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Regulatory Authority Recognition

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A handwritten signature in black ink, appearing to read 'Fabio Quintino', enclosed within a large, loopy oval stroke.

Fabio Pereira Quintino, IMDRF Chair

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Preface

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

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Introduction

Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition,” originally finalized in 2013, is being republished as IMDRF/MDSAP WG/N3FINAL:2016 (Edition 2). Edition 2 was necessary after revisions were made in ISO/IEC 17021-1:2015 which replaced ISO/IEC 17021-1:2011 normative requirements in N3 Final:2013. The editorial revisions made to this edition can largely be categorized as: (1) re-organization of clauses and revision to some clause titles to align with ISO/IEC 17021-1:2015; (2) deletion of the original MDSAP provision where Auditing Organization that are Regulatory Authorities did not have to engage a separate committee for safeguarding impartiality since the requirement for such a committee has been eliminated in ISO/IEC 17021-1:2015; and, (3) a new exception in clause 9.5 is added to restore the requirement in the original IMDRF MDSAP N3:2013 document due to changes in ISO/IEC 17021-1:2015 requirements, this exception will also ensure consistency with the IMDRF Informational Document IMDRF/MDSAP WG/N29 Final:2015. Annex A has been added to this edition to detail the specific change.

This is one document in a collection of documents produced by the International Medical Device Regulators Forum (IMDRF) intended to implement the concept of a Medical Device Single Audit Program (MDSAP). Two documents, this document IMDRF MDSAP WG N3 – “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition” and IMDRF MDSAP WG N4 – “Competence and Training Requirements for Auditing Organizations,” are complementary documents. These two documents N3 and N4 are focused on requirements for an Auditing Organization and individuals performing regulatory audits and other related functions under the respective medical device legislation, regulations, and procedures required in its regulatory jurisdiction.

Two additional documents, IMDRF MDSAP WG N5 – “Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations” and IMDRF MDSAP WG N6 - “Regulatory Authority Assessor Competence and Training Requirements,” are complementary documents. These two documents N5 and N6 are focused on how Regulatory Authorities and their assessors will evaluate or “assess” medical device Auditing Organizations’ compliance to the requirements in the IMDRF MDSAP N3 and N4 documents.

In addition, IMDRF MDSAP WG N11 defines a method to “grade” nonconformities resulting from a Regulatory Authority assessment of an Auditing Organization and to document the decision process for recognizing an Auditing Organization or revoking recognition.

This collection of IMDRF MDSAP documents will provide the fundamental building blocks by providing a common set of requirements to be utilized by the Regulatory Authorities for the recognition and monitoring of entities that perform regulatory audits and other related functions. It should be noted that in some jurisdictions the recognition process is called designation, notification, registration, or accreditation. IMDRF developed MDSAP to encourage and support global convergence of regulatory systems, where possible. It seeks to strike a balance between the responsibilities of Regulatory Authorities to safeguard the health of their citizens as well as their obligations to avoid placing unnecessary burdens upon Auditing Organizations or the

regulated industry. IMDRF Regulatory Authorities may add additional requirements beyond this document when their legislation requires such additions.

The purpose of this document is to define the requirements for medical device Auditing Organizations performing regulatory audits and other related functions. Both the audit process and the conclusions made by an Auditing Organization are subject to further review by the applicable Regulatory Authority in the countries and regions where the medical device is manufactured and/or placed on the market.

1.0 Scope

In the past, various Regulatory Authorities have identified shortcomings in the standards being utilized for the recognition of organizations that conduct medical device audits for regulatory purposes. These standards were considered to be too generic and focused on commercial entities for commercial purposes. However, many organizations that work in the regulated environment of medical devices must comply with these generic requirements for other purposes.

Prior to developing this document the IMDRF MDSAP working group analyzed many existing standards, guidance documents, and regulatory requirements, including those authored by the International Accreditation Forum (IAF), to identify a basis for the recognition of auditing organizations. However, IMDRF Regulatory Authorities have no official status within groups such as the IAF, or any voice in IAF governance or IAF mutual recognition agreements, that would allow the Regulatory Authorities to revise IAF documents to meet the needs of the regulators. It was also determined that the standard most commonly utilized is the ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) standard ISO/IEC 17021-1:2015 entitled, “Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements.” Medical device Regulatory Authorities also have little influence in the standards organization that produces this standard and cannot simply change the standard for medical device regulatory purposes. Therefore, IMDRF Regulatory Authorities recognized the need for a different set of requirements for medical device Auditing Organizations, using existing standards where possible.

The conclusion of the work group’s analysis was to allow ISO/IEC 17021-1:2015 to act as the generic base requirements and then utilize this IMDRF MDSAP document to add prescriptive requirements for medical device Auditing Organization and to negate or eliminate certain of these generic base requirements, which were meant for commercial entities, when the Auditing Organization is also a Regulatory Authority. Auditing Organizations that are also Regulatory Authorities have other laws and requirements that cover these deleted generic requirements in different ways.

ISO/IEC 17021-1:2015 is being utilized as a normative reference within this IMDRF document. When the ISO/IEC 17021 standard is revised, the IMDRF will have to assess the new version of the standard and determine if this IMDRF document also requires revision. Further, there is an expectation that the Regulatory Authority assessment of medical device Auditing Organizations includes both the generic normative requirements in addition to the specific requirements added

or deleted by this document. Therefore, this document’s clause numbers are aligned with the relevant subsection in ISO/IEC 17021-1:2015.

This document applies to Auditing Organizations that audit medical device manufacturers and may perform other related functions. The medical device Auditing Organization requirements include evaluation of the effectiveness of the manufacturer’s quality management system (QMS) as well as aspects of evaluation, including:

- product/process related technologies (e.g. injection molding, sterilization); and,
- evidence of adequate product technical documentation in relation to relevant regulatory requirements.¹

This document does not provide additional requirements for product certification (ISO/IEC 17065:2012) or the requirements of product testing (ISO/IEC 17025:2005).

