IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

Title: Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews

Authoring Group: IMDRF GRRP Working Group

Date: February 7, 2020

Table of Contents

Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world.

Introduction

This is one document in a collection of documents produced by the International Medical Device Regulators Forum (IMDRF) intended to improve the efficiency and effectiveness of the review process for marketing of medical devices. Two documents, IMDRF GRRP WG N40 – *Competence, Training, and Conduct Requirements for Regulatory Reviewers* and IMDRF GRRP WG N59 – *Requirements for Medical Device Conformity Assessment Bodies for Regulatory Authority Recognition*, are complementary documents. These two documents are focused on requirements for organizations conducting marketing review(s) of medical devices and IVD medical devices and individuals performing regulatory reviews and other related functions under their respective medical device legislation, regulations, and procedures required in their regulatory jurisdiction.

Two additional documents, IMDRF GRRP WG N61 – *Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews* and this document, IMDRF GRRP WG N## - *Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews* are complementary documents. These two documents N61 and N## are focused on how Regulatory Authorities will evaluate or "assess" a CAB's compliance to the requirements in the IMDRF GRRP N59 and N40 documents.

This collection of IMDRF GRRP documents will provide the fundamental building blocks by providing a common set of requirements to be utilized by the Regulatory Authorities for the recognition and monitoring of entities that perform regulatory reviews and other related functions. It should be noted that in some jurisdictions the recognition process is called designation, notification, registration, or accreditation.

IMDRF developed these documents to encourage and support global convergence of regulatory systems, where possible, seeking to strike a balance between the responsibilities of Regulatory Authorities to safeguard the health of their citizens as well as their obligations to avoid placing unnecessary burdens upon medical device CABs or the regulated industry. IMDRF Regulatory Authorities may add additional requirements beyond this document when their legislation requires such additions.

The purpose of this document is to specify competence and training requirements that shall be demonstrated and maintained by Regulatory Authorities for personnel involved in the assessment of Conformity Assessment Bodies performing regulatory reviews of marketing submissions.

The requirements contained within this document are for personnel involved in assessments and recognition decisions assessing conformity with the IMDRF GRRP WG N59 document, and includes:

- Defining knowledge, skills, and abilities.
- Criteria for various degrees of competence based on roles in assessments and recognition decisions.
- Assisting in the evaluation and development of Regulatory Authority Assessors.
- Providing a basis for identifying training needs.

1.0 Scope

This document applies to Regulatory Authorities conducting assessments of Conformity Assessment Bodies (CABs). Adherence to this document and its requirements will help mitigate the risk of inconsistent or ineffective assessments of CABs by ensuring that Regulatory Authority personnel have the necessary competence and training before conducting an assessment or participating in a decision to recognize a CAB. The Competence Matrices described in Appendix A identify requirements for training and assists in the development of programs for personnel involved in assessments and recognition decisions.

The functions covered by a Regulatory Authority, 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 application for recognition to determine assessment team competence requirements, select assessment team members, and determine assessment duration	n/a	Recognition Manager
Assessment of a CAB's management system	Lead Assessor / Assessor	n/a
Assessment of the CAB's competence (IMDRF GRRP WG N40)	Lead Assessor / Assessor/Technical Experts	n/a
Assessment of the conformity of the CAB with regulatory requirements (IMDRF GRRP WG N59)	Lead Assessor / Assessor/Technical Experts	n/a
Approval of Assessment Results	n/a	Recognition Manager

