MDS-IR1

Implementing Rule on SFDA's Requirements for Conformity Assessment Bodies **Conducting Medical Devices Technical Review** and/or **Audit Activities**

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Chapter One
(General Rules)

Article One

This document is a requirement adopted by the Saudi Food and Drug Authority (SFDA) on the bases of the Medical Device Interim Regulation and, in particular Chapter Seven. Thereof, Issued by SFDA Board of Directors decree number (1-8-1429) and dated 27 December 2008, and amended by SFDA Board of Directors decree number (4-16-1439) dated 27 December 2017.

Article Two

This Implementing Rule, in accordance with the Medical Devices Interim Regulation, specifies and refines the provisions of its Chapter Seven in relation to the responsibilities, competence and governance of the Conformity Assessment Bodies.

Article Three: Definitions

KSA: means the Kingdom of Saudi Arabia.

SFDA: means Saudi Food and Drug Authority

Party: means any natural or legal person.

Medical Device: means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Audit: means a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Authorized representative (AR): means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.

Conformity Assessment Body: (CAB) means a third party, established within the KSA, independent of both the manufacturer and user of the medical device that is subject to assessment.

Distributor: means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

Importer: means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another jurisdiction, available in the KSA.

Manufacturer: means any natural or legal person with responsibility for design and/or manufacture of a regulated device with the intention of making the device available for use, under his name; whether or not such a device is designed and/or manufactured by that person himself or on his behalf by another person(s).

Placing on the market: means the first making available in return for payment or free of charge of a medical device, with a view to distribution and/or use within the KSA, regardless of whether it is new or fully refurbished.

Auditor: A person with the demonstrated personal attributes and competence to conduct an audit.

Conformity assessment: means the systematic examination of evidence generated, and procedures undertaken, by the manufacturer, under requirements established in the Medical Devices Interim Regulation and its Implementing Rules, to determine that a regulated device complies with all relevant requirements.

Accessories: means a product intended specifically by its manufacturer to be used together with a medical device to enable that medical device to achieve its intended purpose.

Competence: Demonstrated personal attributes and demonstrated ability to apply knowledge and skills.

Establishment: any place of business within the KSA that is involved in the manufacture and/or placing on the market and/or distribution of medical devices or acting on behalf of the manufacturer.

In Vitro Diagnostic (IVD) medical device: means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.

Person: is a term that includes legal entities such as a corporation, partnership or an association.

Quality Management System (QMS): is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.

Auditing Organization: An organization that audits a medical device manufacturer for conformity with quality management system requirements and other medical device regulatory requirements.

Chapter Two
(Applying for Designation as a CAB for Medical Devices Technical Review)

Article Four: Technical Documentation Review

A. SFDA requires all medical devices intended to be place in the market and/or put into service to have a written marketing authorization issued by SFDA, except exempt devices.

B. SFDA itself or by a CAB it designates will perform the technical review of medical devices and their accessories that will be supplied to the KSA market (including contact lenses and laser surgical equipment for cosmetic rather than medical purposes, and their accessories).

C. After the CAB conducted a technical review, it shall provide a certificate with technical report and recommendation covering all elements of the technical evaluation.

D. Where justified by post-market performance history or other concerns, the SFDA may at any time require the organization to re-evaluate the technical documentation of the medical devices.

Article Five

The CAB applying for designation under the provisions of the Medical Devices Interim Regulation and its Implementing Rules shall submit the following required information to the SFDA:

A. The name and contact details (i.e. postal address in a format that allows location to be established, telephone number and e-mail address) of the registered place of business of the candidate CAB, and of its parent organization, together with contact persons at both locations.

B. A description of the organizational structure and management of the CAB and its relationship to other parts of the parent and any subsidiary organization, if any. Information shall be provided on the qualifications, duties, responsibilities, and authorities of management and other employees of the CAB, as they relate to the Medical Devices Interim Regulation.

