Proposed Draft

International Medical Device Regulators Forum

Title: Auditor Competency and Training Requirements for Organizations undertaking Audits of Medical Device Manufacturers

Authoring Group: IMDRF MDSAP Work Group

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This document is being released as a proposed document for public comment in April through June 14, 2013. No comments will be accepted after June 14, 2013. All comments should be sent on the IMDRF Comment form to the Medical Device Single Audit Program (MDSAP) Working Group Chair, Ms. Kim Trautman at mailto:Kimberly.Trautman@fda.hhs.gov with a copy to the IMDRF Secretariat mailto:IMDRF.Secretariat@tga.gov.au.
Introduction

The purpose of this document is to specify competency requirements that shall be demonstrated and maintained by recognized Auditing Organization for personnel involved in medical device regulatory audits and decision making. Regulatory Authorities do not qualify, authorize, or otherwise accredit or license auditors.

The requirements contained within this document are for personnel involved in audits and decision making functions for assessing conformity with regulatory requirements for medical device manufacturers, and includes:
- Defining knowledge, skills, and abilities.
- Criteria for various degrees of competency based on roles in audits and decision making functions.
- Assisting in evaluation and development.
- Providing a basis for identifying training needs.

1.0 Scope

This document applies to recognized Auditing Organizations conducting audits of a medical device manufacturer for Regulatory purposes. Adherence to this document and its requirements will help mitigate the risk of inconsistent or ineffective assessments of manufacturers by ensuring that Auditing Organization personnel have the necessary commitment, competency, experience, and training before conducting an audit or undertaking a decision making function. The Competency Matrix described in Annex D identifies requirements for training and assists in the development of programs for personnel involved in audits and decision making functions.

This document relates to functions performed by an Auditing Organization and for the assigned roles described in Table 1.

<table>
<thead>
<tr>
<th>Functions</th>
<th>Audit On-site</th>
<th>Audit/Decision Off-site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conduct a review of the assessment application to determine audit team competence requirements, select audit team members, and determine audit duration</td>
<td>n/a</td>
<td>Program Administrator</td>
</tr>
<tr>
<td>Assessment of a quality management system</td>
<td>Lead Auditor / Auditor</td>
<td>n/a</td>
</tr>
<tr>
<td>Assessment of product related technologies</td>
<td>Technical Expert</td>
<td>n/a</td>
</tr>
<tr>
<td>Assessment of technical documentation</td>
<td>*Lead Auditor / Auditor / Technical Expert</td>
<td>Technical Expert</td>
</tr>
<tr>
<td>Assessment of conformity with Regulations</td>
<td>Lead Auditor / Auditor / Technical Expert</td>
<td>Final Reviewer / Technical Expert</td>
</tr>
</tbody>
</table>

Table 1: Auditing organization Functions and Roles
* Lead Auditor /Auditor through Design and Development Review and/or the Technical Expert may perform technical documentation reviews on site for lower risk medical devices.

2.0 Reference(s)

- ISO 9000:2005 - Quality management systems — Fundamentals and vocabulary
- GHTF/SG1/N78:2012 - Principles of Conformity Assessment for Medical Device
- ISO 19011:2011 - Guidelines for quality and/or environmental management system auditing

3.0 Definitions

3.1 Audit: A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. (ISO 9000:2006 clause 3.9.1)

3.2 Auditing Organization: An organization that audits a medical device manufacturer for conformity with quality management system requirements. Auditing organizations may be an independent commercial organization or a Regulatory Authority which perform regulatory audits.

3.3 Auditor: A person with the demonstrated personal attributes and competence to conduct an audit. (ISO 9000:2006 clause 3.9.9)

3.4 Code of Conduct: A statement of the expected behaviors for personnel involved in audits and decision making functions within an Auditing Organization and incorporating the elements defined in IMDRF/MDSAP/N3R4 – Recognition for Organizations undertaking Audits of Medical Device Manufacturers

3.5 Competence: Demonstrated personal attributes and demonstrated ability to apply knowledge and skills. (ISO 9000:2006 clause 3.9.14)

3.6 Competency Matrix: Chart that defines competencies for personnel involved in audits and decision making functions and sets the behaviors or performance characteristics requiring the application of knowledge, skills, and understanding in accordance with the audit program and defined performance standards.