Table 1: Regulatory Authority Functions and Roles

2.0 Reference(s)

- IMDRF GRRP WG/N59 *Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews*
- IMDRF GRRP WG/N40 *Competence, Training, and Conduct Requirements for Regulatory Reviews*
- IMDRF GRRP WG/N61 – Regulatory Authority Assessment Method for Recognition and Surveillance of Medical Device Conformity Assessment Bodies
- GHTF/SG1/N78:2012 - *Principles of Conformity Assessment for Medical Device*
- International Organization for Standardization (ISO)/ International Electrotechnical Commission (IEC) ISO/IEC 17065:2012 - *Conformity Assessment – Requirements for bodies certifying products, processes and services*
- ISO 9000:2015 **-** *Quality management systems — Fundamentals and vocabulary*
- ISO/IEC 17000:2004 **–** *Conformity assessment – Vocabulary and general principles*
- ISO/IEC 17067:2013 - *Conformity assessment -- Fundamentals of product certification and guidelines for product certification schemes*

3.0 Definitions

3.1 *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)

3.2 *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.

3.3 *Assessor:* An employee of a Regulatory Authority with the demonstrated personal attributes and competence to conduct an assessment of a Conformity Assessment Body.

3.4 *Competence:* Ability to apply knowledge and skills to achieve intended results. (ISO 9000:2015, Clause 3.10.4)

3.5 *Conformity Assessment Body (CAB):* A body other than a Regulatory Authority engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled. (IMDRF GRRP WG/N40:2017)

3.6 *Lead Assessor:* The individual responsible for leading the assessment team. The Lead Assessor manages an assessment team, prepares the assessment plan, conducts any assessment related meetings, and submits the formal assessment report.

3.7 *Quality Management System*: A QMS comprises activities by which the organization identifies its objectives and determines the processes and resources required to achieve desired results. The QMS manages the interacting processes and resources required to provide value and realize results for relevant interested parties. The QMS enables top management to optimize the use of resources considering the long and short term consequences of their decision. A QMS provides the means to identify actions to address intended and unintended consequences in providing products and services. (ISO 9000: 2015, Clause 2.2)

3.8 *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. (GHTF/SG1/N78:2012)

3.9 *Recognition Manager:* A person(s) that is responsible for conducting a review of the application for recognition to determine assessment team competence requirements, select assessment team members, and determine assessment duration. This person is also responsible for the reviews of the assessment activities and for the approval of the assessment results.

3.10 *Regulatory Review:* A review of a medical device that is conducted to assess conformity with regional regulations or standards.

Note 1: A regulatory review is performed by Regulatory Reviewer(s), and on occasion, the Regulatory Authority and/or recognized Conformity Assessment Body may consult with Technical Expert(s) to assist in specific aspects of the regulatory review process.

Note 2: Depending on the complexity of the medical device, it may be necessary for a team of regulatory reviewer(s) and/or technical expert(s) to conduct the regulatory review to ensure all required competencies are addressed.

Note 3: A regulatory review consists of an assessment of documentation and/or evaluation/testing of physical medical devices and includes the recommendation and associated decision-making processes. The scope of the review is dependent on the Regulatory Authority's requirements. (IMDRF GRRP WG/N40: 2017)

3.11 *Regulatory Reviewer:* An individual from a recognized CAB responsible for routinely performing regulatory reviews of medical devices. This may include for example, premarket reviewers, product specialists, assessors, etc. (Modified from IMDRF GRRP WG/N40: 2017)

3.12 *Technical Expert:* For the purposes of this document, a technical expert is an individual who is consulted on an *ad hoc* basis to provide specific technical knowledge or expertise to the CAB assessment process. This may include an individual employed by the Regulatory Authority or their recognized CAB or external to these organizations, as permitted by the Regulatory Authority.

Note 1: Areas of expertise could include, for example, clinical, design, manufacturing, etc.

4.0 Responsibilities

It is the responsibility of a Regulatory Authority to collect and maintain evidence that demonstrates that personnel involved in assessments and recognition decisions meet the specified competence requirements contained within this document.

The Regulatory Authority 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 assessments and recognition decisions 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. Assessors-in-training may be included in the assessment team but shall not perform assessments without direction or guidance from the Lead Assessor.

5.0 Commitments

The Recognizing Authority shall ensure and document 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 a CAB, a manufacturer, or its personnel shall be notified to the recognizing authority.

