

Section 5A



QCI – AIMED Voluntary Initiative on Medical Devices

Indian Certification of Medical Devices (ICMED) Scheme

CBs Auditor Competence Requirements for ICMED 13485 Plus

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1. Introduction

- 1.1 This is one document in a collection of documents produced by the QCI intended to implement the concept of a Medical Device third party assessment under the ICMED 13485 Plus scheme of ICMED.
- 1.2 These documents are focused on requirements for CBs and individuals performing regulatory audits and other related functions under the ICMED plus scheme and/or country, and/or region-specific regulatory regimes.
- 1.3 In addition, ICMED 13485 plus scheme has defined method to “grade” nonconformities resulting from the audits and procedures to document the decision-making process for recognizing an Auditing Organization or revoking recognition in the document “Certification Process for system certification”
- 1.4 This collection of ICMED 13485 plus scheme documents will provide the fundamental building blocks by providing a common set of requirements to be utilized by the QCI for the recognition and monitoring of entities that perform regulatory audits and other related functions. It should be noted that in some jurisdictions the recognition process is called designation, notification, registration, or accreditation.
- 1.5 The purpose of this document is to specify competence and training requirements that shall be demonstrated and maintained by CBs for personnel involved in performing regulatory audits of medical device manufacturers.
- 1.6 The requirements contained within this document are for personnel involved in assessments and recognition decisions assessing conformity with the ICMED 13485 Plus scheme for product certification, and includes:
 - 1.6.1 Defining knowledge, skills, and abilities.
 - 1.6.2 Criteria for various degrees of competence based on roles in assessments and recognition decisions.
 - 1.6.3 Assisting in the evaluation and development of the CB Auditors.
 - 1.6.4 Providing a basis for identifying training needs of the CB Auditors.

2. Scope

- 2.1 This ICMED 13485 plus scheme document applies to QCI conducting assessments of CBs. Adherence to this document and its requirements will help mitigate the risk of inconsistent or ineffective assessments of CBs by ensuring that CBs personnel have the necessary competence before conducting an assessment or participating in a decision to certify a medical device manufacturer. The Competence Matrix described in Appendix A identifies requirements for training and assists in the development of programs for personnel involved in assessments and recognition decisions.
- 2.2 The functions covered by QCI, within the scope of this document, and the independence of the roles assigned are described in Table 1.



Functions	Assessment	Decision Making
Conduct a review of the assessment application to determine assessment team competence requirements, select assessment team members, and determine assessment duration	n/a	Program Administrator
Assessment of the CB's management system	Lead Auditor / Assessor	n/a
Assessment of the CB's competence	Lead Auditor / Assessor	n/a
Assessment of the conformity of the CBs with regulatory requirements	Lead Auditor / Assessor	n/a
Approval of Assessment Results	n/a	Recognition Manager
Table 1: QCI Functions and Roles		

3. Reference(s)

- 3.1. ICMED plus scheme documents
- 3.2. IMDRF & GHTF
- 3.3. ISO/IEC 17000:2020 – *Conformity assessment – Vocabulary and general principles*
- 3.4. ISO/IEC 17021:2015 - *Conformity Assessment – Requirements for bodies providing audit and certification of management system.*
- 3.5. IAF MD 9:2017 – *Application of ISO/IEC 17021-1:2015 in the field of medical device quality management systems (ISO 13485).*

4. Definitions

- 4.1 Audit: A systematic, independent, and documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled. (ISO 17000:2004)
- 4.2 Assessment: A systematic, independent, and documented process for obtaining assessment evidence and evaluating it objectively to determine the extent to which assessment criteria are fulfilled.
- 4.3 Auditing Organization: An organization that audits a medical device manufacturer for conformity with quality management system requirements and other medical device regulatory requirements. Auditing Organizations may be an independent organization or a Regulatory Authority which perform regulatory audits.
- 4.4 Auditor: A person with the demonstrated personal attributes and competence to conduct an audit. (ISO 9000:2005 clause 3.9.9)