3.7 Final Reviewer: An experienced auditor, who hasn't participated in the audit under review, who performs a review of the audit and finalizes the classification of the audit results.

3.8 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.
3.9 **Program Administrator:** The person that conducts a review of the assessment application to determine audit team competence requirements, select audit team members, and determine audit duration.

3.10 **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)

3.11 **Technical Documentation:** The documented evidence, normally an output of the quality management system, which demonstrates compliance of a device to the *Essential Principles of Safety and Performance of Medical Devices*. (GHTF/SG1/N78:2012 and GHTF/SG1/N46:2008)

3.12 **Technical Expert:** A person who provides specific knowledge or expertise to the audit team. (ISO 9000:2006 clause 3.9.11)

4.0 **Responsibilities**

It is the responsibility of the Auditing Organization to collect and maintain evidence that demonstrates that personnel involved in audits and decision making functions meet the minimum specified competency requirements contained within this document.

The Auditing Organization is expected to have documented processes to: (1) initially qualify personnel involved in audits and decision making functions to the specified requirements contained within this document, based on demonstrated competence; (2) ensure that the competence of personnel involved in audits and decision making functions is maintained on a continuing basis; (3) provide personnel with appropriate support and resources where needed and, (4) maintain records of these activities including a signed Code of Conduct for each person involved in the Regulatory Audit process. Auditors-in-training may be included in the audit team, but shall not audit without direction or guidance from the Lead Auditor.

The Auditing Organization’s processes for establishing and maintaining competence of personnel involved in audits and decision making functions is subject to assessment by the recognizing Regulatory Authority.

On request, Auditing Organizations are to provide feedback of their experiences with regards to the competence requirements for personnel involved in audits and decision making functions to the recognizing Regulatory Authority, for the purpose of refining the competency criteria and training requirements defined in this document.
5.0 Commitment to Impartiality and Confidentiality

Each person involved in audits and decision making functions shall sign a declaration that attests to a commitment to comply with all applicable rules, regulations, policies, values, and codes of conduct of the Auditing Organization. The initial declaration shall include or be part of a disclosure of any potential conflicts of interest, including prior association with a manufacturer or its personnel. The employing Auditing Organization shall implement appropriate arrangements to manage perceived or actual conflicts of interest.

6.0 Entry Level Requirements

An Auditing Organization shall apply their own procedures for formally selecting, training, and approving personnel involved in audits and decision making functions using the requirements and criteria contained within this document.

The following are the minimum pre-requisite education, experience, and competencies to be demonstrated and maintained by personnel involved in audits and decision making functions.

6.1 Pre-requisite Education

Lead Auditors, Auditors, Final Reviewers, and Technical Experts should hold a diploma from a university or technical college in medicine, science, or engineering. Disciplines of interest include, for example:

- Biology
- Microbiology
- Chemistry
- Biochemistry
- Computer hardware and software technology
- Material sciences
- Engineering - electrical, mechanical, biomedical, clinical, bioengineering,
- Human physiology
- Medicine
- Pharmacy
- Physics and biophysics

The educational requirement shall remain a strong basis for classification of Technical Knowledge. Typically Technical Experts develop expertise directly related to their educational background. In addition, there is a strong link to educational background for Technical Knowledge in “horizontal” production technology areas such as sterilization.

Program Administrators should hold certificates or diplomas for successful completion of secondary school education qualifications.
In exceptional cases, a demonstration of equivalent knowledge and skills may be acceptable. The Auditing Organization shall justify and document the reasons for accepting alternatives to the education requirements.

6.2 Pre-requisite Experience

Potential Lead Auditors and Auditors, Final Reviewers, Technical Experts 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.

Potential Lead Auditors, Final Reviewers, and Technical Experts 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 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 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. An Auditing Organization shall justify and document such cases.