6.0 Entry Level Requirements

A Regulatory Authority 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 prerequisite education, experience, and competencies to be demonstrated and maintained by staff involved in assessments and recognition decisions.

6.1 Education

Lead Assessors, Assessors, Recognition Managers, and Technical Experts should hold a bachelor's degree from a university or technical college in health, medicine, science, engineering, or another relevant discipline. The educational requirement shall remain a strong basis for classification of Technical Knowledge. Typically personnel develop expertise directly related to their educational background.

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

6.2 Experience

Lead Assessors, Assessors, Recognition Managers, and Technical Experts 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. They shall demonstrate at least four years of full-time experience in the field of medical devices or related sectors (e.g. industry, regulatory review, healthcare, or research). Successful completion of other formal qualifications (advanced degrees) can substitute for a maximum of three years of working experience.

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 a regulatory review position for a regulatory authority whereby they have acquired and demonstrated in-depth knowledge of the application of regulatory review principles for medical devices, the application of regulations, as well as the evaluation of compliance of medical device manufacturers to standards and regulations. A Regulatory Authority shall justify and document such cases.

6.3 Competence Requirements

Three broad categories of competencies are required for Lead Assessors, Assessors, Recognition Managers, and Technical Experts:

- **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).

- **Functional Competencies:** those generic skills applicable to all personnel developed through experience and required to perform assessments (e.g., time management, teamwork, effective use of information technology).

- **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, device subject matter expertise).

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. At entry point it may not be possible to evaluate or fulfill all three categories. In this case, the Regulatory Authority shall establish methods for evaluating and fulfilling these competencies so that the Lead Assessors, Assessors, Recognition Managers, and Technical Experts possess the requisite competencies prior to the assignment of responsibility for any assessment or recognition activities.

6.3.1 Foundational Competencies

Adaptability: Demonstrates the ability to use or consider nontraditional methods; makes changes in response to demands, new scientific findings, and circumstances.

Attitude: Has a sense of mission to protect the life and health of people and to serve the public.

Communication: Expresses or presents ideas, both orally and in writing, in a clear, concise, accurate and logical fashion, taking into consideration the target audience. Has a good command of language(s) and uses an appropriate business writing style. Creates clear and concise reports and presentations that are based on objective evidence. Uses correct spelling, grammar, and punctuation to produce logical, unambiguous, and accurate written documentation and correspondence. Communicates ideas, information, and messages, which may contain technical material, in a logical, organized, and coherent manner.

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.

Cultural Sensitivity: Is observant and respectful to different cultures.

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 rely on relevant objective evidence 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. Understands and respects the confidential nature of regulatory information.

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.

Objectivity: Makes a balanced assessment of the relevant circumstances and is not unduly influenced by their own interests or by others in forming judgments.

Observant: Actively observing physical surroundings and activities.

Perception: Is instinctively aware of and able to understand complex regulatory situations.

Tenacity: Is persistent and focuses on achieving objectives.

6.3.2 Functional Competencies

Autonomy: Ability to work independently and adjust to unforeseen circumstances with minimal assistance.

Business Processes: Has the willingness and ability to apply current policies, procedures, work instructions, and other business processes of the organization to complete work objectives.

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.

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.

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.

Project Management: Plans, organizes, directs, monitors, and evaluates their work and the work of others, as applicable, and according to established policies and procedures.

Records Management: Maintains accurate, transparent, and objective records of facts and observations of the assessment process.

Supervision: Plans, organizes, directs, monitors, and evaluates the work of others assigned to assessment projects. Provides constructive feedback to assessment team members. Ability to identify skill needs and methods for performance improvement; assists with handling performance issues.

Teamwork: Possesses the ability to work collaboratively while respecting different points of view and working towards a common goal.

Time Management: Monitors progress against objectives and completes duties in timely and effective manner.

6.3.3 Technical Competencies

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.