- 4.5 Assessor: An employee of a Regulatory Authority with the demonstrated personal attributes and competence to conduct an assessment of an Auditing Organization.
- 4.6 Competence: Demonstrated personal attributes and demonstrated ability to apply knowledge and skills. (ISO 9000:2006 clause 3.9.14)
- 4.7 Lead Auditor: The individual responsible for leading the audit team. The Lead Auditor manages an audit team, prepares the audit plan, conducts any audit related meetings, and submits the formal audit report.
- 4.8 Program Administrator: A person(s) that conducts a review of the audit application to determine audit team competence requirements, select audit team members, and determine audit duration.
- 4.9 Regulatory Authority: A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. (GHITF/SG1/N78:2012)
- 4.10 Recognition Manager: A person responsible for the reviews of the assessment activities and for the approval of the assessment results.

5. Responsibilities

- 5.1 It is the responsibility of a CB to collect and maintain evidence that demonstrates that personnel involved in audits (ICMED 13485 and ICMED 13485 Plus) meet the specified competence requirements contained within this document.
- 5.2 The CB is expected to have a documented processes to: (1) initially qualify their staff, who are involved in assessments and recognition decisions to the requirements specified within this document, based on demonstrated competence; (2) ensure that the competence of personnel involved in audits is maintained on a continuing basis; (3) provide personnel with appropriate support and resources where needed and, (4) maintain records of these activities for each person involved in the recognition process. Auditor-in-training may be included in the audits team but shall not perform audits without direction or guidance from the Lead Auditor.
- 5.3 On request, QCI may provide feedback of their experiences with regards to the competence requirements for personnel involved in assessments and recognition decisions to the Regulatory Authority or competent authorities of a country / region for the purpose of refining the competence criteria and training requirements defined in this document.

6. Commitments

The CBs shall ensure that each person involved in assessments and recognition decisions commits to comply with all applicable rules, regulations, and policies. Any potential conflicts of interest, including prior association with an Auditing Organization, a manufacturer, or its personnel shall be documented.

7. Entry Level Requirements

A CB shall apply its own procedures for formally selecting, training, and approving personnel involved in assessments and recognition decisions using the requirements and criteria contained within this document.

The following are the pre-requisite education, experience, and competencies to be demonstrated and maintained by staff involved in audits and certification.

7.1 Pre-requisite Education

7.1.1 Lead Auditors, Auditors, and Recognition Managers, should hold a degree from a government recognized university or technical college in medicine, science, or engineering. Disciplines of interest include, for example:

- 7.1.1.1 Biology
- 7.1.1.2 Microbiology
- 7.1.1.3 Chemistry
- 7.1.1.4 Biochemistry
- 7.1.1.5 Computer hardware and software technology
- 7.1.1.6 Material sciences
- 7.1.1.7 Engineering - electrical, electronics, mechanical, biomedical, clinical, bioengineering,
- 7.1.1.8 Human physiology
- 7.1.1.9 Medicine
- 7.1.1.10 Pharmacy
- 7.1.1.11 Physics and biophysics
- 7.1.1.12 Veterinary medicine

7.1.2 The educational requirement shall remain a strong basis for classification of Technical Knowledge. Typically, personnel develop expertise directly related to their educational background.

7.1.3 Program Administrators should hold certificates or diplomas for successful completion of secondary school education qualifications.

7.1.4 In exceptional cases, a demonstration of equivalent knowledge and skills may be acceptable. The CBs shall justify and document the reasons for accepting alternatives to the education requirements.

7.2 Pre-requisite Experience

7.2.1 Potential Lead Auditors and Auditors, Recognition Managers, and Program Administrators shall be able to demonstrate sufficient experience to have acquired the requisite knowledge and skills to successfully perform the functions required to perform their designated tasks.

7.2.2 Potential Lead Auditors and auditors, and Recognition Managers shall demonstrate at least four years of full-time experience in the field of medical devices or related sectors (e. g. industry, audit, healthcare, or research). Successful completion of other formal qualifications (advanced degrees) can substitute for a maximum of two years of working

experience.

- 7.2.3 In exceptional cases, a shorter duration of experience, or experience in areas not mentioned above, may be acceptable. Such cases may include, for example, individuals employed in an audit, inspectional or enforcement position for a regulatory authority whereby they have acquired and demonstrated in-depth knowledge of the application of quality management principles to medical device manufacturing, the application of regulations, as well as the evaluation of compliance of medical device manufacturers to standards and regulations. A CB shall justify and document such cases.