Potential Final Reviewers shall demonstrate at a minimum the experience and skills of a Lead Auditor.

Potential Technical Experts shall demonstrate at a minimum advanced experience and expertise in a particular process, medical device, or technology classified as Technical Knowledge.

6.3 Pre-requisite Competency Requirements

Three broad categories of competencies are required for potential Lead Auditors, Auditors, Technical Experts, and Final Reviewers:

- **Foundational Competencies**: those generic skills, personal attributes, and behaviors applicable to all personnel and developed through experience (e.g. Adaptability, Diligence, Analytical thought, Communication, etc.)

- **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, Working Documents, etc.)

- **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, Sustainability, Internal Management Controls, Health and Safety Impacts, etc.)

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

6.3.1 Foundational Competencies

1. Ethics: Able to act in a responsible, fair, truthful, sincere, honest, and discreet manner with fortitude, even though these actions may not always be popular and may sometimes result in disagreement or confrontation.

(See also; ISO 19011 – Cl 7.2.2 – ethical - fair, truthful, sincere, honest and discreet; and acting with fortitude, i.e. able to act responsibly and ethically, even though these actions may not always be popular and may sometimes result in disagreement or confrontation;)

2. Objectivity: Demonstrates an impartial, unbiased mental attitude free of conflicts of interest; makes a balanced assessment of the relevant circumstances and not unduly influenced by their own interests or by others in forming judgments.

(See also; ISO 19011 – Cl 7.2.2 - open-minded, i.e. willing to consider alternative ideas or points of view)

3. Reasoning: Makes timely and sound decisions after appropriate evaluation of input or information.

(See also; ISO 19011 – Cl 7.2.2 - decisive, i.e. able to reach timely conclusions based on logical reasoning and analysis)

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.

(See also; ISO 19011 – Cl 7.2.2 - self-reliant, i.e. able to act and function independently whilst interacting effectively with others and collaborative, i.e. effectively interacting with others, including assessment team members and the Auditing Organization personnel. See also; ISO 17021 – Appendix D - professional, i.e. exhibiting a courteous, conscientious and generally business-like demeanor in the Workplace)

5. Analysis: Seeks relevant, reliable, and competent information for use in problem solving and decision making. Uses sound logic to develop alternative solutions and recommendations.

6. Communication: Communicates ideas in a style that is clear, concise, fluent, and to-the-point, takes audience needs into consideration in oral, written and presentation communications.

7. Diligence: Exercises prudence and caution during the conduct of the assessment such that a reasonable person would conclude that steps taken and the resulting conclusion were arrived at in a logical manner using all relevant information available.
8. **Adaptability:** Demonstrates the ability to use or consider nontraditional methods; makes changes in response to demands and circumstances.
   (See also; ISO 19011 – Cl 7.2.2 - versatile, i.e. able to readily adapt to different situations)
9. **Tenacity:** Persistent
   (See also; ISO 19011 – Cl 7.2.2 - tenacious, i.e. persistent and focused on achieving objectives)
10. **Intuition:** Makes judgments in the absence of complete factual information using perspectives from past experiences and observations.
   (See also; ISO 19011 – Cl 7.2.2 - perceptive, i.e. aware of and able to understand situations)
11. **Observation:** Draws on past experience to obtain visual facts on conditions as they exist and makes comparisons of actual vs. recorded information; compares reality to standards, policies, or procedures to derive opinion on compliance.
   (See also; ISO 19011 – Cl 7.2.2 - observant, i.e. actively observing physical surroundings and activities)

**6.3.2 Functional Competencies**

1. **Information Technology:** Has the willingness and ability to apply; electronic technology to complete work objectives, 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.
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 auditing organization.
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.
   (See also; ISO 19011 – Cl 7.2.2 - open to improvement, i.e. willing to learn from situations, and striving for better assessment results)
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.
   (See also; ISO 19011 – Cl 7.2.2 - diplomatic, i.e. tactful in dealing with people)
5. **Supervision:** Plans, organizes, directs, monitors, and evaluates the work of others assigned to assessment projects.
   (See also ISO19011 - Clause 7.2.3.4)
6. **Writing Literacy**: Prepares reports and presentations that are clear, concise, and based on the objective evidence.