C. A description and organization chart to illustrate the professional relationship between the employees located within the KSA and those located elsewhere, in particular, those based with the parent organization.

D. Information on the CAB's and parent organization's knowledge and experience of the regulated devices.

E. Details of the CAB's liability insurance arrangements.

F. Details of the CAB's legal status under KSA law.

G. Details of the CAB's policy and arrangements to safeguard the confidentiality of the information obtained or created during the performance of its duties

H. Details of the CAB's policy and arrangements to ensure its management and employees will carry out their duties in an independent, objective, ethical and impartial manner, and will avoid any conflicts of interest

I. A description of the CAB's quality management procedures.

J. An attestation that the CAB has implemented the policies and procedures described in paragraphs G, H and I of this Article, and an undertaking to maintain the number, qualifications and experience of its employees at a level sufficient to allow proper functioning of the CAB.

Chapter Three
(Applying for Designation as a QMS Auditing organization)

Article Six: Quality Management System Auditing

A. SFDA requires from establishments and overseas manufacturers to apply QMS complying with the standard entitled "Medical devices -- Quality management systems -- Requirements for regulatory purposes (ISO 13485:2016)" or any identical adopted standards for the same issue/version.

B. SFDA itself or by an Auditing Organization it designates will perform auditing for QMS of establishment and overseas manufacturer.

C. The audit of the QMS of establishment and overseas manufacturer shall take place before the SFDA authorizes the devices to be placed on the KSA market.

D. At the conclusion of a satisfactory audit, the Auditing Organization shall issue a certificate to confirm the QMS meets the requirements of the SFDA. The certificate shall be accompanied by an audit report indicating any weaknesses or non-conformity. The certificate shall indicate the period of validity, which shall not exceed three years.

E. Where justified by post-market performance history or other concerns, the SFDA may at any time require the Auditing organization to re-audit the QMS.

Article Seven

The Auditing organization applying for designation under the provisions of the Medical Devices Interim Regulation and its Implementing Rules shall submit the following required information to the SFDA.

A. The name and contact details (i.e. postal address in a format that allows location to be established, telephone number and e-mail address) of the registered place of business of the candidate Auditing organization, and of its parent organization, together with contact persons at both locations.

B. A description of the organizational structure and management of the Auditing organization and its relationship to other parts of the parent and any subsidiary organization, if any. Information shall be provided on the qualifications, duties, responsibilities, and authorities of management and other employees of the Auditing organization, as they relate to the Medical Devices Interim Regulation.

C. A description and organization chart to illustrate the professional relationship between the employees located within the KSA and those located elsewhere, in particular, those based with the parent organization.

D. Information on the Auditing organization and parent organization's knowledge and experience of the regulated devices.

E. Details of the Auditing organization liability insurance arrangements.

F. Details of the Auditing organization legal status under KSA law.

G. Details of the Auditing organization policy and arrangements to safeguard the

confidentiality of the information obtained or created during the performance of its duties

H. Details of the Auditing organization policy and arrangements to ensure its management and employees will carry out their duties in an independent, objective, ethical and impartial manner, and will avoid any conflicts of interest

I. A description of the Auditing organization quality management procedures.

J. An attestation that the organization has implemented the policies and procedures described in paragraphs G, H and I of this Article, and an undertaking to maintain the number, qualifications and experience of its employees at a level sufficient to allow proper functioning of the organization.