The following is explicitly excluded from the scope of this document due to the lack of regulatory convergence:

- the premarket reviews (e.g. Design Dossier Examinations, Premarket Applications, Shounin Applications, Product Registration/Notifications) typically performed by product specialist(s); and,
- the final decisions of safety and performance/effectiveness of a medical device made by any Regulatory Authority.

The functions covered by an Auditing Organization, within the scope of this document, and the independence of the roles assigned are described in Table 1.

| Functions | Audit | Decision Making |
|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|------------------------|
| Review the manufacturer’s application to determine audit team competence required, select the audit team members, and determine audit duration | n/a | Program Administrator |
| Evaluation of quality management system | Lead Auditor / Auditor | n/a |
| Evaluation of product/process related technologies | Technical Expert | n/a |
| Evaluation of Technical Documentation ² | Technical Expert | n/a |
| Evaluation of Regulations | Lead Auditor / Auditor / Technical Expert | n/a |
| Approval of Results | n/a | Final Reviewer |

Table 1: Auditing Organization Functions and Roles

¹ To the extent possible during on-site audits in accordance with the applicable regulatory system.

² To the extent possible during on-site audits in accordance with the applicable regulatory system.

2.0 Reference(s)

Normative Reference:

- International Organization for Standardization (ISO)/ International Electrotechnical Commission (IEC) ISO/IEC 17021-1:2015 - *Conformity Assessment – Requirements for bodies providing audit and certification of management system – Part 1: Requirements.*
- GHTF/SG3/N19:2012 - *Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange*

General References:

- GHTF/SG1/N78:2012 - *Principles of Conformity Assessment for Medical Device.*
- GHTF/SG1/N46:2008 - *Principles of Conformity Assessment of In Vitro Diagnostic (IVD) Medical Devices.*
- GHTF/SG1/N71:2012 - *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device.'*
- ISO/IEC 17000:2004 – *Conformity assessment – Vocabulary and general principles*

3.0 Definitions

- 3.1 *Audit:* A systematic, independent, and documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled. (ISO 17000:2004)
- 3.2 *Auditing Organization:* An organization that audits a medical device manufacturer for conformity with quality management system requirements and other medical device regulatory requirements. Auditing Organizations may be an independent organization or a Regulatory Authority which perform regulatory audits.
- 3.3 *Medical device:* 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,
 - 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.

Note: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for in-vitro fertilization or assisted reproduction technologies.

(GHTEF/SG1/N71:2012)

For clarification purposes, in certain regulatory jurisdictions, devices for cosmetic/aesthetic purposes are also considered medical devices.

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

4.0 Principles

There are no requirements for an Auditing Organization under Section 4 - Principles.

ISO/IEC 17021-1:2015 states, “4.1.1 - These principles described in this clause provide the basis for the subsequent specific performance and descriptive requirements in this part of ISO/IEC 17021. This “part of ISO/IEC 17021” does not give specific requirements for all situations that can occur. These principles should be applied as guidance for the decisions that may need to be made for unanticipated situations. Principles are not requirements.”

5.0 General requirements

5.1 Legal and contractual matters

Country specific laws and regulations, outside the medical device Regulatory Authority’s

purview, may be applicable to the manufacturer for certain legal and financial responsibilities.

A legal entity is ineligible to be an Auditing Organization if the entity has been found guilty of an offence against national laws or regulations related to medical devices, or relating to any fraudulent or dishonest practices.

Exceptions to ISO 17021-1:2015

A Regulatory Authority that is undertaking the activities of an Auditing Organization is not required to have a legal contractual arrangement with the medical device manufacturer if the Regulatory Authority performs those activities under their respective legislation.

Specific Requirements for Medical Device Auditing Organizations

- 5.1.1 An Auditing Organization shall make available to the recognizing Regulatory Authority(s) information about organizational structure, ownership and the legal or natural persons exercising control over the Auditing Organization.
- 5.1.2 If the Auditing Organization is a legal entity that is wholly or partly owned by a larger organization, the Auditing Organization shall clearly document the activities, structure, and governance of that larger organization as well as its relationship with the Auditing Organization.
- 5.1.3 If the Auditing Organization wholly or partly owns other legal entities, the Auditing Organization shall clearly define and document the activities and responsibilities of those other entities, as well as their legal and operational relationships with the Auditing Organization.

In addition, an Auditing Organization that maintains multiple offices that perform some part of the audit process shall ensure that the roles and responsibilities of the Auditing Organization and their other locations are defined and implemented.
- 5.1.4 The Auditing Organization (when not a Regulatory Authority) shall have legally enforceable arrangements with medical device manufacturers allowing personnel from the Regulatory Authority, which authorized their recognition, to observe and assess the Auditing Organization's audits. The agreement shall allow personnel from the Regulatory Authority access to records and documents pertaining to the manufacturer that is relevant to the audit and decision making process upon request.
- 5.1.5 The Auditing Organization (when not a Regulatory Authority) shall have legally enforceable arrangements with medical device manufacturers that will allow Regulatory Authorities to share all documents and records related to medical device audits with other Regulatory Authorities that have formal established confidentiality agreements between governments which covers provisions for protecting proprietary information and trade secret information.

5.2 Management of impartiality

The requirements of this section in no way preclude exchanges of technical or regulatory information between an Auditing Organization and a manufacturer.

