and initiate corrective action;
e) there shall be a system to record any deviations in the product as compared to the documented characteristics defined for that product;
f) there shall be a system to handle unintended acceptance and/or use of non-conforming products.

7.5 Purchase

7.5.1 Organization shall have a procurement system that supports product quality

a) there shall be a system to select and evaluate suppliers based on their ability to supply product as per product/organisation requirements;
b) purchase requirements including purchase product specification shall be adequately specified before placing order to the suppliers;
c) there shall be a system to check the quality and specifications of input components that are used in the manufacturing of the final product;
d) the input components shall be selected based on pre-defined and documented criteria and undergo verification before usage;
e) there shall be a system to identify and separate the non-conforming input components and to prevent their unintended use in the manufacturing process;
f) there shall be a system to ensure the use of proper instruments and equipment for the manufacturing process of all products.


8.1 Organization shall be led by a management which promotes quality in products and consistency in processes

a) there shall be evidence of management effort to promote quality & safety in all the products;
b) there shall be defined and documented roles and responsibilities for every member of organization;
c) there shall be documented procedures to monitor and measure the performance of quality management system;
d) there shall be records of compliance of all regulatory and/or national/state regulations;
e) there shall be a defined procedure to update the requirement of quality management system, regulatory requirements and product safety guidelines;

f) there shall be evidence of compliance to the market authorization regulations for all the products.

8.2 Organization shall have appropriate and adequate number of audits

a) there shall be documented procedures to conduct audits;

b) audits shall be conducted at specified time intervals by qualified and competent auditors, independent of the area of their activity;

c) there shall be evidence for the action taken on the recommendations of the audit findings along with reasons for not taking action (if any);

d) there shall be records of internal and/or external audits of the processes of the facility and the records are preserved for a specified time period.

8.3 Organization ensures product safety, reliability and credibility

a) there shall be a documented management policy for preserving and promoting products quality;

b) there shall be defined and documented procedures to promote product reliability and reasons for failing product reliability is analyzed and recorded;

c) there shall be procedures to educate the existing and new customers/users of the product, of any changes in the product quality and safety before or after its sale and/or use;

d) there shall be a procedure to collect, analyze and incorporate customer/user feedback in enhancing the product quality;

e) adequate information shall be provided to the customer/user about scope, limitations and jurisdiction of any legal dispute that may arise about the product;

f) there shall be a policy to bring to public notice any adverse events or potentially adverse events that could arise due to manufacturing fault in the product that are already sold;

g) there shall be a policy to bring to the notice of appropriate national/ state/ regulatory authority, any adverse events or potentially adverse events that could arise due to manufacturing fault in the product that are already sold;

h) there shall be a policy to take appropriate permission from national/ state/ regulatory authority, before including a medical device product for any clinical trial that needs to be conducted to establish the efficacy of effect of the medical device. Not applicable for clinical evaluation & investigations;

i) there shall be special instructions for use of the product for special groups of users like neonates, children, elderly, physically and/or mentally differently able users of the product;

j) the organization shall have established procedures for incorporating continuous quality improvement in the product;

8.4 Assessment and improvement in the Quality Management System

a) there shall be a system for the assessment and improvement of Quality Management System;
b) there shall be a system to collect view, feedbacks and reports on performance of Quality Management System;

c) there shall be a system for detection of failures/ non conformities in Quality Management System;

d) there shall be a system to initiate action to rectify the failures/ non conformities identified in the Quality Management System and prevent it's reoccurrence.
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2. ISO 10002, Quality management – Customer satisfaction – Guidelines for complaints handling in organizations
3. ISO 10012, Measurement management systems - Requirements for measurement processes and measuring equipment
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5. ISO 11135, Medical devices - Validation and routine control of ethylene oxide sterilization (Corrigendum 1 published 1994)
6. ISO 11137, Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization (Corrigendum 1 published 1995; Amendment 1 published 2001)
7. ISO 13641, Elimination or reduction of risk of infection related to in vitro diagnostic medical devices
8. ISO 13683, Sterilization of health care products - Requirement for validation and routine control of moist heat sterilization in health care facilities
9. ISO 14155-1, Clinical investigation of medical devices for human subjects - Part 1: General requirements
10. ISO 14155-2, Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans
11. ISO 14160, Sterilization of medical devices - Validation and routine control of sterilization of Single-use medical devices incorporating materials of animal origin by liquid chemical sterilants
12. ISO 14937, Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilizing agent
14. ISO 14971, Medical devices - Application of risk management to medical devices
15. ISO 15223-1, Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements
16. ISO 19011, Guidelines for quality and/or environmental management systems auditing.
Amendment Sheet

RECORD OF CURRENT STATUS OF THE
Technical Criteria for Certification of Medical Devices
The current status of each page and the history of change of the Technical Criteria for Certification of Medical Devices are set out below.

<table>
<thead>
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- Highlighting is used within the text of the Requirements to identify current amendments with any deleted text shown with a strikethrough.
- Previous amendments or revisions are incorporated into the text. Where text on an individual page is amended the page will be reissued.
- Each reissued page is identified in the header as a ‘page amendment’ making reference to the “revision number” and the “revision issue date”.