2. *Medical devices:* Knowledge of medical devices and the related manufacturing activities, including:
    - their intended use
    - types of medical devices including their complexities, technologies, and risk classifications
    - safety and risks of medical devices
    - processes and technologies used by medical device manufacturers

3. *Assessment Procedures and Methods:* An understanding of the Regulatory Authority's procedures and criteria; an understanding of the relevant standard, and related parts, used for

the recognition of a CAB; and an understanding of standards and techniques for auditing quality management systems.

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.

5. *Voluntary Consensus Standards and Guidance Documents:* Knowledge of the Regulatory Authority's recognized medical standards and guidance documents (including IMDRF documents) commonly used in product realization (design and manufacturing) for the medical devices under regulatory review, as applicable based on the assigned tasks. Knowledge of product specific standards and guidance documents and their application depending on the products being assessed.

7.0 Competence Evaluation

The Regulatory Authority shall assess and periodically monitor the competence of Lead Assessors, Assessors, Recognition Managers, and Technical Experts. The Regulatory Authority shall evaluate Lead Assessors, Assessors, Recognition Managers, and Technical Experts against updated or current competence criteria for continued recognition of competence at least every year. Lead Assessors, Assessors, Recognition Managers, and Technical Experts competence levels will differ and depend on their roles in the assessment program. Records of the evaluation shall be maintained.

7.1 Methods of Evaluation

The Regulatory Authority shall evaluate the competence of Lead Assessors, Assessors, Technical Experts, and Recognition Managers using a combination of evaluation and monitoring methods that may include:

- Review of records of regulatory reviews, education, training, etc.
- Feedback from peers, supervisors and stakeholders
- Interviews
- Testing

7.2 Competence Evaluation Criteria

The Regulatory Authority shall evaluate the Foundational, Functional, and Technical competencies (Section 6.3) against the minimal criteria established below. The Regulatory Authority may choose to include additional criteria.

Evaluation Criteria for Foundational Competencies

Foundational Competencies	Evaluation Criteria
Adaptability	Accepts feedback as an opportunity to learn and improve their skills.
Attitude	Personally adheres to the laws, regulations, and policies of the Regulatory Authority
	Understands the potential impact of the assessment decisions that are made.
Communication	Communicates in an accurate, clear, organized, concise, grammatically correct, and responsive manner, both orally and in writing.
	Uses written communications that are adequately supported, logical, and effectively convey the intended message.
	Uses oral communications that are adequately supported, logical, and effectively convey the intended message.
Critical and Analytical Thinking	Demonstrates the ability to solve problems and make decisions based on sound logic and reasoning.
	Utilizes reasoning to analyze, compare, and interpret information to solve problems.
Cultural Sensitivity	Respects cultural differences.
Integrity	Demonstrates ethical behavior by ensuring integrity in personal actions and in administering the Regulatory Authority's business practices.
	Prevents and resolves any perceived, actual, or potential conflicts of interest.
	Preserves confidentiality of classified information when applicable.
	Is accountable for their own behavior and actions.
Interpersonal Skills	Connects and relates well with a diverse group of individuals including stakeholders and other individuals at all levels within the organization.
Objectivity	Demonstrates the ability to judge fairly without partiality or external influence.
Observant	Demonstrates the ability to actively observe physical surroundings and activities to identify potential issues.
Perception	Raises and escalates, as appropriate, any ethical issues.