7. **Time Management**: Monitors progress against objectives; completes duties in timely, complete, and effective manner.

8. **Records Management**: Documents work procedures, situations observed while performing assessment steps, issues identified, assessment against standards, support for opinions, and resolutions/recommendations for action.

9. **Legal Protections**: Applies legal privileges and demonstrates how to maintain legal protection of communications and information identified as part of the assessment process.

10. **Cultural Sensitivity**: Observant and respectful to the culture of the Auditing Organization (See also; ISO 19011 – Cl 7.2.2 - culturally sensitive)

11. **QMS**: Understands and follows the prescribed policy, procedures, and forms for the organization’s own quality management system.

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

### 6.3.3 Technical Competencies

1. **Quality Systems**: The principles and applications of medical device quality systems standards, regulations, and guidance documents (e.g. Global Harmonization Task Force Study Group 3 guidance documents).

2. **Regulatory requirements**: An understanding of the medical device regulatory requirements of the participating Regulatory Authorities for which the person will be working in to enable an assessment of the applicability and compliance with such standards, laws and regulations.

3. **Medical devices**: An understanding of medical devices and the requisite 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, and the typical organization of, medical device manufacturers

4. **Auditing Procedures and Techniques**: An understanding of the Auditing Organization’s procedures and criteria; an understanding of the relevant standard, and related parts, used for the recognition of the Auditing Organization; and an understanding of auditing standards and techniques for auditing Quality Management Systems.
5. **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.

6. **Risk Management:** Knowledge of risk management principles including:
   - Risk Analysis – systematically identifying hazards (i.e. undesirable outcomes and consequences considering environmental impacts and health and safety exposures) and estimating risks (expressed as the severity of exposure, or impacts, and the probability of occurrence)
   - Risk evaluation – comparing estimated risks against criteria to determine the acceptability of the risk
   - Risk Control – mitigating and maintain the likelihood and/or severity of risk to acceptable levels
   - Monitoring the effectiveness of controls - through production and post-production information

### 7.0 Training requirements

The following are the minimum activities undertaken to establish initial competency and to maintain proficiency.

#### 7.1 Mandatory Initial Training

Final Reviewers, Lead Auditors, Auditors and Technical Experts, are to undertake any new training mandated by the recognizing 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.

Final Reviewers, Lead Auditors, and Auditors shall have successfully completed the following training prior to performing independent work for the Auditing Organization:

- 40 hours of class room training in the ISO 9001 standard including a minimum of 8 hours dedicated to the additional requirements of ISO 13485. In cases of already qualified ISO 9001 auditors, a minimum of 8 hours of class room training in the additional requirements of ISO 13485. Any alternative evidence of equivalent training by other means shall be justified and documented.

- 32 hours of training in medical device regulations, and auditing for conformity to those regulations, or equivalent, plus sufficient additional time for each set of jurisdictional regulatory requirements within the scope of recognition for the Auditing Organization and commensurate with the existing experience of the trainee.

- 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 GHTF/SG3/N15R8)
Specified training documented in a training plan and including; the relevant procedures of the Auditing Organization’s quality management system, 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, prior to a recognition audit. An Auditing Organization may use evidence of relevant audits performed for another Auditing Organization to show fulfillment of this training requirement.

Technical Experts shall have successfully completed the following training prior to performing independent work for the Auditing Organization:

- For each recognition in a category of Technical Knowledge, irrespective of whether this is the first or a later category to be qualified, the Auditing Organization shall document evidence of appropriate training and knowledge for the Technical Expert in the Technical Knowledge category. This may be in the form of training in the requirements of relevant standards, training in the characteristics of, or requirements for, products, product, or process technologies, or training in the clinical indications for a product category, etc.

- 32 hours of training in medical device regulations, and auditing for conformity to those regulations, or equivalent, plus sufficient additional time for each set of jurisdictional regulatory requirements within the scope of recognition for the Auditing Organization and commensurate with the existing experience of the trainee.

