ICMED 9000

QCI – AIMED Voluntary Initiative on Medical Devices

Indian Certification of Medical Devices

Technical Criteria for Certification of Medical Devices – ICMED 9000

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Technical Committee for QCI – AIMED Voluntary Initiative on Medical Devices

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1 Scope

1.1 Scope of Document

This document specifies the requirements for a quality management systems for medical device industry which

a) needs to demonstrate its ability to consistently provide medical devices that meet customer and applicable statutory and regulatory requirements, and
b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

1.2 Relationship with ISO 9001

The requirements prescribed in this document shall be read with the requirements prescribed in ISO 9001:2015.

1.3 Application

All requirements of this document are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this document cannot be applied due to the nature of an organization and its products, this can be considered for exclusion.

If any requirement(s) of this document 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, provided such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

2. References

The following referenced documents are necessary for the application of this document:

a) ISO 9000:2015 Quality management systems — Fundamentals and vocabulary
b) ISO 9001:2015 Quality Management System - Requirements

3. Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 and ISO 9001:2015 apply. Throughout the text of this document, wherever the term “product” occurs, it can also mean “service”.

4. Quality management systems	Corresponding Clause of ISO 9001:2015
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;	4.4.1, 4.4.2
b) the system includes identification of indicators to measure the effectiveness of the quality management system as well as Quality Objectives at relevant functions and processes. The system shall include the planning for achieving these quality objectives as well as for measuring its effectiveness;	4.4.1, 6.2.1, 9.3
c) the periodicity of measuring of these indicators is defined and documented;	9.3
d) the processes required for the implementation of the quality management system are identified and documented.	4.4.1
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 after assessing the risks and opportunities associated with the QMS, assign the responsibilities and authorities for these processes;	4.4.1
b) there shall be defined criteria to measure the compliance and effectiveness of all the processes;	4.4.1 (c)
c) there shall be a system to measure the adequacy of inputs required for the implementation of all the processes;	4.4.1 (a)
d) there shall be a system to evaluate and improve the processes based on measurement of defined indicators.	4.4.1 (g) & (h)
4.2.1 The organization shall determine the process components	
a) the organization shall determine the time line for completion of each process;	4.4.1 (a), (b) & (c)
b) there shall be a system to determine the resources needed for the processes, make them available as and when required and also track any delay of time period in the completion of processes;	4.4.1 (d) & (h)
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;	4.4.1 (c), 8.4.2
d) the various components of all processes with the organization shall be defined and documented;	4.4.1 (a)
e) the organization shall identify individuals responsible for achieving the set Quality Objectives as well as for all the processes including management representative (M.R.);	4.4.1 (e), 5.3, 6.2.2
f) all the processes required for manufacturing, identification, storing, pre-market authorization, sale, installation, maintenance, repair and disposal shall be documented for every product.	8.1

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;	4.3, 4.4.2
b) defined the quality policy and quality objectives which are communicated, understood and applied within the organization;	5.2, 6.2.1
c) documents required for planning, implementation and control of all operations of the organization;	4.4.2
d) documented product specifications for each category, type and model of medical device manufactured in the facility;	8.1, 8.2.2
e) there exists a procedure to test, review, improve and approve, periodically, the quality management system for adequacy;	4.4.1, 9.3
f) a system is established to check the compliance of the QMS with the national/state regulations on manufacture of medical devices;	8.2.2, 8.4.2, 8.5.5
g) a process to prevent the use of out-dated QMS procedures and documents by having an established system of updating the documented information	7.5
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;	7.5.1
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;	7.5.3
c) responsibility for record maintenance shall be given to identified personnel;	7.5.2
d) records shall be preserved and maintained in environmentally safe conditions;	7.5.3.2
e) management shall document and establish procedures to:	7.5.3
i. access, issue and obtain copy of records;	7.5.3.2
ii. address theft of records or conducting investigation for missing records.	7.5.3.1
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;	8.1, 8.6,
b) records that establish that products are not conforming to product specifications and standards shall be maintained;	8.7
c) records of audits, management reviews and observations of compliance / non-compliance shall be kept under the supervision of authorised personnel;	7.5, 9.2, 9.3, 10.2