Tenacity	Accepts challenging work assignments

Evaluation Criteria for Functional Competencies

Functional Competencies	Evaluation Criteria
Autonomy	Requires supervision commensurate with the individual's competency.
	Takes initiative in problem solving.
Business Processes	Adheres to the Regulatory Authority's internal and external policies and processes.
	Participates in training on internal policies, procedures, or business support systems and effectively demonstrates the application of these policies, procedures, and systems.
Conflict Resolution	Uses effective listening and negotiation skills.
Information Technology	Applies available electronic technology to complete assessments.
Interviewing	Uses effective communication skills to conduct and document interviews of individuals.
	Verifies the accuracy of information obtained during interviews and utilizes this information to identify follow-up actions.
Project Management	Allocates time and resources to efficiently accomplish all tasks.
Records Management	Maintains accurate records.
Supervision	Demonstrates the ability to effectively evaluate others work.
	Demonstrates the ability to direct others' work through delegation of responsibilities and tasks.
Teamwork	Coordinates and/or participates in assessments with appropriate individuals and team members to ensure a thorough process.
	Fosters/facilitates cooperation, communication and consensus to accomplish a common goal both individually as well as a part of a team.
	Represents the team consensus with respect to regulatory review recommendations, actions, and decisions.
Time Management	Completes work within applicable timeframes.

Evaluation Criteria for Technical Competencies

Technical Competencies	Evaluation Criteria
Regulatory Requirements	Keeps abreast of applicable regulatory requirements.
	Demonstrates regulatory knowledge of the Regulatory Authority to enable an assessment of the applicability and compliance with such laws and regulations.
	Provides information and guidance to stakeholders on current and new regulatory requirements.
	Establishes, maintains, and further develops regulatory knowledge by completing initial training and CPD and is able to apply the skills/knowledge acquired towards regulatory review and assessment processes.
Medical Devices	Keeps abreast of and assesses the scientific and/or clinical advances, relevant to medical devices through activities such as training, literature reviews, etc.
	Establishes, maintains, and further develops medical device knowledge by completing initial training and CPD and is able to apply the skills/knowledge acquired towards regulatory review and assessment processes.
Assessment Procedures and Methods	Keeps abreast of the Regulatory Authority's assessment procedures and methods.
	Establishes, maintains, and further develops knowledge of assessment methods by completing initial training and CPD and is able to apply the skills/knowledge acquired towards regulatory review and assessment processes.
Statistical Analysis	Demonstrates knowledge of basic concepts of probability and statistics.
	Effectively applies concepts of probability and statistics to representative sampling and trend analyses.
Voluntary Consensus Standards and Guidance Documents	Keeps abreast of applicable voluntary consensus standards.
	Keeps abreast of applicable guidance documents.
	Provides information and guidance to stakeholders on current and new guidance documents.

7.3 Competence Evaluation Matrices

The initial and ongoing competence level required for each role are described below. Regulatory Authorities shall use this information to formulate and maintain training plans for Lead Assessors, Assessors, Recognition Managers, and Technical Experts to ensure that they achieve

the necessary competence levels. The learning process could include; formal assessment skills training and education, on the job assessment experience, professional development activities, supervisor/manager coaching and mentoring, etc.

The following tables should serve as a guide for rating an individual's competence level for each of the competencies outlined in the tables above. The Regulatory Authority shall record the evidence to support any rating applied to a particular competency during an evaluation.

Competence Level[1]	Description	Rating
Expert (Recognized Authority)	Individual can perform the actions associated with the skill without assistance and is considered to be an expert in the skill.	5
Advanced (Applied Theory)	Individual can perform the actions associated with this skill without assistance.	4
Intermediate (Practical Application)	Individual is able to successfully complete tasks in this competency as requested. Assistance from an expert may be required at times, but they can usually perform the skill independently.	3
Novice (Limited Experience)	Individual should have the level of experience gained in a classroom and/or experimental scenarios or as a trainee on-the-job. They may need help when performing this skill.	2
Fundamental Awareness (Basic Knowledge)	Individual should have a common knowledge or an understanding of basic techniques and concepts.	1
Not Applicable	Individual is not required to apply or demonstrate this competency	0

