**Please complete and include with your application to be recognized as a MDSAP Auditing Organization.**

**COMPANY NAME:**

| **IMDRF N4** | | **DOCUMENTATION** | | | **REMARKS**  **(Are these activities performed by your organization? If not, by whom?)** |
| --- | --- | --- | --- | --- | --- |
| Criterion | Req. | Manual  (state document number) | Procedure  (state document number) | Other documents  (state document number) |  |
| **IMDRF/WG/N4 FINAL:2013** |  |  |  |  |  |
| **1.0 Scope** |  |  |  |  |  |
| **2.0 References** |  |  |  |  |  |
| **3.0 Definitions** |  |  |  |  |  |
| **4.0 Responsibilities** |  |  |  |  |  |
| AO responsible for collecting and maintaining evidence of competence in accordance with N4 | 4.0 |  |  |  |  |
| AO to have documented processes to: |  |  |  |  |  |
| 1. Initially qualify personnel involved in auditing activities to specified requirements | 4.0 |  |  |  |  |
| 1. Ensure competence of personnel is maintained | 4.0 |  |  |  |  |
| 1. Provide personnel with support and resources where needed | 4.0 |  |  |  |  |
| 1. Maintain records of these activities | 4.0 |  |  |  |  |
| 1. Including a signed Code of Conduct (in accordance with IMDRF MDSAP WG N3 clause 7.1.6) | 4.0 |  |  |  |  |
| Auditors-in-training not to audit without supervision. | 4.0 |  |  |  |  |
| **5.0 Commitment to Impartiality and Confidentiality** |  |  |  |  |  |
| Each person involved in auditing activities shall sign a Code of Conduct and disclose potential conflicts of interest, including prior association with a manufacturer or its personnel. | 5.0 |  |  |  |  |
| AO shall implement arrangements to manage perceived or actual conflicts of interest. | 5.0 |  |  |  |  |
| **6.0 Entry Level Requirements** |  |  |  |  |  |
| AO shall apply its own procedures for selecting, training, and approving personnel involved in audit and decision making functions using requirements in N4. | 6.0 |  |  |  |  |
| **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. (consult N4 for disciplines of interest) | 6.1 |  |  |  |  |
| Program Administrators should hold certificates or diplomas for successful completion of secondary school education qualifications. | 6.1 |  |  |  |  |
| Educational requirements to form basis for classification of Technical Knowledge. In exceptional cases, demonstration of equivalent knowledge and skills may be acceptable. AO shall justify and document reasons for accepting alternatives to educational requirements. | 6.1 |  |  |  |  |
| **6.2 Pre-requisite Experience** |  |  |  |  |  |
| Potential Lead Auditors and Auditors, Final Reviewers, Technical Experts and Program Administrators shall demonstrate sufficient experience to have acquired required skills and knowledge to perform assigned tasks. | 6.2 |  |  |  |  |
| Potential Lead Auditors, Final Reviewers, and Technical Experts shall demonstrate at least four years of relevant full-time experience. Successful completion of other formal qualifications (advanced degrees) can substitute for a maximum of three years of working experience. | 6.2 |  |  |  |  |
| In exceptional cases, a shorter duration of experience, or experience in areas not mentioned above, may be acceptable. AO shall justify and document such cases. | 6.2 |  |  |  |  |
| Potential Final Reviewers shall demonstrate the experience and skills of a Lead Auditor. | 6.2 |  |  |  |  |
| Potential Technical Experts shall demonstrate advanced experience and expertise in a particular process, medical device, or technology classified as Technical Knowledge. (refer to Appendix A) | 6.2 |  |  |  |  |
| **6.3 Pre-Requisite Competence Requirements** |  |  |  |  |  |
| For Lead Auditors, Auditors, Technical Experts and Final Reviewers, the three categories of competencies – Foundational Competencies, Functional Competencies, and Technical Competencies - 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 all three categories. In this case, the Auditing Organization shall evaluate and update competence requirements at a later point in the process of training and other recognition activities | 6.3, 6.3.1, 6.3.2, 6.3.3 |  |  |  |  |
| **6.3.1 Foundational Competencies** | ------ |  |  |  |  |
| **6.3.2 Functional Competencies** | ------ |  |  |  |  |
| **6.3.3 Technical Competencies** | ------- |  |  |  |  |
| **7.0 Training Requirements** |  |  |  |  |  |