Specific Requirements for Medical Device Auditing Organizations

- 5.2.1 The Auditing Organization shall be an entity that is independent of the manufacturer of the medical device in relation to which it performs audits. The Auditing Organization shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer. (Economic operator can be such entities as distributors, authorized representative or importer)
- 5.2.2 The Auditing Organization shall have documented and implemented a structure and procedures for safeguarding and promoting independence, objectivity, and impartiality throughout its organization, personnel, and audits. These procedures shall effectively identify, investigate, and resolve any case in which a conflict of interests may arise. The Auditing Organization shall document any investigation, outcome, and resolution.
- 5.2.3 The Auditing Organization, its top-level management and the personnel, including their spouses or children, responsible for carrying out the audits shall not:
- be the designer, manufacturer, supplier, installer, distributor, importer, purchaser, owner, user, or maintainer/servicer of the medical devices which they assess, nor the authorized representative of any of those parties. This shall not preclude the use of assessed medical devices that are necessary for the operations of the Auditing Organization (e.g. measuring equipment) or the use of such medical devices for personal purposes;
 - be involved in the design, manufacture or construction, the marketing, installation, use or maintenance/servicing of those medical devices, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgment or integrity in relation to audits;
 - offer or provide any service which may undermine the confidence in their independence, impartiality, or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorized representative, a supplier, or a commercial competitor, as regards to the design, manufacture or construction, marketing, installation, use or maintenance/servicing of the medical device or processes subject to audit; and,
 - use the services of any organization or individual that has provided consultancy services to the manufacturer, his authorized representative or a supplier being audited by the Auditing Organization, related to the QMS or items in the previous indent, within a period of three years since the last consultancy services were rendered.

Note: This does not preclude general training activities relating to medical device

regulations, general QMS training, or related standards that are not manufacturer specific. This also does not preclude Regulatory Authorities that are also Auditing Organizations from advising manufacturers on regulatory submissions (e.g. pre-clinical investigation meetings).

- 5.2.4 The Auditing Organization shall document any involvement in consultancy services in the field of medical devices undertaken by personnel prior to taking up employment with the Auditing Organization at the time of employment. The Auditing Organization shall monitor and resolve any potential conflicts of interest according to criteria set out in this document.
- 5.2.5 If an Auditing Organization's top-level management or the personnel responsible for carrying out audits were former employees of a medical device manufacturer or provided consultancy services in the field of medical devices for a specific manufacturer prior to taking up employment with the Auditing Organization, such personnel shall not be assigned to activities for that specific manufacturer or companies belonging to the same organization for a period of three years.
- 5.2.6 The Auditing Organization shall not advertise, commit to, guarantee, or imply the outcome of the audits by the Auditing Organization on the basis of financial or other inducements.
- 5.2.7 The Auditing Organization shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect the independence, impartiality, or objectivity of its audits.
- 5.2.8 To enhance the commitment to impartiality and the appearance of impartiality, an auditor may not be the lead auditor for more than three consecutive audits for the same manufacturer's site, although the auditor may be a member of an auditing team for the site.
- Note: The Auditing Organization will make every effort to change the composition of the audit team for a site over time to strengthen the perception of impartiality.
- 5.2.9 The Auditing Organization shall require all personnel to formally commit themselves by a signature, or equivalent, to comply with the Auditing Organization's rules relating to confidentiality and independence from commercial and other interests, and any existing or prior association with any manufacturer audited by the Auditing Organization.
- 5.2.10 If the Auditing Organization is a legal entity that is wholly or partly owned by a larger organization, the requirements for impartiality in this document are applicable to both the Auditing Organization and the organization to which it belongs.
- 5.2.11 The individuals involved in the process for managing threats on impartiality (see ISO/IEC 17021-1:2015 clause 5.2.2) shall have access to individual(s) who have experience and knowledge related to medical devices in order to obtain independent expert opinions.

5.3 Liability and financing

Specific Requirements for Medical Device Auditing Organizations

- 5.3.1 The Auditing Organization shall take out liability insurance unless the government, in accordance with national law, covers liability, or the Regulatory Authority itself is directly responsible for the audits.

The justification for the scope and overall financial value of liability insurance shall be documented and include consideration of the level and geographic scope of activities of the Auditing Organization and the risk profile of the devices being assessed by the Auditing Organization.

- 5.3.2 The Auditing Organization shall have at its disposal the financial resources required to conduct its audits and related business operations.

6.0 Structural requirements

6.1 Organizational structure and top management

Specific Requirements for Medical Device Auditing Organizations

- 6.1.1 The Auditing Organization shall ensure that its personnel are current in practices and knowledge in relation to medical device technologies and regulatory requirements for conducting audits of medical device manufacturers.

- 6.1.2 The Auditing Organization shall have the organizational capacity to include management, administrative support, and infrastructure to undertake all contracted activities.

- 6.1.3 The Auditing Organization shall participate in any regulatory coordination group established for the purpose of keeping the Auditing Organization's personnel current on medical device legislation, guidance documents, standards, and best practice documents adopted in the applicable regulatory systems.

- 6.1.4 The Auditing Organization shall consider and adopt prescribed guidance and best practice documents, unless deviation from them is duly justified.

- 6.1.5 The Auditing Organization shall prescribe and adopt a code of conduct for Auditing Organizations in the field of medical devices. The code of conduct shall provide a mechanism for monitoring and verification of its implementation. Violations to the code of conduct must be investigated and appropriate action taken. (See 7.1.6)

- 6.1.6 The Auditing Organization shall document roles, responsibilities, and lines of reporting for all personnel, including subcontractors, involved or potentially involved in medical device audits and decision processes.

- 6.1.7 The Auditing Organization shall have documented processes and procedures to ensure that personnel in the Auditing Organization do not review and approve their own work. Prior to a final decision, the auditor's work will be reviewed and approved by a person independent of the audit team.