- 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 GHTF/G3/N15R8)

- Specified training documented in a training plan and including; the relevant procedures of the Auditing Organization’s quality management system, a sufficient number of technical documentation reviews witnessed by the trainee, and a sufficient number of technical documentation reviews performed by the trainee and peer reviewed by an experienced Technical Expert, prior to being qualified to perform independent technical documentation reviews. An Auditing Organization may use evidence of technical documentation reviews performed for another Auditing Organization to show fulfillment of this training requirement.

Program Administrators shall have successfully completed specified training documented in a training plan in the relevant procedures of the Auditing Organization’s quality management system.

7.2 Continual Professional Development

In accordance with the Code of Conduct, personnel involved in audits and decision making functions shall commit themselves to continually improve their proficiency, effectiveness, and quality of work.
Lead Auditors and Auditors, Final Reviewers, Technical Experts and Program Administrators shall fulfill a minimum requirement for continual professional development (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 Auditing Organization 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 audits or decision making functions. Personnel with a broad scope of competence may require more CPD hours per year to maintain their competence. Auditing Organizations shall not permit additional hours carried forward to count as CPD hours in future years.

8.0 Auditor, Technical Expert and Final Reviewer Experience Requirements

Before undertaking independent auditing, Auditors-in-training shall demonstrate at least 20 on-site audit days of a medical device manufacturer’s quality management system, which have been observed by a Lead Auditor, conducted in the previous 12 months and with at least 4 complete audits as a member of an audit team.

Lead Auditors shall demonstrate participation in at least 6 audits that total at least 15 audit days in each subsequent 12 month period. At least 2 of these audits shall be complete audits.

Before recognition as a Lead Auditor, Lead Auditors-in-training shall have successfully concluded all requirements for an Auditor. Lead Auditors-in-training shall demonstrate at least 35 on-site audit days of a medical device manufacturer’s quality management system with at least 3 complete audits conducted within the previous 12 months. Lead Auditors-in-training shall demonstrate at least 15 audit days as Team Leader. Lead Auditors-in-Training are only qualified as a Lead Auditor after a successful witness audit has been documented by a qualified Lead Auditor.

Lead Auditors shall demonstrate participation in at least 6 audits that total at least 15 days in each subsequent 12 month period. At least 2 of these audits shall be an initial audit or re-audit. At least 2 of these audits shall be performed as an audit team leader.

Technical Experts shall demonstrate at a minimum advanced experience in a particular process, medical device, or technology classified as Technology Knowledge. A maximum of 10% of the Technical Experts required experience may be derived from time spent meeting the educational requirement, based on detailed written justifications. For recognition in a first Technical Knowledge category, the Technical Expert must have successfully complete 3 technical documentation reviews. Alternatively, reviews of design dossiers (or their equivalent) in the relevant Technical Knowledge category may count toward this requirement. Already approved Technical Files may be used for recognition purposes. For recognition in an additional
Technical Knowledge category, the Technical Expert shall provide evidence of relevant and adequate product training, knowledge, and/or experience.

Technical Experts shall perform 5 technical documentation reviews in each 12 month period. Reviews of significant changes in technical documentation to a product can count for a maximum of 50% of the 5 technical documentation reviews in each 12 month period.

Technical Experts for process related technology reviews shall perform 5 off-site/on-site reviews in each 12 month period.

Final Reviewers must have 2 years of seniority/experience in regulatory audits of medical device manufacturers and have successfully concluded all requirements for a Lead Auditor.

Final Reviewers authorized to monitor training and approve, suspend or withdraw recognition for Technical Experts must have adequate seniority/experience in technical documentation reviews.

Auditing Organization’s shall record the Technical Knowledge of their Auditors, Lead Auditors, and Technical Experts. This record of Technical Knowledge shall be kept current and used by the Program Administrator to assign auditors and technical experts to specific audits. See Appendix A – Classification of Technical Knowledge

9.0 Competency Evaluation

9.1 Competency Evaluation Criteria

Lead Auditor, Final Reviewer, Technical Expert, and Auditor competency levels will differ and depend on their roles in the assessment program.