Chapter Four
(Responsibilities of the SFDA)

Article Eight

1. The SFDA shall review and assess the information and documents provided by the organization to ensure it meets these requirements. Where necessary, the SFDA shall ask for additional information.
2. The SFDA will determine organization designation fees.
3. When satisfied, the SFDA shall issue the organization with a Certification of designation.
4. Where the organization is unable to fulfill the SFDA requirements, the SFDA shall withdraw the designation until the shortcoming has been corrected.
5. The SFDA shall publish a list of the designated organizations and the activities for which each has been designated.
6. The SFDA is responsible for ensuring the organization has procedures in place to ensure its staff is impartial, has the highest degree of professional integrity, has the requisite competence to assess the regulated devices for which it has been designated, and is free from all pressures and inducements, particularly financial, which might influence its judgment.
7. The SFDA shall monitor and audit the performance of organizations. It shall ensure each organization has, and retains, the competences required of it to carry out their tasks.
8. The SFDA will conduct audits in different stages such as:
   8.1. Initial audit: the first audits performed by the SFDA during the assessment on the application of organization.
   8.2. Surveillance audit: Audits performed to check that appropriate systems and procedures continue to be in place.
   8.3. Witnessed/observed audit: Audits performed while the organization is conducting an audit. The SFDA auditors will check the organizations related procedures and its compliance with the requirements.
9. The SFDA may determine that it is necessary to initiate and conduct an investigation in case of any relevant issue related to the organization. The investigation may involve the inspection of the resources of an organization, record keeping and to interview the personnel and/or subcontractors etc.

Chapter Five
(Responsibilities of the CAB and Auditing organization)

Article Nine: Resources

1. The organization shall maintain resources sufficient in terms of both expertise and quantity to undertake their responsibilities in a competent, transparent, neutral, independent and impartial manner. The organization shall use the resources of its parent organization to supplement those located in the KSA.
2. The organization shall, without delay, inform the SFDA of any change regarding the information provided in the application for designation.
3. Organization employees involved in conformity assessment evaluations shall have knowledge of this Implementing Rule and its Annexes as well as general experience of the regulated devices for which the CAB has been designated.
4. Organization employees involved in QMS audits shall have knowledge of this Implementing Rule and its Annexes, general experience of the regulated devices for which the organization has been designated, and particular experience of QMS applied by manufacturers of medical devices.
5. The organization shall obtain SFDA approval for any technical reviewer, QMS auditor and/or manager involved in the relevant organization activities. The organization shall submit a proof of qualification that fulfilled SFDA criteria.
6. The organization shall maintain a record of persons involved in each assessment, including those based outside the KSA. This record should be made available to the SFDA upon request or during an audit of the organization.

Article Ten: Independence and impartiality

The organization shall implement and maintain procedures to ensure the advice provided to the SFDA is impartial. In particular:

1. Employees shall be impartial and free from engagements and influences which could affect their objectivity, and in particular, for a regulated device that is the subject of a market authorization application. They shall not:
   - be involved in the design, construction, marketing, installation, servicing or supply of that regulated device;
   - have been involved in the provision of consultancy services in respect of the regulated device;
   - have a financial interest in the manufacturer, importer or distributor of the regulated device.
2. The impartiality of the organization and the employees involved in evaluations shall be established and documented. This will include any identification and investigation of potential conflict of interests, together with the outcome of any such investigation.

Article Eleven: Confidentiality and due professional care

1. The organization shall implement and maintain a documented policy to safeguard the confidentiality of the information obtained or created during the performance of an assessment, or of a QMS audit. There shall be no disclosure of such documents and information to any party other than the SFDA, without the written approval of the establishment or overseas manufacturer concerned.
2. Due professional care, diligence and good judgment shall be practiced at all times in the conduct of an assessment or QMS audit, and in the management of supporting activities, in accordance with a documented procedure.

Article Twelve: quality management procedure

1. The organization shall implement and maintain its own QMS to ensure that the evaluations it conducts satisfy the requirements of the Regulation. This procedure shall cover, as a minimum, control of documents, control of records, management review, internal audits, and corrective and preventive actions.
2. This QMS shall ensure that assessments, or audits of a manufacturer's QMS, are performed in accordance with defined and documented methodologies and techniques designed to provide consistency of approach for regulated devices of the same classification, consistent with the SFDA requirements of the Medical Devices Regulation.