Foundational Competencies	Lead Assessor	Assessor	Recognition Manager	Technical Expert
Adaptability	5	4	4	3
Attitude	5	4	3	3
Communication	5	4	3	4
Critical and Analytical Thinking	5	5	4	4
Cultural Sensitivity	5	5	2	3
Integrity	5	5	5	5
Interpersonal Skills	5	4	4	3
Objectivity	5	5	4	5
Observant	5	5	3	4
Perceptive	5	4	3	5
Tenacious	5	5	3	4

[1] NIH Proficiency Scale (https://hr.nih.gov/working-nih/competencies/competencies-proficiency-scale)

Table 1 - Foundational Competence Levels

Functional Competencies	Lead Assessor	Assessor	Recognition Manager	Technical Expert
Autonomy	5	4	5	4
Business Processes	5	4	5	2
Conflict Resolution	5	4	5	3
Information Technology	5	4	4	3
Interviewing	5	5	1	2
Project Management	5	3	5	3
Records Management	5	4	5	3
Supervision	5	3	3	0
Teamwork	5	5	4	3
Time Management	5	5	5	5

Table 2 - Functional Competence Levels

Technical Competencies	Lead Assessor	Assessor	Recognition Manager	Technical Expert
Regulatory Requirements	5	5	3	4
Medical Devices	5	5	3	5
Assessment Procedures and Methods	5	5	4	1
Statistical Analysis	4	4	1	4
Voluntary Consensus Standards and Guidance Documents	5	5	2	5

Table 3 - Technical Competence Levels

7.4 Re-Evaluation

A Regulatory Authority shall evaluate Lead Assessors, Assessors, Recognition Managers, and Technical Experts for continued recognition of competence at least every 3 years.

A Regulatory Authority shall confirm skills and personal attributes of Lead Assessors and Assessors through an observed assessment every 3 years.

8.0 Training Requirements

The Competence Levels described in Section 7.3 above 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

The following sections outline the mandatory initial training required for Lead Assessors, Assessors, Recognition Mangers, and Technical Experts. Existing Assessors, Lead Assessors, Recognition Managers, and Technical Experts may use experience and other alternative evidence to satisfy these mandatory initial training requirements in this clause when this document is introduced into each jurisdiction. Such cases may include, for example, when these Assessors, Lead Assessors, Recognition Managers, and Technical Experts have acquired and demonstrated in-depth training, knowledge and experiences of the assessment of quality management systems of CABs. A Regulatory Authority shall justify and document such cases.

8.1.1 Lead Assessors, Assessors, and Recognition Managers

Lead Assessors, Assessors, and Recognition Managers are to undertake any new training mandated by the Regulatory Authority 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.

Lead Assessors, Assessors, and Recognition Managers shall have successfully completed the following training prior to performing independent work for the Regulatory Authority:

- 40 hours of class room training in quality management systems (e.g. ISO 9001, ISO 13485, etc.).

- 24 hours of training in voluntary consensus standards and guidance documents to include ISO/IEC 17065:2012 and IMDRF GRRP WG N40, N47, N52, and N59, and assessing for conformity to those requirements by utilizing IMDRF GRRP WG N61, or equivalent,

- 32 hours in medical device regulatory requirements to including the jurisdictional regulatory requirements within the scope of recognition for the Regulatory Authority and commensurate with the existing experience of the trainee.

- 8 hours of training in risk management principles related to the design of a medical device (e.g. ISO 14971)

- Specified training documented in a training plan and including; the relevant procedures of the Regulatory Authority, a sufficient number of assessments witnessed by the trainee, and a sufficient number of assessments performed by the trainee under supervision, and observed by a Lead Assessor. (See section 9.0 below). A Regulatory Authority may use evidence of relevant assessments performed for another Regulatory Authority to show fulfillment of this training requirement.

Any alternative evidence of experience or equivalent training by other means shall be justified and documented.

8.1.2 Technical Experts

The Regulatory Authority shall determine requirements for the initial training of Technical Experts according to the requirements outlined in IMDRF GRRP WG/N40. This may be in the form of training in relevant regulatory requirements, processes of the Regulatory Authority, product specific standards and guidance documents. The Technical Expert shall receive training commensurate with the assigned tasks and specific product area of focus. Technical knowledge is implied and initial training in these technical aspects may not be required for the Technical Expert.