An Auditing Organization is to assign one of four levels for each competency depending on the person’s role:

<table>
<thead>
<tr>
<th>Importance</th>
<th>Requirement</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical Skill or Knowledge</td>
<td>Must have</td>
<td>4</td>
</tr>
<tr>
<td>Important Skill or Knowledge</td>
<td>Should have</td>
<td>3</td>
</tr>
<tr>
<td>Helpful Skill or Knowledge</td>
<td>Preferable to have</td>
<td>2</td>
</tr>
<tr>
<td>Skill or Knowledge Not Critical</td>
<td>Not necessary</td>
<td>1</td>
</tr>
</tbody>
</table>

A Competency Matrices describe the initial and ongoing competency level required for each role. See Appendix B.

Auditing Organizations shall use the Competency Matrix to formulate and maintain training plans for Lead Auditors, Final Reviewers, Technical Experts, and Auditors to ensure that they achieve the necessary competency 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.
9.2 Methods of Evaluation: Initial and Ongoing Monitoring.

Auditing Organizations shall evaluate the competency of Lead Auditors/Final Reviewers, Technical Experts, and Auditors using a combination of monitoring methods that may include:

- Review of records of audits or inspections, education, training, etc.
- Feedback from peers and supervisors
- Interviews
- Observation of performance
- Testing

9.3 Re-Evaluation

An Auditing Organization shall evaluate Lead Auditors/Final Reviewers, Technical Experts, and Auditors for continued recognition of competency at least every 3 years.

An Auditing Organization shall confirm skills and personal attributes of Lead Auditors and Auditors through a witness audit every two years.

10.0 Reaffirmation of Code of Conduct

Personnel involved in the audit are to reaffirm their commitment to the Code of Conduct on an annual basis. This should be in the form of a signed statement kept on file.

11.0 Records of Pre-requisites, Competency Evaluation and Monitoring

Auditing Organizations will maintain current and accurate records associated with the evaluation and maintenance of competencies. Auditor competency files and audit logs shall demonstrate how auditors meet the requirements contained in this document and are to include:

- Auditor name, position, and contact information.
- Pre-requisite and subsequent education
- Results of evaluation of the Auditor’s competence in the role of Lead Auditor/Final Reviewer, Technical Expert, or Auditor according to the requirements in this document.
- Audit/Inspection/Assessment experience
- Training participation and outcomes
- 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)
- An Audit Log

An Auditing Organization shall make these records available to the recognizing Regulator Authority upon request. The Program Administrator shall maintain a list of Lead Auditors, Auditors, and Technical Experts. The list is to be updated annually.
12.0 Remediation

An Auditing Organization shall suspend the recognition of personnel that fail to meet the requirements for the maintenance of competency or renewal of recognition. An Auditing Organization 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 audit experience requirement defined in this document. In such cases, the person under remediation shall not act as a Lead Auditor or Final Reviewer.

The Auditing Organization shall observe an auditor successfully performing a full audit in order to have recognition re-instated.

A Technical Expert shall be assessed under supervision and recognition confirmed by the Final Reviewer based on the outcome of this review.
### Appendix A – Classification of Technical Knowledge

#### Knowledge of Medical Devices

Auditing Organizations shall utilize the following tables to classify Technical Knowledge and record the relevant classification in personnel files.