Article Thirteen: Legal requirements

1. The organization shall be a legal entity under KSA law, or a defined part of a legal entity, such that it can be held legally responsible for all its activities in the KSA, including the decisions it makes.
2. The organization shall have a registered place of business within the KSA.

Article Fourteen: Liability insurance

The organization shall have appropriate liability insurance to provide for any claims and litigation arising from its activities.

Annex (1):

- Competence and Training Requirements for CAB and Auditing Organizations

* IMDRF/MDSAP WG/N4FINAL:2013

1- **Education**

- Lead Auditors, Auditors, Final Reviewers, and Technical Experts should hold a diploma or a higher degree 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 should be a basis for classification of Technical Knowledge. However, 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.

2- **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 assigned tasks.

- 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.

- 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 system 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 the experience and skills of a Lead Auditor. Potential Technical Experts shall demonstrate advanced experience and expertise in a particular process, medical device, or technology classified as Technical Knowledge.

3- **Competence 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, critical and analytical thinking, communication, etc.)
  - **Functional Competencies:** those generic skills applicable to all personnel developed through experience and required to perform audits (e.g. project management; time management; teamwork; effective use of information technology; 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, health and safety impacts, etc.)

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

4- **Foundational Competencies**

- *Integrity:* Abides by a strict code of ethics and behaviour; chooses an ethical course of action and does the right thing, even in the face of opposition; encourages others to behave accordingly. Treats others with honesty, fairness, and respect; makes decisions that are objective and reflect the just treatment of others. Takes responsibility for accomplishing work goals within accepted timeframes; accepts responsibility for one's decisions and actions and for those of one's group, team, or department; attempts to learn from mistakes.

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

- *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.

- *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.

- *Communication:* Expresses or presents ideas, both orally and in writing, in a clear, concise, accurate and logic fashion, taking into consideration the target audience. Has a good command of language(s) and uses an appropriate business writing style, using objective, specific language; uses punctuation correctly, verifies spelling, and writes grammatically correct. Listens actively; asks clarifying questions and summarizes or paraphrases what others have said to verify understanding.

- *Adaptability: Demonstrates the ability to use or consider nontraditional methods; makes changes in response to demands and circumstances.*

- *Tenacious: Persistent and focused on achieving objectives.*

- *Perceptive: Instinctively aware of and able to understand situations.*

- *Observant: Actively observing physical surroundings and activities.*

5- Functional Competencies

- *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.

- *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.

- *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.

- *Supervision:* Plans, organizes, directs, monitors, and evaluates the work of others assigned to assessment projects.

- *Writing Literacy:* Creates clear and concise reports and presentations that are based on objective evidence. Uses correct spelling, grammar, and punctuation to produce logical and accurate written documentation and correspondence. Communicates ideas, information, and messages, which may contain technical material, in a logical, organized, and coherent manner.

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

- *Records Management:* maintains accurate and objective records of facts and observations made.

- *Cultural Sensitivity:* Observant and respectful to different cultures.

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

6- Technical Competencies

- *Regulatory requirements:* Knowledge of the medical device regulatory requirements of the recognizing Regulatory Authority(s) to enable an assessment of the applicability and compliance with such laws, regulations, and standards. Including knowledge of the principles and applications of medical device quality management system requirements, risk management system requirements, etc.

- *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

- *Auditing Standards and Techniques:* Knowledge of standards and techniques for auditing quality management systems.

- *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.

7- Training requirements

- The Competence Levels 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:

a. 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 could encompass new or revised requirements that were not part of the individual's previous training.

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

- Class room training in quality management systems (e.g. ISO 9001) and medical device quality management system requirements (e.g. ISO 13485).
- Class room training in the SFDA medical device regulations within the scope of recognition for the CAB and commensurate with the existing experience of the trainee.
- Class room 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.