7.3 Pre-requisite Competence Requirements

Three broad categories of competencies are required for potential Lead Auditors, Auditors, and Recognition Managers:

- 7.3.1. **Foundational Competencies:** those generic skills, personal attributes, and behaviors applicable to all personnel and developed through experience (e.g., adaptability, diligence, critical and analytical thinking, communication, etc.)
- 7.3.2. **Functional Competencies:** those generic skills applicable to all personnel developed through experience and required to perform assessments (e.g., project management; time management; teamwork; effective use of information technology; etc.)
- 7.3.3. **Technical Competencies:** those unique skills developed through experience and specific knowledge applicable to personnel depending on the scope of activities needed to address subject areas (e.g., regulatory requirements, risk assessment, health and safety impacts, etc.)

The attributes and skills described in the three categories of competence are to be evaluated as part of entry level requirements, as well as through training and other recognition activities.

7.3.1 Foundational Competencies

- 7.3.1.1. **Integrity:** Abides by a strict code of ethics and behavior; chooses an ethical course of action and does the right thing, even in the face of opposition; encourages others to behave accordingly. Treats others with honesty, fairness, and respect; makes decisions that are objective and reflect the just treatment of others. Takes responsibility for accomplishing work goals within accepted timeframes; accepts responsibility for one's decisions and actions and for those of one's group, team, or department; attempts to learn from mistakes.
- 7.3.1.2. **Objectivity:** Makes a balanced assessment of the relevant circumstances and not unduly influenced by their own interests or by others in forming judgments.
- 7.3.1.3. **Critical and Analytical Thinking:** Seeks relevant, reliable, and competent information for use in problem solving and decision making. Uses sound logic and reasoning to identify strengths and weaknesses of alternative solutions, conclusions, or approaches. Uses reasoning to analyze, compare, and interpret information to draw conclusions.

- 7.3.1.4. **Interpersonal Skills:** Establishes and maintains positive working relationships with a diverse group of contacts. Works effectively as a team member during the assessment process. Recognizes and considers input from all assessment program stakeholders.
- 7.3.1.5. **Communication:** Expresses or presents ideas, both orally and in writing, in a clear, concise, accurate and logic fashion, taking into consideration the target audience. Has a good command of language(s) and uses an appropriate business writing style, using objective, specific language; uses punctuation correctly, verifies spelling, and writes grammatically correct.
- 7.3.1.6. **Listens actively;** asks clarifying questions and summarizes or paraphrases what others have said to verify understanding.
- 7.3.1.7. **Adaptability:** Demonstrates the ability to use or consider nontraditional methods; makes changes in response to demands and circumstances.
- 7.3.1.8. **Tenacious:** Persistent and focused on achieving objectives.
- 7.3.1.9. **Perceptive:** Instinctively aware of and able to understand situations.
- 7.3.1.10. **Observant:** Actively observing physical surroundings and activities.

7.3.2 Functional Competencies

- 7.3.2.1. **Information Technology:** Has the willingness and ability to apply electronic technology to complete work objectives, to use new techniques, and/or technologies as a routine part of assessments and has a working knowledge of how to use regulatory and functional databases and systems.
- 7.3.2.2. **Interviewing:** Plans, conducts, and documents results of discussions with individuals in such a manner as to achieve assessment objectives; ability to determine accuracy of information from interviewees and potential indicators of further follow-up action. Skilled in obtaining relevant, reliable, and useful information from individuals at all levels in the audited organization.
- 7.3.2.3. **Teamwork:** Provides constructive feedback to assessment team members. Ability to identify skill needs and methods for performance improvement; assists with handling performance issues. Provides environment to maximize Auditor proficiency.
- 7.3.2.4. **Conflict Resolution:** Recognizes the potential and actual sources of personnel conflict from assessment program stakeholders. Achieves results through diplomatic handling of disagreements and potential conflict; works effectively and cooperates with other individuals and departments to resolve conflicts.
- 7.3.2.5. **Supervision:** Plans, organizes, directs, monitors, and evaluates the work of others assigned to assessment projects.
- 7.3.2.6. **Writing Literacy:** Creates clear and concise reports and presentations that are based on objective evidence. Uses correct spelling, grammar, and punctuation to produce logical and accurate written documentation and correspondence. Communicates ideas,

information, and messages, which may contain technical material, in a logical, organized, and coherent manner.