| Non-Active Medical Devices | Non-Active Implants (excluding Dental Implants) | Non-Active Cardiovascular Implants  
|                           |                                                  | Non-Active Orthopedic Implants  
|                           |                                                  | Non-Active Soft Tissue Implants  
|                           |                                                  | Non-Active Functional Implants  
| Medical Devices for Wound Care | Bandages and Dressings  
|                           | Suture Material  
|                           | Other Non-Active devices for wound care  
| Non-Active Dental Devices | Non-Active Dental Equipment and Instruments  
|                           | Dental Materials  
|                           | Dental Implants  
| General Non-Active Medical Devices | Non-Active Devices for anesthesia, emergency and intensive care  
|                           | Non-Active Devices for injection, infusion, transfusion and dialyses  
|                           | Non-Active Orthopedic and Rehabilitation Devices  
|                           | Non-Active Measuring Devices  
|                           | Non-Active Ophthalmic Devices  
|                           | Non-Active Instruments  
|                           | Devices for Contraception  
|                           | Non-Active Devices for disinfection, cleaning and rinsing  
|                           | Non-Active Devices for In-Vitro Fertilization (IVF) and Assisted Reproduction Technologies (ART)  
| Other Non-Active Medical Devices | Specify  
| Active Non Implantable Medical Devices | Monitoring Devices | Active Devices for monitoring vital physiological parameters  
|                           | Active Devices for monitoring non-vital physiological parameters  

January 31, 2013
| Imaging Devices                                                                 | • Imaging Devices using Ionizing Radiation  
|                                                                              | • Imaging Devices using non-ionizing Radiation  
| Devices for Radiation and Thermotherapy                                     | • Devices using Ionizing radiation  
|                                                                              | • Devices using non-ionizing radiation  
|                                                                              | • Device for Thermotherapy  
|                                                                              | • Devices for Lithotripsy  
| General Active non-implantable Medical Devices                              | • Active devices for extracorporeal circulation, infusion and hemapheresis  
|                                                                              | • Active devices for respiratory therapy, oxygen therapy, and inhalation anesthesia  
|                                                                              | • Active Devices for stimulation and inhibition  
|                                                                              | • Active surgical devices  
|                                                                              | • Active Ophthalmic devices  
|                                                                              | • Active Dental Devices  
|                                                                              | • Active devices for disinfection and sterilization  
|                                                                              | • Active rehabilitation devices and active prostheses  
|                                                                              | • Active devices for patient positioning and transport  
|                                                                              | • Software  
|                                                                              | • Active devices for In-Vitro Fertilization (IVF) and Assisted Reproduction Technologies (ART)  
| Other Active Non-Implantable Medical Devices                                 | • Specify  

| Active Implantable Medical Devices                                           | Devices for stimulation or inhibition  
| Devices delivering Drugs or other substances                                 |
| Devices substituting or replacing organ functions                           |
| Radioactive seeds for interstitial radiotherapy                             |
| Other active implantable medical devices                                    |
| **In Vitro Diagnostic Medical Devices** | **Reagents and reagent products, calibrators and control materials for In Vitro Diagnostic Medical Devices** | • clinical chemistry  
• immunochemistry  
• hematology  
• microbiology  
• infectious immunochemistry  
• histology/cytology  
• genetic testing |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In Vitro Diagnostic Instruments and software</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **In Vitro Diagnostic medical devices for near-patient use** | • devices for home use  
• near-patient use other than home use |
| **Other In Vitro Diagnostic medical devices** | • Specify |

### Medical Devices incorporating specific substances or technologies

<table>
<thead>
<tr>
<th><strong>Medical device containing medicinal or biologically active substances</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical devices containing or manufactured using tissue of animal origin</strong></td>
</tr>
<tr>
<td><strong>Medical devices containing human blood derivatives</strong></td>
</tr>
<tr>
<td><strong>Medical devices using micro-machinery and MEMS</strong></td>
</tr>
<tr>
<td><strong>Medical devices containing nanomaterial</strong></td>
</tr>
<tr>
<td><strong>Medical devices using biologically active coatings or materials being wholly or mainly absorbed by the body</strong></td>
</tr>
</tbody>
</table>

An Auditing Organizations shall further stratify and record knowledge of medical devices to indicate knowledge of specific manufacturing technologies, production methods or advanced topics.
Knowledge of Manufacturing Technologies

Knowledge of specific manufacturing technologies and their quality practices shall be recorded in the personnel files of auditors. Examples include:

- Thin and thick film techniques
- Manufacturing techniques for microelectronics
- Manufacturing techniques for micro-machinery
- Aseptic processing
- Welding techniques
- Manufacturing techniques for ceramics and sol-gels
- Manufacturing techniques involving polymers (extrusion, injection molding, etc.)
- Metal manufacturing techniques (casting, shaping, heat treating, etc.)
- Textile and fiber manufacturing technologies, weaving
- Packaging techniques