| The Competence Levels described in Appendix B of N4 shall be used to identify requirements for training and the development of training programs for personnel involved in audits and decision making functions. | 7.0 |  |  |  |  |
| **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(s) within the designated timeframes. Such training will count toward annual Continual Professional Development (CPD) hours. | 7.1 |  |  |  |  |
| 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 quality management systems including a minimum of 8 hours dedicated to additional medical device quality management system requirements  • 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 and their application within a quality management system. | 7.1 |  |  |  |  |
| • Specified training documented in a training plan [i.e. records]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.  Any alternative evidence of equivalent training by other means shall be justified and documented. | 7.1 |  |  |  |  |
| 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, the Auditing Organization shall document evidence of appropriate training and knowledge for the Technical Expert in the Technical Knowledge category [i.e. records.] This may be in the form of training in the requirements of relevant standards, training in the characteristics of, or requirements for, products, or process technologies, or training in the clinical indications for a product category, etc. | 7.1 |  |  |  |  |
| • 32 hours of training in medical device 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 and their application within a quality management system.  • Specified training documented in a training plan [i.e records] 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. | 7.1 |  |  |  |  |
| 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. | 7.1 |  |  |  |  |
| **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. | 7.2 |  |  |  |  |
| Lead Auditors and Auditors, Final Reviewers, Technical Experts and Program Administrators shall fulfil a 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 the Auditing Organization’s internal procedures and processes shall not count toward CPD hours. Audits or work performed shall not count towards 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. | 7.2 |  |  |  |  |
| **8.0 Auditor, Technical Expert and Final Reviewer Experience Requirements** |  |  |  |  |  |
| There must be documented evidence of successful completion of the mandatory initial training (see 7.1 above) prior to fulfilling the following requirements. | 8.0 |  |  |  |  |
| **8.1 Auditors-in-training, Auditors, Lead Auditor-in-training, and Lead Auditors** |  |  |  |  |  |
| Before undertaking independent auditing, auditors will be considered Auditors-in-training.  To be qualified as an Auditor, the Auditor-in-training shall participate as a member of an audit team for at least 20 on-site audit days.  The Auditor-in-training must be observed by a Lead Auditor, the audits must be conducted within 12 months, and at least 2 of these audits must be initial or re-audits/recertification audits. | 8.1 |  |  |  |  |
| 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 must be initial or re-audits/recertification audits in order to maintain the necessary experience and qualification. | 8.1 |  |  |  |  |
| Before recognition as a Lead Auditor, Lead Auditors-in-training shall have successfully concluded all requirements for an Auditor above. Lead Auditors-in-training shall demonstrate at least an additional 15 on-site audit days leading an audit, at least 3 of these audits must be initial or re-audits / recertification audits, and these audits must be conducted within 12 months.  Lead  Auditors-in-Training are only qualified as a Lead Auditor after a successful witness audit has been documented by a qualified Lead Auditor. | 8.1 |  |  |  |  |
| 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 must be initial or re-audits/recertification audits. At least 2 of these audits shall be performed as a Lead Auditor in order to maintain the necessary experience and qualification. | 8.1 |  |  |  |  |
| **8.2 Technical Experts** |  |  |  |  |  |
| Technical Experts shall demonstrate 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 completed 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 documentation 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. | 8.2 |  |  |  |  |