d) *records of compliance to regulatory requirements shall be maintained, including certificates required for establishing and running a medical device manufacturing site;*	7.1.3, 5.1.2, 8.2
e) records of improvisation or change in manufacturing technique, infrastructure, and training of staff shall be maintained;	8.5.6 , 7.2
f) records of all preventive and corrective actions performed, shall be maintained;	10.2.2
g) records of all verifications, validations and calibrations shall be maintained;	7.1.5, 8.5, 9.1.3
h) records of all user/customer feedback and complaints shall be maintained;	8.2.1, 9.1.2, 9.3.2
i) records of components used for verification of product quality shall be maintained;	, 7.1.5, 9.1.1
j) *records of all sale, installation and product commissioning shall be maintained.*	8.2.3/ 8.6
4.4 Context of an organization	
a) The medical devices manufacturer shall determine the external and internal factors that can affect the quality management system of the organization.	4.1
b) The medical devices manufacturer shall determine the relevant requirements of the relevant interested parties in order to prevent any adverse effect on the quality management system of the organization.	4.2
c) The medical devices manufacturer shall develop a system to monitor the changes in the external and internal factors as well as in the expectations of the relevant interested parties in order to prevent adverse effect on the quality management system of the organization.	4.1, 4.2
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;	5.1.1
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;	9.3.1
c) top Management shall establish a procedure to identify customer requirements and to measure the capability of the organization to meet those requirements;	5.1.2
d) there shall be a system to ensure that quality objectives and quality management system is communicated to all the divisions of the organization;	5.2.2, 6.2.1, 7.3

e) The management shall identify indicators to measure the performance of QMS in all the divisions of the organization, which includes collection of suitable data for performance measurement.	6.2.1
f) The management shall consider the issues / factors and relevant requirements of relevant interested parties as per 4.4 and determine the risks and opportunities that need to be addressed.	6.1.1
g) The Management shall plan the actions to address the identified risks and opportunities and plan to integrate and implement these actions into its QMS processes.	6.1.2
h) The Management shall identify the methods to evaluate the effectiveness of the actions planned and taken.	6.1.2
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;	7.1.2
b) the organization shall have documented information on the skills, trainings and experience required by each category of personnel required in the production process;	7.2
c) the organization shall have a documented procedure for selection, induction, training and performance monitoring and appraisal of each category of personnel;	7.2
d) the organisation shall comply with statutorily required qualifications and competence levels for performing specific tasks;	7.2
e) the organisation shall ensure that personnel hired on temporary basis/daily wages/short term contract, are competent to deliver the inputs in the product manufacturing process and this is measured before their involvement with the manufacturing process;	7.2
f) the personnel shall be made aware of duties, responsibilities and expectations so as to promote product quality;	7.3
g) The Medical Devices Manufacturer shall determine the knowledge necessary for the operations of its processes and to achieve conformity to the Medical Devices and allied services and make the same available to the extent necessary, either from internal sources or from external providers of knowledge.;	7.1.6
h) The Medical Devices Manufacturer shall monitor the changing needs and trends and shall consider its current knowledge to determine the necessity of additional knowledge and required updates;	7.1.6, 6.3
6.2. Organization shall have defined & documented policy and procedure for training the personnel	
a) there shall be a procedure to identify training requirements and a documented training schedule/calendar for various categories of personnel;	7.2

b) records of trainings shall be maintained for a specified time period;	7.2
c) there shall be a procedures to monitor and measure the performance of personnel after the training programs;	7.2
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.	7.2
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 made operational in the manufacturing facility, as per the requirement of the products and manufacturing processes;	7.1.1, 7.1.3, 7.1.4, 7.1.5
b) appropriate energy storage and transmission equipment shall be in operational state and national/state certifications of these installations shall be valid as on date;	7.1.4, 7.1.5
c) appropriate and adequate fire prevention and fire-fighting installations shall be in functional state in the manufacturing facility;	7.1.4, 7.1.5
d) the equipment existing in the manufacturing facility shall have been assessed for their appropriateness for the manufacturing process and is documented;	7.1.4, 7.1.5
e) all such equipment shall comply with national / state / manufacturer's guidelines for installation, commissioning and functioning;	7.1.4, 7.1.5
f) the appropriate equipment/ facilities shall be adequately installed in the manufacturing facility for effective communication within the different sections of the facility.	7.1.4, 7.1.5
6.3.1.1 Specific area requirements shall be met adequately	
The manufacturing area shall be identified into sections of appropriate size so as to prevent mix-up of conforming & non-conforming products.	8.5.2, 7.1.3, 8.7
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;	7.1.4, 7.1.5
b) there shall be a documented process planning to monitor, control and maintain the required environment;	7.1.4, 7.1.5
c) areas that need special environment conditions due to nature of products at specific stages of production, shall be monitored;	7.1.4, 7.1.5
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;	7.1.4, 7.1.5
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.	7.1.4, 7.1.5
6.3.2.1 The organization shall maintain proper waste management & disposal system	