- 7.3.2.7. **Time Management:** Monitors progress against objectives and completes duties in timely and effective manner.
- 7.3.2.8. **Records Management:** Maintains accurate and objective records of facts and observations made.
- 7.3.2.9. **Cultural Sensitivity:** Observant and respectful to different cultures.
- 7.3.2.10. **Autonomy:** Ability to work independently and adjust to unforeseen circumstances with minimal assistance.

7.3.3 Technical Competencies

- 7.3.3.1. **Regulatory requirements:** Knowledge of the medical device regulatory requirements of the recognizing Regulatory Authority(s) to enable an assessment of the applicability and compliance with such laws, regulations, and standards; Including knowledge of the principles and applications of medical device quality management system requirements, risk management system requirements, etc.
- 7.3.3.2. **Medical devices:** Knowledge of medical devices and the related manufacturing activities, including:
 - a. their intended use
 - b. types of medical devices including their complexities, technologies, and risk classifications
 - c. product standards
 - d. safety and risks of medical devices and
 - e. processes and technologies used by medical device manufacturers.
- 7.3.3.3. **Assessment Procedures and Methods:** An understanding of the CBs QMS (ISO 13485) and Regulatory Authority's procedures and criteria; an understanding of the relevant standard, and related parts, used for the recognition of an Auditing Organization; and an understanding of standards and techniques for auditing quality management systems.
- 7.3.3.4. **Statistical Analysis:** Knowledge of the basic concepts of probability and statistics including mean, median, confidence level and standard deviation as it relates to representative sampling and trend analysis.

Note: Also Refer requirements as listed in IAF MD 9:2017

8. Training requirements

The Competence Levels described in Appendix A are used to identify requirements for training and the development of programs for personnel involved in audits and decision-making functions.

The following are activities undertaken to establish initial competence and to maintain proficiency.

8.1 Mandatory Initial Training

- 8.1.1. Lead Auditors and Auditors, are to undertake any new training mandated by the QCI and ICMED plus scheme within the designated timeframes. Such training could encompass new or revised requirements that were not part of the individual's previous training. Such training will count toward annual Continual Professional Development (CPD) hours.
- 8.1.2. Lead Auditors and Auditors shall have successfully completed the following training prior to performing independent work for the Regulatory Authority:
 - 8.1.2.1. 40 hours of class room training in quality management systems (e.g., ISO 9001) including a minimum of 8 hours dedicated to additional medical device quality management system requirements (e.g., ISO 13485). In cases of already qualified quality management system auditors, a minimum of 8 hours of class room training in the additional medical device quality management system requirements.
 - 8.1.2.2. 32 hours of training in regulatory requirements to include ISO/IEC 17021-1:2015, India MDR 2017, ICMED plus scheme, and assessing for conformity to those requirements by utilizing, or equivalent, plus sufficient additional time for each set of jurisdictional regulatory requirements within the scope of recognition for the Regulatory Authority and commensurate with the existing experience of the trainee.
 - 8.1.2.3. 8 hours of training in risk management principles, preferably related to the design of a medical device (e.g., ISO 14971) and their application within a quality management system. (e.g., ISO 13485 and India MDR 2017)
- 8.1.3. Any alternative evidence of experience or equivalent training by other means shall be justified and documented.
 - 8.1.3.1. Specified training documented in a training plan and including; the relevant procedures as laid down in regulations and or ICMED plus Scheme, a sufficient number of audits witnessed by the trainee, and a sufficient number of audits performed by the trainee under supervision, and observed by a Lead Auditor. (See section 8.0 below)
- 8.1.4. Program Administrators shall have successfully completed specified training documented in a training plan in the relevant procedures of the CB's quality management system.
- 8.1.5. Recognition Manager shall have experience or initial training in regulatory requirements.
- 8.1.6. Existing Auditors, Lead Auditors, and Recognition Managers may use experience and other alternative evidence to satisfy these mandatory initial training requirements in this clause. Such cases may include, for example, when these Auditors, Lead Auditors, and Recognition Managers have acquired and demonstrated in-depth training, knowledge and experiences of the assessment of quality management systems of CBs. CBs shall justify and document such cases.