| 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 3 of the 5 technical documentation reviews in each 12 month period. | 8.2 |  |  |  |  |
| Technical Experts for process related technology reviews shall perform 5 off-site /on-site reviews in each 12 month period. | 8.2 |  |  |  |  |
| **Final Reviewers** |  |  |  |  |  |
| Final Reviewers must have 2 years’ experience in regulatory audits of medical device manufacturers and have successfully concluded all requirements for a Lead Auditor. | 8.2 |  |  |  |  |
| Final Reviewers authorized to monitor training and approve, suspend or withdraw recognition for Technical Experts must have adequate seniority/experience in technical documentation reviews. | 8.2 |  |  |  |  |
| **Technical Knowledge** |  |  |  |  |  |
| Technical Knowledge may be categorized or coded by Regulatory Authorities. The Auditing Organization must define a method of assigning Technical Knowledge with regards to the requirements of the recognizing Regulatory Authority(s). | 8.2 |  |  |  |  |
| 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 Administrators to assign auditors and technical experts to specific audits.  See Appendix A – Example of Technical Knowledge Classification | 8.2 |  |  |  |  |
| **9.0 Competence Evaluation** |  |  |  |  |  |
| **9.1 Competence Evaluation Criteria** |  |  |  |  |  |
| The initial and ongoing competence level required for each role is described in Appendix B. Auditing Organizations shall use this information to formulate and maintain training plans for Program Administrators, Lead Auditors/Final Reviewers, Auditors, and Technical Experts to ensure that they achieve the necessary competence levels. | 9.1 |  |  |  |  |
| **9.2 Methods of Evaluation: Initial and Re-Evaluation** |  |  |  |  |  |
| Auditing Organizations shall evaluate the competence 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 the audited manufacturers, peers, and supervisors  • Interviews  • Observation of performance  • Testing | 9.2 |  |  |  |  |
| **9.3 Re-evaluation** |  |  |  |  |  |
| An Auditing Organization shall evaluate Lead Auditors/Final Reviewers, Technical Experts, and Auditors for continued recognition of competence at least every 3 years. | 9.3 |  |  |  |  |
| An Auditing Organization shall confirm skills and personal attributes of Lead Auditors and Auditors through a witness audit every 3 years. | 9.3 |  |  |  |  |
| **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. | 10.0 |  |  |  |  |
| **11.0 Records of Pre-requisites, Competence Evaluation and Monitoring** |  |  |  |  |  |
| Auditing Organizations shall maintain current and accurate records associated with the evaluation and maintenance of competencies. | 11.0 |  |  |  |  |
| Auditor competence 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 | 11.0 |  |  |  |  |
| An Auditing Organization shall make these records available to the recognizing Regulatory Authority(s) upon request. | 11.0 |  |  |  |  |
| The Auditing Organization shall maintain a list of Lead Auditors, Auditors, and Technical Experts. The list is to be reviewed annually and updated as necessary. | 11.0 |  |  |  |  |
| **12.0 Remediation** |  |  |  |  |  |
| An Auditing Organization shall suspend the recognition of personnel that fail to meet the requirements for the maintenance of competence or renewal of recognition. | 12.0 |  |  |  |  |
| An Auditing Organization shall prepare a remediation plan in order to bring the person back into compliance. | 12.0 |  |  |  |  |
| 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 fulfil the audit experience requirement defined in this document. In such cases, the person under remediation shall not act as a Lead Auditor or Final Reviewer. | 12.0 |  |  |  |  |
| The Auditing Organization shall observe an auditor successfully performing a full audit in order to have recognition re-instated. | 12.0 |  |  |  |  |
| A Technical Expert shall be assessed under supervision and recognition confirmed by the Final Reviewer based on the outcome of this review. | 12.0 |  |  |  |  |
| **Appendix A – Example of Technical Knowledge Classification** |  |  |  |  |  |
| **Appendix B – Competence Information** |  |  |  |  |  |
| A Program Administrator, Lead Auditor, Auditor, or Technical Expert is required to attain a competence level for each foundational, functional and technical competence, depending on their role, and in accordance with the following tables. |  |  |  |  |  |