a) *the waste management regulations as per national/state shall be complied with;*	7.1.4, 7.1.5
b) *the infrastructure for waste management & disposal systems shall be checked by an appropriate authority and records maintained;*	7.1.4, 7.1.5
c) *the waste management & disposal system shall not endanger the quality or conformity of the product;*	7.1.4, 7.1.5
d) *the personnel shall be adequately trained to follow a documented waste management & disposal system;*	7.2
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.	8.7
6.3.2.2 The organization has a plan for the cleanliness of the facility	
The reagents, chemicals or other items used for cleaning, fumigation or disinfection and the procedure for their use shall be available.	7.1
6.3.3 Resources (manmade or natural) required to maintain appropriate environment shall be available in right quality & quantity	
a) the quality and quantity of water available in the facility shall be appropriate for the production process and this appropriateness shall be scientifically established and observations recorded;	7.1.4, 7.1.5
b) the quality of air available in the facility shall be appropriate for the production process and this appropriateness shall be scientifically established and observations recorded;	7.1.4, 7.1.5
c) the air velocity and direction shall be appropriate for the production process;	7.1.4, 7.1.5
d) records of trends of controlled environment shall be maintained for a specified time period;	7.1.4, 7.1.5
e) lighting requirements shall be specified and complied for various stages of production.	7.1.4, 7.1.5
6.3.3.1 Organisation shall plan for maintenance of all components of infrastructure	
a) there shall be a documented periodic preventive maintenance plans for building, equipment and other utility installations in the facility;	7.1.1, 7.1.3, 7.1.6
b) the records of preventive maintenance shall be maintained as per a specified period;	7.1.3, 7.1.6
c) organisation shall identify person(s) who is (are) responsible for carrying out the maintenance;	7.1.2, 7.2 , 7.4
d) maintenance procedure shall be documented, the lapses, delays and/or exclusions in maintenance schedule shall be brought to the notice of identified personnel;	7.1.1, , 7.1.6
e) the recommendations for conducting major repair that may arise during such maintenance, shall be documented along with action taken report.	7.1.1, 7.1.2, 7.1.6, 7.3, 7.4
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;	8.1
b) the objectives of quality management system shall be integrated throughout product realization;	8.1
c) the organization shall maintain a production schedule;	8.1
d) the records of past production schedules shall be maintained as per a defined and documented policy of the organization.	8.1
7.1.2 Organization shall established criteria for product acceptance	
a) there shall be system to measure conformance of products throughout the product realization process;	8.1, 8.6, 9.1.3
b) the product shall be verified and validated against pre-determined standards;	8.1, 8.6, 9.1.3
c) there shall be documented acceptance and rejection criteria for all products;	8.1, 8.6, 9.1.3
d) there shall be a system of monitoring and testing of all processes that can influence product quality, acceptance and rejection.	8.1, 9.1.3
7.1.3 Product realization shall meet intended and implied requirements	
a) the product shall meet the requirements of the customer from the point of completion of the products till the point of final use and shall be documented.	8.2.2, 8.6
b) the product shall meets national/state regulations. There shall be a system for determining the changes in the product, services and/or processes in order to meet the national / state regulation as well as the customer requirement/s and the same shall be carried out in a planned manner;	6.3, 8.2.2, 8.2.4
c) 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;	8.2.2
d) changes in product specifications shall be brought to the knowledge of users/Customers.	8.2.1, 8.2.3
7.1.4 The manufacturing plan incorporate product quality & safety	
a) the various phases of manufacturing shall be identified;	8.5.1
b) defined controls shall exist at various stages to check and ensure product conformity;	8.5.1
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;	8.5.1
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;	8.3.2, 8.5.1
e) product identification shall be done based on specified criteria;	8.5.2
f) personnel shall be made aware of the manufacturing plan, of their roles and interactions during the various stages of the plan;	8.5.1

g) verification and validation of quality parameters for the product shall be performed as per a documented process;	8.5.1, 9.1.3
h) verification and validation of measuring instruments used for product manufacturing shall be performed as per a documented process;	7.1.5.1
i) records of all calibrations, verification, validations and traceability shall be maintained as per a defined policy.	7.1.5.2
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;	7.4
b) communications to the users/customers regarding product quality, precautions, product installation, maintenance and use is done under an established procedure;	8.2.1
c) enquiries, contracts or order handling, including amendments;	8.2.1
d) customer feedback, including customer complaints.	8.2.1
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;	8.5.2
b) there shall be a defined policy to ensure traceability of the final products;	8.5.2
c) the traceability shall be ensured to the extent defined for various products.	8.5.2
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;*	8.5.2, 8.5.4
b) *the extent and type of labelling shall include precautionary material specific to the medical device;*	8.5.2
c) *there shall be a system to communicate information on packaging and storing;*	8.5.2, 8.5.4
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;*	8.5.2, 8.5.4
e) *labelling tags for intended use shall be attached according to an appropriate system to each product.*	8.5.2
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;*	8.5.1