8.2 Continual Professional Development

- 8.2.1. Personnel involved in assessments and recognition decisions shall commit themselves to continually improve their proficiency, effectiveness, and quality of work.
- 8.2.2. Lead Auditors and Auditors, Recognition Managers and Program Administrators shall fulfill a requirement for CPD:
 - 8.2.2.1. 6 hours of professional development per year; and,
 - 8.2.2.2. 8 hours of annual training on changes to regulatory requirements and updates on relevant guidance documents pertaining to the regulations, or equivalent.
- 8.2.3. Mandatory annual training or re-training on internal CB procedures and processes shall not count toward CPD hours. In order to count toward CPD hours, training shall maintain or augment existing competencies, or be provided for the acquisition of new competencies relevant to the roles and responsibilities in assessment and recognition decisions (e. g. new or modified regulatory requirements, policies & procedures, and emerging technologies). Personnel with a broad scope of competence may require more CPD hours per year to maintain their competence. Regulatory Authorities shall not permit additional hours carried forward to count as CPD hours in future years.
- 8.2.4. Advanced Training Elements for Auditors: Includes areas like process validation, sterilization and related processes, plastic and electronic manufacturing processes, risk management.

9. Lead Assessor, and Assessor Experience Requirements

- 9.1 CB shall identify authorization of its auditors using Technical Areas as defined in Annex A of IAF MD 9:2017)
- 9.2 Before undertaking independent audit, Auditors-in-training shall demonstrate on-site audit experience of an Auditing Organization's management system, which has been observed by a Lead Auditor, with at least 4 complete audits (comprising 20 man-days in preferably an accredited QMS program and 50% of this shall be preferably against ISO 13485), as a member of an audit team.
- 9.3 If the Auditor-in training has experience and qualifications as an auditor, then 2 completed audits (ISO 13485) as member of an audit team is required before undertaking an independent audit.
- 9.4 Auditor shall demonstrate participation in at least 2 audits in each subsequent 12 - month period.
- 9.5 Before recognition as a Lead Auditor, Lead Auditor-in-training shall have successfully concluded all requirements for an Auditor. Lead Auditors in-training shall demonstrate at least 3 complete audits as Team Leader in ISO 13485 audits, under supervision of an approved Team Leader.
- 9.6 If the Auditor-in training has experience and qualifications as a Lead Auditor, then 2 completed audits (ISO 13485) as member of an audit team is required before undertaking an independent audit.

- 9.7 Lead Auditors shall demonstrate participation in at least 2 complete audits in each subsequent 12-month period.

Note: For ICMED 13485 & ICMED 13485 Plus: For one-time initial qualification, some other evaluation methods such as audit experience as auditor or team leader in other technically similar areas, may be used.

- 9.8 **Technical File Review:** Personnel (may include auditors/Lead auditors) involved in the review of Technical Files/dossiers, pertaining ICMED 13485 Plus, shall be specifically trained and authorized for this purpose. They should have knowledge and expertise in all areas of a Technical File review (e. g. QMS, specific product knowledge, product standards, design development, Essential principles of safety and performance, risk management, manufacturing technology, packaging, labelling, PMS & Vigilance, stability testing & shelf life, biocompatibility, chemical & biological testing, preclinical and clinical investigation/data etc.).

For authorization of personnel for this specific purpose CB may consider knowledge, skills, and experience in specific products (Product categories covered by the Technical Areas mentioned in IAF MD 9:2017 (Annex A, Table, Refer Last column)).

10. Competence Evaluation

10.1 Competence Evaluation Criteria

- 10.1.1. Program Administrator, Lead Auditor, Auditor, and Recognition Manager competence levels will differ and depend on their roles in the audit program.