6.2 Operational Control

Specific Requirements for Medical Device Auditing Organizations

No specific requirements

7.0 Resource requirements

7.1 Competence of personnel

Specific Requirements for Medical Device Auditing Organizations

- 7.1.1 An Auditing Organization shall comply with the specific requirements for the competence and maintenance of competence that can be found in the IMDRF MDSAP WG N4 - “Competence and Training Requirements for Auditing Organizations,”
- 7.1.2 An Auditing Organization shall have access to the necessary administrative, technical, and scientific personnel with technical knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies.
- 7.1.3 The management of the Auditing Organization shall have appropriate knowledge and processes to: set up and operate a system for the selection of the auditing personnel, the verification of their competence, the assignment of their tasks, their initial and ongoing training, and, their instruction and monitoring to ensure that personnel who administer and perform the audits are competent to fulfill the tasks required of them.
- 7.1.4 The Auditing Organization shall identify at least one individual within its senior management having overall responsibility for all medical device audits, within the scope of this document.
- 7.1.5 An Auditing Organization shall be capable of carrying out all the tasks assigned to it with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the Auditing Organization itself or on its behalf and under its responsibility.
- 7.1.6 Auditing Organizations are to ensure that auditors and other personnel involved in regulatory audits understand the importance of a code of conduct in maintaining integrity. Auditing Organizations are to keep signed statements of adherence to a code of conduct for personnel involved in regulatory audits. The signed statement shall attest to at least the following elements included in the Auditing Organization’s code of conduct:
 - 1. To act in a professional and ethical manner at all times.
 - 2. To faithfully represent the interests of the recognizing Regulatory Authority(s).
 - 3. Not to act in any way prejudicial to the interests or reputation of the recognizing Regulatory Authority(s).
 - 4. Not to act in any way prejudicial to the integrity or objectives of the recognizing Regulatory Authority(s).

5. To disclose any relationship, or financial interest, past or present, that may create a conflict of interest, or the appearance of a conflict of interest, and to notify management of any new conflicts of interest or potential conflicts of interest as soon as the case may arise.
6. Not to participate in any activity or relationship that may impair, or may appear to impair, one's objectivity, impartiality, or professional judgment.
7. Not to accept any inducement, gift, commission, discount or any other benefit not available to the general public from medical device manufacturers, their agents, their representatives, or economic operators.
8. To record and report truthfully and accurately audit evidence in an impartial and unbiased way.
9. To record and report truthfully and accurately any material facts that may affect the reliability of audits.
10. Not to provide any consulting services to audited manufacturers.
11. Not to disclose, verbally or written, any information obtained in the course of audits to any third party, not including the recognizing Regulatory Authority(s), unless authorized in writing or required by law.
12. Not to use information obtained in the course of audits for any personal gain.
13. Not to undertake any audits for which one does not possess the required skills, knowledge or experience, formal designation or responsibility.
14. Not to undertake any audits in a language where one is not proficient without the support of a translator and/or interpreter.
15. To continually improve one's proficiency, effectiveness, and quality of work.
16. To disclose to management, without delay, any breach of this statement by oneself or a colleague and to cooperate fully in the investigation of such a breach.

7.2 Personnel involved in the auditing activities

Specific Requirements for Medical Device Auditing Organizations

- 7.2.1 The personnel responsible for identifying competence requirements for the auditor to perform specific audits, and the personnel responsible for final review and decision-making on conformity to quality management system requirements, shall be employees of the Auditing Organization and shall have proven knowledge and experience in the following:
- the medical devices legislation, relevant guidance documents and standards adopted in the applicable regulatory system;
 - the types of qualifications, experience and expertise relevant to medical device audits;
 - a broad base of medical device technologies, the medical device industry and the design and manufacture of medical devices;
 - the Auditing Organization's quality management system, related procedures and the required qualification criteria; and,

- the training requirements for personnel involved in medical device audits.

7.3 Use of individual external auditors and external technical experts

Specific Requirements for Medical Device Auditing Organizations

- 7.3.1 An external auditor or external technical expert is not to be responsible for identifying competence requirements for the auditor or technical expert to perform specific activities, and is not to be responsible for final review and decision-making on conformity to regulatory requirements.
- 7.3.2 Where an Auditing Organization uses external technical experts in the context of the audit, the Auditing Organization shall have adequate competence in such product areas, to verify the appropriateness and validity of objective evidence provided by the external expert in order for the Auditing Organization to make the final review and decision on conformity to regulatory requirements.
- 7.3.3 The Auditing Organization shall document all arrangements with external auditors and external technical experts and provide that information to the recognizing Regulatory Authority(s) on request. The Auditing Organization shall ensure that all external auditors and external technical experts allow the recognizing Regulatory Authority(s) to assess or witness the activities conducted for the Auditing Organization.
- 7.3.4 It is the Auditing Organization's responsibility to ensure that any external auditors and external technical experts are directly assessed by the Auditing Organization to ensure consistency with the IMDRF MDSAP WG N3 and N4 requirements.

7.4 Personnel records

Specific Requirements for Medical Device Auditing Organizations

- 7.4.1 In addition to the records required under IMDRF MDSAP WG N4, the Auditing Organization shall establish and maintain individual auditor personnel records:
- that document the auditor's assigned roles; and,
 - that documents the evidence that the relevant qualifications, training, knowledge, or experience of the individual auditor satisfies the competence requirements for assigned roles.

These personnel records shall be updated when roles are assigned. Documentation of the activities actually performed (audit log) required in IMDRF MDAP WG N4 shall be updated at a minimum annually.

7.5 Outsourcing

For the purposes of this clause an external organization is one that is not subject to the Auditing Organization's quality management system.

Specific Requirements for Medical Device Auditing Organizations

- 7.5.1 Where an Auditing Organization uses an external organization for auditing or for technical expertise, the Auditing Organization shall be responsible for identifying competence requirements for any auditor or technical expert supplied to perform specific activities, and the final review and decision-making on the conformity to regulatory requirements.
- 7.5.2 Where an Auditing Organization uses an external organization for auditing or for technical expertise, the Auditing Organization shall have adequate competence in such product areas to verify the appropriateness and validity of objective evidence provided by the external organization, to make the final review and decision on conformity to regulatory requirements.
- 7.5.3 The Auditing Organization shall document all arrangements with external organizations and provide that information to the recognizing Regulatory Authority(s) on request. The Auditing Organization shall ensure that the external organizations allow the recognizing Regulatory Authority(s) to assess or witness activities outsourced by the Auditing Organization.
- 7.5.4 It is the Auditing Organization's responsibility to ensure that all individuals utilized by an external organization that are involved in a regulatory audit are directly assessed by the Auditing Organization to ensure consistency with the IMDRF MDSAP WG N3 and N4 requirements.