8.2 Maintenance Training

In accordance with the code of conduct as outlined in IMDRF GRRP WG/N40, individuals involved in the assessment and recognition processes shall commit themselves to continually improve their proficiency, effectiveness, and quality of work by acquiring further knowledge. Lead Assessors, Assessors, and Recognition Managers shall receive training to maintain their skills. This training should address changes to regulatory requirements; new and updated relevant guidance documents, or standards; new or updated assessment techniques and requirements. Training should also address changes to internal policies, procedures, or business support systems.

These requirements may not apply to Technical Experts because they are consulted on an *ad hoc* basis. The Regulatory Authority may define requirements as appropriate for the maintenance of Technical Expert status.

8.3 Continual Professional Development (CPD)

Personnel involved in assessments and recognition decisions shall commit themselves to continually improve their proficiency, effectiveness, and quality of work.

Lead Assessors and Assessors, and Recognition Managers shall fulfill a requirement for CPD:

- 6 hours of professional development per year; and,
- 8 hours of annual training on changes to regulatory requirements and updates on relevant guidance documents pertaining to the regulations, or equivalent.

Mandatory annual training or re-training on internal Regulatory Authority 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. 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. CPD may include, for example, attendance at internal seminars or teleconferences; attendance, participation, and/or presentation at scientific/technical, regulatory, and professional meetings; or continuation of practical work in professional field (e.g. clinical practice) where applicable.

These requirements may not apply to Technical Experts because they are consulted on an *ad hoc* basis. The Regulatory Authority may define requirements as appropriate for the maintenance of Technical Expert status to ensure the quality and usability of the advice provided or the regulatory review performed by the Technical Expert.

9.0 Lead Assessor and Assessor Experience Requirements

Before undertaking independent assessment, Assessors-in-training shall demonstrate on-site assessment experience of a CAB's management system, which has been observed by a Lead Assessor, with at least 4 complete assessments as a member of an assessment team. If the Assessor-in training has previous experience and qualifications as an auditor or lead auditor, then 2 completed assessments as a member of an assessment team may be sufficient before undertaking an independent assessment.

Assessors shall demonstrate participation in at least 1 assessment per assessment cycle in each subsequent 12-month period.

Before recognition as a Lead Assessor, Lead Assessors-in-training shall have successfully concluded all requirements for an Assessor. Lead Assessors-in-training shall demonstrate at least 2 complete assessments as Team Leader within the previous 24 months. Lead Assessors-

in-Training are only qualified as a Lead Assessors after a successful observed assessment by a qualified Lead Assessor.

Lead Assessors shall demonstrate participation in at least 1 complete assessment in each subsequent 12-month period.

10.0 Records of Prerequisites, Competence Evaluation and Monitoring

Regulatory Authorities shall maintain current and accurate records associated with the evaluation and maintenance of competencies. Assessor competence files and assessment logs shall demonstrate how Assessors meet the requirements contained in this document and are to include:

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

The Recognition Manager shall maintain a list of Lead Assessors and Assessors.

11.0 Remediation

In the event that a Lead Assessor, Assessor, Recognition Manager, or Technical Expert fails to meet the requirements for the maintenance of competence, the Regulatory Authority shall prepare a remediation plan in order to bring the individual back into compliance. When an individual is under remediation, he or she may not conduct assessment or recognition activities except where it is necessary as part of the remediation plan and under appropriate oversight. The remediation plan may include additional training, oversight, and re-evaluation of competencies to return Lead Assessors, Assessors, Recognition Managers, or Technical Expert into compliance. For Lead Assessors or Assessors to be re-recognized, the Regulatory Authority must observe their successful completion of an assessment. Records of remediation shall be maintained.