- 10.1.2. The initial and ongoing competence level required for each role is described in Appendix A. CBs shall use this information to formulate and maintain training plans for Program Administrators, Lead Auditors, Auditors, and Recognition Managers to ensure that they achieve the necessary competence levels. The learning process could include; formal audit skills training and education, on the job audit experience, professional development activities, supervisor/manager coaching and mentoring, etc.

10.2 Methods of Evaluation: Initial and Ongoing Monitoring.

CBs shall evaluate the competence of Lead Auditors, Auditors, and Recognition Manager using a combination of monitoring methods that may include;

- 10.2.1. Review of records of assessments, education, training, etc.
- 10.2.2. Feedback from peers and supervisors
- 10.2.3. Interviews
- 10.2.4. Observation of performance
- 10.2.5. Testing

10.3 Re-Evaluation

- 10.3.1. A CB shall evaluate Lead Auditor, Auditors, and Recognition Managers for continued recognition of competence at least every 3 years.

- 10.3.2. A CB shall confirm skills and personal attributes of Lead Auditors and Auditors through

an observed assessment every 3 years.

11. Records of Pre-requisites, Competence Evaluation and Monitoring

CBs shall maintain current and accurate records associated with the evaluation and maintenance of competencies. Auditor competence files and auditor logs shall demonstrate how Auditors meet the requirements contained in this document and are to include:

- 11.1. Auditor name, position, and contact information.
- 11.2. Pre-requisite and subsequent education
- 11.3. Results of evaluation of the Auditor's competence in the role of Lead Auditor, Recognition Manager, or Auditor according to the requirements in this document.
- 11.4. Audit/Inspection experience
- 11.5. Training participation and outcomes
- 11.6. Scope of demonstrated competence to perform audits including any restrictions (e.g., due to prior experience with a manufacturer which could be considered a conflict of interest)
- 11.7. An Audit/Inspection Log

The Program Administrator shall maintain a list of Lead Auditors and Auditors.

12. Remediation

- 12.1 A CB shall suspend the recognition of personnel that fail to meet the requirements for the maintenance of competence or renewal of recognition. A CB shall prepare a remediation plan in order to bring the person back into compliance. When an Auditor is under remediation, he or she may not participate in audits except where it is necessary as part of the remediation plan and under supervision; or to fulfill the minimum audits experience requirement defined in this document. In such cases, the person under remediation shall not act as a Lead Auditor or Recognition Manager.
- 12.2 The CB shall observe an Auditor successfully performing a complete audit in order to have recognition re-instated.

Appendix A – Competence Matrices

Competence Levels

Program Administrator, Lead Auditor, Auditor, and Recognition Manager are assigned one of three levels for each competence depending on their role in accordance with the following tables.

Importance	Requirement	Competence Level
Critical Skill or Knowledge	Must have	3
Important Skill or Knowledge	Should have	2
Helpful Skill or Knowledge	Preferable to have	1

Foundational Competencies	Program Administrator *	Lead Auditor	Auditor	Recognition Manager
Integrity	3	3	3	3
Objectivity	3	3	3	3
Critical and Analytical Thinking	3	3	3	3
Interpersonal Skills	2	3	3	3
Communication	3	3	2	3
Adaptability	2	3	3	3
Tenacious	2	3	3	3
Perceptive	2	3	3	3
Observant	1	3	3	3

Table 1 - Foundational Competence Levels

Functional Competencies	Program Administrator	Lead Auditor	Auditor	Recognition Manager
Information Technology	3	3	3	2
Interviewing	1	3	3	1
Teamwork	2	3	3	2
Conflict Resolution	3	3	3	3
Supervision	1	3	1	3
Writing Literacy	1	3	2	2
Time Management	2	3	3	2
Records Management	3	3	2	1
Cultural Sensitivity	1	3	3	3
Autonomy	1	3	3	3

Table 2 - Functional Competence Levels

Technical Competencies	Recognition Manager	Lead Auditor	Auditor
Regulatory Requirements	3	3	3
Medical Devices	3	3	3
Auditing Standards and Techniques	1	3	3
Statistical Analysis	1	3	3

Table 3 - Technical Competence Levels

Program Administrators shall have a technical competence of level 3 in the CB's policies and procedures for assessing the application, to determine audit team competence required, selecting the audit team members, and determining audit time.