8.0 Information requirements

8.1 Public information

Specific Requirements for Medical Device Auditing Organizations

- 8.1.1 Where appropriate, the Auditing Organization must comply with specified Regulatory Authority requirements for the method of making information on the certified manufacturers publically accessible.

8.2 Certification documents

Specific Requirements for Medical Device Auditing Organizations

- 8.2.1 When an Auditing Organization issues certificates and reports, the certificates and reports shall meet the Regulatory Authority requirements for certificates and reports.
- 8.2.2 When an Auditing Organization issues reports and certificates, intended for use by a specific Regulatory Authority, the reports and certificates shall accurately document the scope of the audits, audit criteria and the scope of the certifications, including which Regulatory Authority requirements have been assessed. The Auditing Organization shall not exclude any processes, products, or services from the audit scope or the scope of the

certificate, unless the regulations administered by the recognizing Regulatory Authority(s) permit the exclusion.

Specific Requirements for Medical Device Auditing Organizations

8.3 Reference to certification and use of marks

No specific requirements

8.4 Confidentiality

Specific Requirements for Medical Device Auditing Organizations

8.4.1 The Auditing Organization shall have documented procedures in place to ensure the confidentiality of information which comes into its possession during the performance of the audits. Except when disclosure is required by law, the procedure shall apply to its personnel, committees, subsidiaries, external auditors, external technical experts, or outsourced organizations.

8.4.2 Except in relation to information which may be requested by a Regulatory Authority, the personnel of an Auditing Organization and any external auditors, external technical experts, or outsourced organizations, shall observe professional secrecy with regard to information obtained in carrying out their tasks with respect to audits.

8.5 Information exchange between the Auditing Organization and manufacturers

No specific requirements

8.6 Information exchange between the Auditing Organization (when not a Regulatory Authority) and recognizing Regulatory Authority(s)

8.6.1 The Auditing Organization shall designate a function within its organization for timely exchange of information with recognizing Regulatory Authority(s) or to respond to enquiries from recognizing Regulatory Authority(s). The Auditing Organization shall fulfill this function at all times.

8.6.2 The Auditing Organization shall report to the recognizing Regulatory Authority(s) that performed its initial recognition when it becomes aware of any fraudulent activities or counterfeit products. The Auditing Organization is not responsible for establishing objective evidence but must report such activities or products in writing within 5 working days from the date of discovery.

8.6.3 The Auditing Organization shall provide information to the recognizing Regulatory Authority(s) about the audits and decision on conformity to quality management system requirements.

- 8.6.4 The Auditing Organization shall notify the recognizing Regulatory Authority(s) in writing within 5 working days from the date of a decision to refuse, suspend, reinstate, restrict, or withdraw a certificate. The notification shall include a rationale for such action.
- 8.6.5 The Auditing Organization shall notify the recognizing Regulatory Authority(s) in writing within 5 working days, of significant changes relevant to its recognition, in any aspect of its status or operations relating to:
- its legal, commercial, organizational or ownership status;
 - the organizational structure, top management or key personnel;
 - main policies;
 - resources, premises and critical location;
 - scope of recognition as an Auditing Organization; and,
 - other such matters that may affect the abilities of the Auditing Organization to fulfill the requirements for recognition.

8.7 Information exchange between Auditing Organizations

- 8.7.1 When an Auditing Organization ends its relationship with a particular manufacturer, or manufacturing site(s), the Auditing Organization, upon request and with consent of the manufacturer, shall make available to the next Auditing Organization a copy of all the audit reports from the current certification cycle and a valid certificate of that manufacturer or relevant to the manufacturing site(s).

9.0 Process requirements

Specific Requirements for Medical Device Auditing Organizations

- 9.0.1 The Auditing Organization shall document procedures covering at least:
- the request for audits by a manufacturer;
 - the processing of such request, including the verification of the completeness of the documentation, the qualification of the product as a medical device and its classification;
 - the language of the request, of the correspondence and of the documentation to be submitted;
 - where appropriate, the terms of the agreement with the manufacturer or authorized representative;
 - where appropriate, any fees to be charged for audits;
 - the planning, performance, and reporting of initial, surveillance, and re-audit/recertification audits;
 - the process by which the Auditing Organization determines which sites of the manufacturer or their supplier(s) will be audited;
 - the assignment of auditors to a specific activity based on the auditor's competence to perform the audit;

- the decision-making process on the conformity of the quality management system, including, where appropriate, the decision about issue, refusal, suspension, reinstatement, restriction, modification, or withdrawal of certificates as well as possible conditions or limitations to certificate validity;
- the assessment of specified changes to be submitted for prior approval;
- the follow-up of corrections and corrective actions for nonconformities identified during audits; and,
- where appropriate, the renewal of any certificates.

9.1 Pre-certification requirements

Specific Requirements for Medical Device Auditing Organizations

9.1.1 The Auditing Organization shall gather information relating to the name and location of the manufacturer's critical suppliers of products and services as defined by the manufacturer risk management program.

9.2 Planning Audits

Exceptions to ISO 17021-1:2015

Medical device manufacturers will not be afforded the opportunity to object to the composition of the audit team as described in ISO/IEC 17021-1:2015 clause 9.2.3.5. Manufacturers may utilize the appeals process to notify the Auditing Organization of any concerns related to the audit team composition.