Knowledge of Advanced Topics

Where Auditors, Lead Auditors, and Technical Experts have advanced knowledge of special technical areas, this shall be reflected in the personnel files held by the Auditing Organization. Examples include:

- Knowledge of sterilization techniques and their validation
- Knowledge of microbiology and bioburden monitoring
- Knowledge of biocompatibility and its evaluation
- Knowledge of cleanroom processing
- Knowledge of environmental monitoring and controls
- Knowledge of packaging technologies
- Knowledge of stability testing
- Knowledge of risk management practices
- Knowledge of cleaning and disinfection
- Biological evaluation of medical devices
- Clinical evaluation of medical devices
- Physical and chemical evaluation of medical devices
- Knowledge of process validation practices
- Software validation techniques

An Auditing organization may also choose to record knowledge that personnel may have of the use of the device.
Appendix B – Competency Matrices

Rating criteria

Program Manager, Lead Auditor, Auditor, or Technical Expert are assigned one of four levels for each competency depending on their role in accordance with the following tables.

<table>
<thead>
<tr>
<th>Importance</th>
<th>Requirement</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical Skill or Knowledge</td>
<td>Must have</td>
<td>4</td>
</tr>
<tr>
<td>Important Skill or Knowledge</td>
<td>Should have</td>
<td>3</td>
</tr>
<tr>
<td>Helpful Skill or Knowledge</td>
<td>Preferable to have</td>
<td>2</td>
</tr>
<tr>
<td>Supplemental Skill Set</td>
<td>Optional</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 1 - Foundational Competencies

<table>
<thead>
<tr>
<th>Foundational COMPETENCIES</th>
<th>Program Administrator</th>
<th>Lead Auditor</th>
<th>Auditor</th>
<th>Technical Expert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethics</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Objectivity</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Reasoning</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Interpersonal Skills</td>
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<td>4</td>
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<tr>
<td>Analysis</td>
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<td>Communication</td>
<td>4</td>
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<td>3</td>
<td>3</td>
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<tr>
<td>Diligence</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Adaptability</td>
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<td>4</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Tenacity</td>
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<td>4</td>
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<tr>
<td>Intuition</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Observation</td>
<td>2</td>
<td>4</td>
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</table>

Table 1 - Foundational Competencies
### Functional Competencies

<table>
<thead>
<tr>
<th>Competencies</th>
<th>Program Administrator</th>
<th>Lead Auditor</th>
<th>Auditor</th>
<th>Technical Expert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information Technology</td>
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<td>4</td>
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<tr>
<td>Interviewing</td>
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<tr>
<td>Teamwork</td>
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<td>Conflict Resolution</td>
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<tr>
<td>Supervision</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>2</td>
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<tr>
<td>Writing Literacy</td>
<td>2</td>
<td>4</td>
<td>3</td>
<td>3</td>
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<tr>
<td>Time Management</td>
<td>3</td>
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<tr>
<td>Records Management</td>
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<td>3</td>
<td>3</td>
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<tr>
<td>Legal Protections</td>
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<tr>
<td>Cultural Sensitivity</td>
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<td>4</td>
<td>4</td>
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<td>QMS</td>
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<td>2</td>
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<tr>
<td>Autonomy</td>
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</table>

**Table 2 - Functional Competencies**

### Technical Competencies

<table>
<thead>
<tr>
<th>Competencies</th>
<th>Technical Expert*</th>
<th>Lead Auditor</th>
<th>Auditor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Systems</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Regulatory Requirements</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Auditing Procedures and Techniques</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Statistical Analysis</td>
<td>2</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Risk Management</td>
<td>2</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

**Table 3 - Technical Competencies**

* A Technical Expert shall have a technical competency of (4) in their area of expertise
** Program Administrators shall have a technical competency of (4) in the Auditing organizations policies and procedures for assessing the application to determine audit team competence required, selecting the audit team members, and determining audit time.