- For Technical Expert:
  - Each recognition in a category of Technical Knowledge, irrespective of whether this is the first or a later category to be qualified, the CAB 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, or process technologies, or training in the clinical indications for a product category, etc.
  - Specified training documented in a training plan and including; the relevant procedures of the CAB'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.

b. Continual Professional Development

Personnel involved in audits and decision making functions shall commit themselves to continually improve their proficiency, effectiveness, and quality of work. Auditor, Technical Expert and Final Reviewer Experience Requirements
There must be documented evidence of successful completion of the mandatory initial training prior to fulfilling the following requirements.

c. Auditors-in-training, Auditors, Lead Auditor-in-training, and Lead Auditors

- Auditor: Before undertaking independent auditing auditors will be considered an Auditor-in-training. To be qualified as an Auditor, the Auditor-in-training shall participate as a member of an audit team for at least 5 on-site audits. 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.

- Lead Auditor: 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.

- Experience and audits performed at one CAB may carry over to another CAB as long as proper documentation is maintained.

d. 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 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 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.

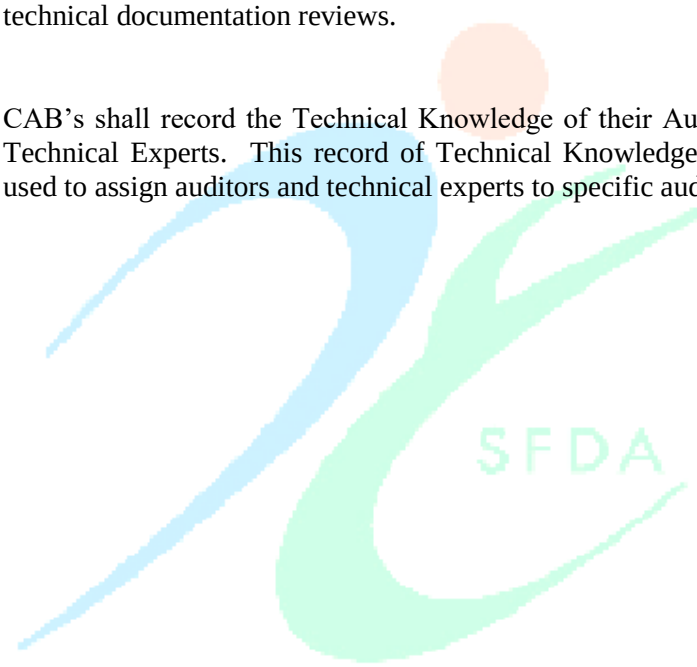
- Technical Experts shall perform 3 technical documentation reviews in each 12 month period. Reviews of significant changes in technical documentation to a product can count for a maximum of 2 of the 3 technical documentation reviews in each 12 month period.

- Technical Experts for process related technology reviews shall perform 3 off-site /on-site reviews in each 12 month period.

- Final Reviewers must have 2 years' experience in regulatory audits 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.

- CAB'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 to assign auditors and technical experts to specific audits.



Annex (2):

- Required types of knowledge and skills for personnel involved with the ISO 13485 activities

The following table specifies the type of knowledge and skills that a CAB shall define for specific functions in addition to ISO/IEC 17021-1 Annex A

Table B.1 – Table of knowledge and skills **Certification functions knowledge and skills**	Personnel conducting the application review to determine audit team competence required, to select the audit team members, and to determine the audit duration	Personnel reviewing audit reports and making certification decisions	Auditor	Personnel managing program
Knowledge of generic quality management system practices	X	X	X	X
Knowledge of legal framework of regulations and role of the CAB	X	X	X	X
Knowledge of medical device risk management, e.g. ISO 14971	X	X	X	X
Knowledge of intended use of medical devices			X *	
Knowledge of risks associated with the medical device			X *	
Knowledge of relevant product standards in the assessment of medical devices			X *	
Knowledge of CAB's ISO 13485 processes	X	X	X	X
Knowledge of Medical Device business/technology	X	X	X *	X

Note: The knowledge could be provided by a technical expert.

* IAF MD 9:2017 Issue 3