Specific Requirements for Medical Device Auditing Organizations

No specific requirements

9.3 Initial Certification

Specific Requirements for Medical Device Auditing Organizations

- 9.3.1 The Auditing Organization shall determine how best to accomplish tasks of Stage 1 and Stage 2 with regards to off-site record review and on-site verifications. The Auditing Organization may combine elements of Stage 1 and Stage 2 to allow for a single on-site visit to the manufacturer.
- 9.3.2 The Auditing Organization shall audit all sites that will be recorded on the certificate. Any sites which are relevant to the manufacturer's quality management system but audited off-site, should not be recorded on the certificate.
- 9.3.3 Stage 2 audit objectives shall specifically include evaluation of:
- the effectiveness of the manufacturer's QMS incorporating the applicable regulatory requirements;

- product/process related technologies (e.g. injection molding, sterilization);
- adequate product technical documentation in relation to relevant regulatory requirements; and,
- the manufacturer's ability to comply with these requirements.

9.4 Conducting on-site audits

Specific Requirements for Medical Device Auditing Organizations

- 9.4.1 Audit reports written by Auditing Organizations shall not contain "Opportunities for Improvement" as this gives the appearance of consulting and may appear to be a conflict of interest. Audit findings shall only document conformity or nonconformity based on objective evidence, or observations. The audit report may document situations which appear to be non-conforming, but where insufficient audit evidence was collected or observed.
- 9.4.2 Auditing organizations shall utilize the Global Harmonization Task Force document, GHTF/SG3/N19:2012, "Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange" to grade any nonconformity that may result from a regulatory audit.
- 9.4.3 Findings from any audit, ("mock audits," "gap audits," or "pre-assessment audits" outside of the scope of Stage 1/Stage 2 audits), shall be documented and taken into consideration when grading nonconformities identified at a subsequent regulatory audit. Audits of manufacturers used as a training audit for Regulatory Authorities, which do not issue any reports or list of findings, are not considered a "mock audit" for purposes of this clause.

9.5 Certification decision

Exceptions to ISO 17021-1:2015

The person(s) assigned by the Audit Organization to make a certification decision shall be employed or shall be under a legally enforceable arrangement with the Auditing Organization. A legally enforceable arrangement with an entity other than the Auditing Organization as described in ISO/IEC 17021-1:2015 clause 9.5.1.2 is not acceptable to make a certification decision on behalf of the Auditing Organization, even if this other entity is under the organizational control of the Auditing Organization. See also IMDRF/MDSAP WG/N29 Final:2015.

Specific Requirements for Medical Device Auditing Organizations

- 9.5.1 An Auditing Organization conducting an initial audit or a recertification audit shall not conclude that a manufacturer complies with regulatory requirements if the Auditing Organization, utilizing the Global Harmonization Task Force document, GHTF/SG3/N19:2012, "Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange":

- has graded one or more nonconformity(ies) as a “5”; or,
- has graded more than two nonconformities as a “4.”

9.5.2 An Auditing Organization conducting an initial audit or a recertification audit shall have sufficient and reliable evidence to support a decision of compliance or non-compliance with regulatory requirements.

9.5.3 An Auditing Organization conducting an initial audit or a recertification audit shall not conclude that a manufacturer complies with regulatory requirements, if the Auditing Organization is aware of information that indicates a public health threat. Such information shall be reported to the recognizing Regulatory Authority in writing within 5 working days. (See 8.6.4)

9.6 Maintaining certification

Exceptions to ISO 17021-1:2015

The Auditing Organization shall schedule recertification audits with sufficient time to complete the recertification process prior to the end of the certificate period. It is not acceptable to have an expired certificate as described in ISO/IEC 17021:2015 Clause 9.6.3.2.5.

Specific Requirements for Medical Device Auditing Organizations

9.6.1 Surveillance audits shall include a review of issues related to medical device safety and effectiveness since the last audit such as complaints, problem reports, vigilance reports, and recalls/field corrections/advisory notices.

9.6.2 Surveillance audit objectives during the audit cycle shall specifically include evaluation of the effectiveness of the manufacturer’s QMS incorporating the applicable regulatory requirements and the manufacturer’s ability to comply with these requirements. In addition:

- new or changed product/process related technologies (e.g. injection molding, sterilization); and,
- new or amended product technical documentation in relation to relevant regulatory requirements.

9.6.3 The Auditing Organization may maintain a manufacturer’s certification based on positive conclusions by the audit team leader in accordance with ISO/IEC 17021-1:2015 clause 9.6.1(a and b) unless the audit team leader is an external auditor, external technical expert, or an auditor or technical expert from an external organization. If the audit team leader is an external auditor, external technical expert, or an auditor or technical expert from an external organization, then an independent review by the Auditing Organization must be performed.

9.6.4 During a recertification audit, the Auditing Organization shall audit all sites that are recorded on the certificate. Any sites which are relevant to the manufacturer’s quality management system but audited off-site, should not be recorded on the certificate.

9.6.5 Recertification audit objectives shall specifically include evaluation of:

- the effectiveness of the manufacturer’s QMS incorporating the applicable regulatory requirements;
- product/process related technologies (e.g. injection molding, sterilization);
- adequate product technical documentation in relation to relevant regulatory requirements; and,
- the manufacturer’s continued fulfillment of these requirements.

9.6.6 Upon request by the recognizing Regulatory Authority(s), the Auditing Organization shall perform a special audit of a manufacturer under the direction of the recognizing Regulatory Authority(s) requesting the special audit.

Note: Recognizing Regulatory Authorities themselves may perform special audits, including unannounced audits, anytime it deems necessary and within the purview of its jurisdiction. These audits performed by the recognizing Regulatory Authority(s) shall serve the dual purpose of auditing the medical device manufacturer and assessing the Auditing organization.

9.6.7 Criteria for unannounced regulatory audits:

1. Auditing Organizations shall carry out unannounced audits if previous audits indicate serious and/or frequent nonconformities. Auditing Organizations shall utilize the Global Harmonization Task Force document, GHTF/SG3/N19:2012, “Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange” to determine if a manufacturer is receiving significant or frequent nonconformities or if a nonconformity has resulted in the release of nonconforming medical devices. An unannounced audit shall occur following any audit that results in:
 - one or more nonconformity(s) graded as a “5”; or,
 - more than two nonconformities graded as a “4.”