b) *there shall be defined & documented process based on which cleaning and /or sterilization is performed;*	8.5.1
c) *there shall be a documented criteria based on which the cleaning and/or sterilization completion is evaluated;*	8.5.1
d) *guidelines shall accompany the products that are to be subjected to cleaning/sterilization before their final use for intended purposes;*	8.5.4
e) *there shall be procedures to prevent contamination of the products by other potentially contaminated products;*	8.5.1, 8.5.4
f) *the suitability of all input components that could influence the sterility of products shall be assessed.*	8.5.1
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;	8.6, 9.1.3
b) any change in product specifications, uses and precautions related to product use shall be incorporated in the relevant documents;	8.3.6
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, 8.2.1
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;*	8.2.2, 8.5.1
b) 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;	8.5.3
c) *the instructions for installation of the product shall be communicated with adequate documentation;*	8.2.1, 8.2.2, 8.5.1, 8.5.4
d) *the shelf life of the product, including its warranty/guarantee period shall be mentioned in the documents supplied to the customer with the product.*	8.5.4
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;	8.7
b) products returned to the manufacturer after delivery to the customer shall undergo a process of identification;	8.7
c) rejected/ returned products to the manufacturer shall be kept separate from the conforming products;	8.7
d) there shall be a system to initiate investigation of the cause of non-conformity and procedures to prevent re-occurrence.	10.2
7.4.4. Non-conformity after dispatch and maintenance procedures shall be determined by the organization	

a) 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;	8.7
b) there shall be a system to preserve the quality of the product during the transit;	8.5.4
c) *any non-conformity arising during the transit shall be brought to the notice of the manufacturer and the customer based on a specific procedure;*	8.5.4, 8.7
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;	9.1.3
b) verification of the product shall be performed according to an established procedure and results shall be documented;	9.1.3
c) validation of the product shall be performed according to an established procedure and results shall be documented;	8.3.4
d) there shall be a system to identify non conformity in final product and initiate corrective action;	8.7, 9.1.3
e) there shall be a system to record any deviations in the product as compared the documented characteristics defined for that product;	8.7
f) there shall be a system to handle unintended acceptance and/or use of non-conforming products.	8.7
7.5 Purchase	
7.5.1 Organization shall have a procurement system that supports product quality	
a) there shall be a system to check the quality and specifications of input components that are used in the manufacturing of the final product;	8.4.3, 9.1.3
b) the input components shall be selected based on pre-defined and documented criteria and undergo verification before usage;	8.4.3, 9.1.3
c) there shall be a system to identify and separate the non-conforming input components and to prevent their unintended use in the manufacturing process;	8.7
d) there shall be a system to ensure the use of proper instruments and equipment for the manufacturing process of all products.	8.5.1
8. Responsibility of Management – Measurement, Analysis and Improvement	
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;	5.1.1, 5.3
b) there shall be defined and documented roles and responsibilities for every member of organization;	5.3
c) there shall be documented procedures to monitor and measure the performance of quality management system;	9.3

d) there shall be records of compliance of all regulatory and/or national/state regulations;	5.1.1
e) there shall be a defined procedure to update the requirement of quality management system, regulatory requirements and product safety guidelines.	6.3, 9.3.1
8.2 Organization shall have appropriate and adequate number of audits	
a) there shall be documented procedures to conduct audits;	9.2
b) audits shall be conducted at specified time intervals by qualified and competent auditors, independent of the area of their activity;	9.2
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);	9.2
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.	9.2
8.3 Organization shall ensure product safety, reliability and credibility	
a) there shall be a documented management policy for preserving and promoting products quality;	8.5.4
b) there shall be defined and documented procedures to promote product reliability and reasons for failing product reliability is analyzed and recorded;	9.1.3
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;	9.1.2
d) there shall be a procedure to collect, analyze and incorporate customer/user feedback in enhancing the product quality;	9.1.2
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;	8.2.2
f) *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;*	5.1.1, 8.3.4
g) the organization shall have established procedures for incorporating continuous quality improvement in the product.	9.1.3, 10.3
8.4 Assessment and improvement in the quality management system	
a) a) there shall be a system for the assessment and improvement of quality management system;	9.3, 10.3
b) there shall be a system to collect view, feedbacks and reports on performance of quality management system;	9.3, 9.1.2, 9.1.3
c) there shall be a system for detection of failures/ non conformities in quality management system;	9.1.3
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.	10.2

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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.

Sl. No.	Date Of Amendment	Page No.	Amendment details
01	August 2016	All	Issue 01
02	January 2019	All	Issue 02 updated to include requirements of ISO 9001:2015

- 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”.