The timing of the unannounced audits should be unpredictable and in addition to the normally scheduled audits. In the case of an unannounced audit due to frequent noncompliance or release of nonconforming medical devices, the auditing organization should allow approximately 6-9 months for the manufacturer to implement their Corrective Action plan, unless the manufacturer has provided evidence that the Corrective Action plan will be completed earlier. These unannounced audits should focus on the noncompliance, and the correction, the corrective action and the systemic corrective action taken for both the manufacturer’s quality management system, as well as any medical devices produced under the nonconformance released to the market or still within the control of the manufacturer.

As a general principle an unannounced audit should be executed by at least two auditors and not take less than one day.

2. Auditing Organizations shall carry out unannounced audits if specific information provides reasons to suspect serious non-conformities of the devices, or of their manufacturer, or if the recognizing Regulatory Authority(s) requests an unannounced audit. These unannounced audits would focus on the specific information of the serious non-conformity or request from the recognizing Regulatory Authority(s).
 3. Unannounced audits on premises of the manufacturer or of his contracted critical suppliers shall be foreseen in the contractual arrangements; both between the manufacturer and the critical supplier, and between the auditing organization and the manufacturers. If a visa is needed to visit the country where the manufacturer is located, the contractual arrangements should contain, as an annex, an invitation to visit the manufacturer or contracted critical supplier at any time and an invitation which leaves the date of visit open. The contractual arrangements shall also contain, as an annex, similar invitations issued by the critical suppliers. The contractual arrangements shall authorize the auditing organizations to end the contract as soon as permanent unannounced access to the premises of the manufacturer or his contracted critical suppliers is no longer assured. The contractual arrangements shall furthermore cover the measures to be taken by auditing organizations to ensure the security of their auditors. It shall provide for a financial compensation for the unannounced audits including security arrangements.
- 9.6.8 An Auditing Organization that performs a special audit at the request of the recognizing Regulatory Authority(s) or an unannounced audit according to the criteria listed in this document shall submit the audit report to the recognizing Regulatory Authority(s) within 15 days from the last day of the audit.
- 9.6.9 If the Auditing Organization suspends, withdraws, cancels, or reduces the scope of a certificate, the Auditing Organization shall inform the recognizing Regulatory Authority(s).

9.7 Appeals

Specific Requirements for Medical Device Auditing Organizations

No specific requirements.

9.8 Complaints

Specific Requirements for Medical Device Auditing Organizations

- 9.8.1 The Auditing Organization shall forward to the recognizing Regulatory Authority(s) information on any complaint (e.g. whistleblowers) it receives about a medical device manufacturer that could indicate an issue related to the safety and effectiveness of

medical devices or a public health risk.

9.9 Records of manufacturers

Specific Requirements for Medical Device Auditing Organizations

No specific requirements.

10.0 Management system requirements for Auditing Organizations

10.1 Options

Specific Requirements for Medical Device Auditing Organizations

10.1.1 The Auditing Organization shall establish, document, implement, maintain, and operate a quality management system that is appropriate to the nature, area, and scale of its audits and capable of supporting and demonstrating the consistent achievement of the requirements of applicable medical device legislation or regulatory policies/programs.

10.1.2 The Auditing Organization shall retain records of conformity to this document for a period of time not less than 15 years.

10.1.3 The Auditing Organization shall perform measuring, monitoring and the analysis of their audit program to provide information relating to the characteristics and trends of their processes such as: consistency in audit reports, bias in identified nonconformances, feedback from medical device manufacturers, etc.

10.1.4 The Auditing Organization when adhering to Option 1 or Option 2 under Clause 10 of ISO/IEC 17021-1:2015, shall conduct internal audits which covers all locations involved in medical device regulatory auditing.

10.2 Option 1: General management system requirements

Specific Requirements for Medical Device Auditing Organizations

No specific requirements.

10.3 Option 2: Management system requirements in accordance with ISO 9001

Specific Requirements for Medical Device Auditing Organizations

No specific requirements.

11.0 Revoking Recognition of an Auditing Organization

The recognition of an Auditing Organization shall be revoked if an Auditing Organization does

not meet the requirements of this document with due process. For further information on revoking recognition, see IMDRF MDSAP WG N11.

Annex A – Differences between IMDRF/MDSAP WG/N3:2016 and IMDRF/MDSAP WG/N3:2013

The document IMDRF/MDSAP WG/N3 is being revised to align its structure to ISO/IEC 17021-1:2015, and address changes introduced by this standard.

| IMDRF/MDSAP WG/N3:2016 | IMDRF/MDSAP WG/N3:2013 | Notes on changes |
|-------------------------------|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Clause No | Clause No | |
| 5.0 | General requirements | 5.0 |
| 5.1 | Legal and contractual matters – preliminary statement | 5.1 |
| 5.1 | Exception | 5.1 |
| 5.1.1 to 5.1.5 | | 5.1.1 to 5.1.5 |
| 5.2 | Management of impartiality | 5.2 |
| 5.2.1 to 5.2.10 | | 5.2.1 to 5.2.10 |
| 5.2.11 | | 6.2.1 |
| | | Wording modified due to the removed requirement in ISO/IEC 17021-1:2015 for a committee for safeguarding impartiality; same intent. |
| 5.3 | Liability and Financing | 5.3 |
| 5.3.1 to 5.3.3 | | 5.3.1 to 5.3.3 |
| 6.0 | Structural Requirements | 6.0 |
| 6.1 | Organizational structure and top management | 6.1 |
| 6.1.1 to 6.1.7 | | 6.1.1 to 6.1.7 |
| 6.2 | Operational controls | |
| | | New ISO/IEC 17021-1:2015 section |
| | | ISO/IEC 17021-1:2015 removes the requirement on committee for safeguarding impartiality. The waiver for Auditing Organizations that are Regulatory Authorities becomes irrelevant. Requirement 6.2.1 is |

| IMDRF/MDSAP WG/N3:2016 | | IMDRF/MDSAP WG/ N3:2013 Clause No | Notes on changes |
|------------------------|---------------------------------------------------------------------------------|--------------------------------------|----------------------------------------------------------------------------------------------|
| Clause No | | | |
| | | | modified and moved as 5.2.11 |
| 7.0 | Resource requirements | 7.0 | |
| 7.1 | Competence of personnel | 7.1 | Change of section title: was “Competence of management and personnel” |
| 7.1.1 to 7.1.6 | | 7.1.1 to 7.1.6 | Unchanged |
| 7.2 | Personnel involved in auditing activities | 7.2 | |
| 7.2.1 | | 7.2.1 | Unchanged |
| 7.3 | Use of individual external auditors and external technical experts | 7.3 | |
| 7.3.1 to 7.3.4 | | 7.3.1 to 7.3.4 | Unchanged |
| 7.4 | Personnel records | 7.4 | |
| 7.4.1 | | 7.4.1 | Unchanged |
| 7.5 | Outsourcing | 7.5 | |
| 7.5.1 to 7.5.4 | | 7.5.1 to 7.5.4 | Unchanged |
| 8.0 | Information requirements | 8.0 | |
| 8.1 | Public information | 8.1 | Change of section title: was “Publicly accessible information” |
| 8.1.1 | | 8.3.1 | Unchanged |
| 8.2 | Certification documents | 8.2 | |
| 8.2.1 to 8.2.2 | | 8.2.1 to 8.2.2 | Unchanged |
| 8.2.2 | | 8.2.2 | |
| | | 8.3 | ISO/IEC 17021-1:2011 Section 8.3 – <i>Directory of certified manufacturers</i> – was removed |
| 8.3 | Reference to certification and use of marks | 8.4 | No specific requirements |
| 8.4 | Confidentiality | 8.5 | |
| 8.4.1 to 8.4.2 | | 8.5.1 to 8.5.2 | Unchanged |
| 8.5 | Information exchange between the Auditing Organization and manufacturers | 8.6 | No specific requirements |

| IMDRF/MDSAP WG/N3:2016 | | IMDRF/MDSAP WG/ N3:2013 Clause No | Notes on changes |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Clause No | | | |
| 8.6 | Information exchange between the Auditing Organization (when not a Regulatory Authority) and recognizing Regulatory Authority(s) | 8.7 | |
| 8.6.1 to 8.6.5 | | 8.7.1 to 8.7.5 | Unchanged |
| 8.7 | Information exchange between Auditing Organizations | 8.8 | |
| 8.7.1 | | 8.8.1 | Unchanged |
| 9.0 | Process requirements | 9.0 | |
| 9.0.1 | | 9.1.1 | This requirement is general and concerns all following subsections |
| 9.1 | Precertification requirements | | Sections 9.1 to 9.6 are completely reorganized |
| 9.1.1 | | 9.2.1 | |
| 9.2 | Planning audits | | |
| | Exception | | This exception was part of former 9.1. |
| 9.3 | Initial Certification | | |
| 9.3.1 to 9.3.3 | | 9.2.3 to 9.2.4 | Unchanged |
| 9.4 | Conducting on-site audits | | |
| 9.4.1 | | 9.1.3 | Unchanged |
| 9.4.2 | | 9.1.2 | Unchanged |
| 9.4.3 | | 9.2.5 | Unchanged |
| 9.5 | Certification decision | | |
| | Exception | | This new exception is necessary to ensure that certification decision remain the exclusive authority of the auditing organization's management responsible for the MDSAP program. |
| 9.5.1 | | 9.2.6 + 9.4.3 | With the re-organization of ISO/IEC 17021-1:2015, combined and moved 9.2.6 and 9.4.3 identical requirements applicable to the certification decision |

| IMDRF/MDSAP WG/N3:2016 | | IMDRF/MDSAP WG/ N3:2013 Clause No | Notes on changes |
|-------------------------------|-----------------------------------------------------------------|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Clause No | | | |
| | | | following the initial audit or the recertification audit respectively. |
| 9.5.2 | | 9.2.7 + 9.4.4 | With the re-organization of ISO/IEC 17021-1:2015, combined and moved 9.2.7 and 9.4.4 identical requirements applicable to the certification decision following the initial audit or the recertification audit respectively. |
| 9.5.3 | | 9.2.8 + 9.4.5 | With the re-organization of ISO/IEC 17021-1:2015, combined and moved 9.2.8 and 9.4.5 identical requirements applicable to the certification decision following the initial audit or the recertification audit respectively. |
| 9.6 | Maintaining certification | | |
| 9.6.1 | | 9.6.1 | Unchanged |
| 9.6.2 to 9.6.4 | | 9.3.1 to 9.3.3 | Unchanged |
| 9.6.5 to 9.6.6 | | 9.4.1 to 9.4.2 | Unchanged |
| 9.6.7 to 9.6.9 | | 9.5.1 to 9.5.3 | Unchanged |
| 9.6.10 | | 9.6.1 | Unchanged |
| 9.7 | Appeals | 9.7 | No specific requirements |
| 9.8 | Complaints | 9.8 | No specific requirements |
| 9.9 | Records of manufacturers | 9.9 | No specific requirements |
| 10.0 | Management system requirement for Auditing Organizations | 10.0 | |
| 10.1 | Options | 10.1 | |
| 10.1.1 to 10.1.3 | | 10.1.1 to 10.1.3 | Unchanged |
| 10.2 | Option 1: General management system requirements | 10.3 | No specific requirements |
| 10.3 | Option 2: Management | 10.2 | No specific requirements |

| IMDRF/MDSAP WG/N3:2016 | | IMDRF/MDSAP | Notes on changes |
|-------------------------------|---------------------------------------------------------|----------------------------------|-------------------------|
| Clause No | | WG/ N3:2013 Clause No | |
| | system requirements in accordance with ISO 9001 | | |
| 11.0 | Revoking recognition of an Auditing Organization | 11.0 | Unchanged |