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PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title: Medical Device Single Audit Program (MDSAP): Medical Device Regulatory Audit Reports

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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. The document has been subject to consultation throughout its development.

Introduction

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, 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.

Three additional documents, IMDRF/MDSAP WG/N5 – "Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations," IMDRF/MDSAP WG PD1/N8 Rev 2 – "Guidance on Regulatory Authority Assessment Methods of Auditing Organization's Processes" and IMDRF/MDSAP WG/N6 - "Regulatory Authority Assessor Competence and Training Requirements," are complementary documents. These three documents N5, N6 and N8 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 – "MDSAP Assessment and Decision for the Recognition of an Auditing Organization" - 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 document IMDRF/MDSAP WG/N24 describes the format and content of MDSAP medical device regulatory audit reports submitted to regulatory authorities. The audit report serves as a written record of the audit team's determination of the extent of fulfillment of specified requirements. It also serves to demonstrate the application of the rules of the recognized Auditing Organization's conformity assessment scheme. It enables the Auditing Organization to capture in a consistent manner the evidence of a manufacturer's conformity with the audit criteria for the MDSAP, and will facilitate the exchange of information between Regulatory Authorities.

This collection of IMDRF MDSAP documents 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.

To prevent the confusion between audits of manufacturers performed by auditors within an Auditing Organizations and audits of Auditing Organizations performed by medical device Regulatory Authority assessors, in this document, the latter are designated as “assessments.”

1.0 Scope

The scope of this guidance document is limited to the information that participating MDSAP Regulatory Authorities require in medical device regulatory audit reports, the format of reports and the information necessary for participating MDSAP regulatory authorities to effectively use the audit reports in accordance with their legislation.

The Auditing Organization shall utilize this reporting model for all audits other than stage 1. For a Surveillance or Special Audit, it shall record in detail the applicable elements audited and identify those elements not within the scope of the audit.

2.0 References

In addition to the definitions below, the definitions found in the following documents apply:

ISO 9000:2005 – Quality management systems – Fundamentals and vocabulary

ISO/IEC 17000:2004 – Conformity assessment – Vocabulary and general principles

ISO/IEC 17021:2011 – Conformity assessment –Requirements for bodies providing audit and certification of management systems

IMDRF/MDSAP WG/N3 – Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition

IMDRF/MDSAP WG/N4 – Competency and Training Requirements for Auditing Organizations

GHTF/SG3/N19:2012 – Nonconformity Grading System for Regulatory Purposes and Information Exchange

3.0 Definitions

Auditing Organization (AO)

An organization that audits a medical device manufacturer for conformity with quality management system requirements. Auditing organizations may be independent organizations or a Regulatory Authority which performs regulatory audits. (IMDRF/MDSAP WG/N3)

Manufacturer

Any natural or legal person1 with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

Notes:

1. This 'natural or legal person' has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.
2. The manufacturer's responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.
3. 'Design and/or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labeling, relabeling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.
4. Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.
5. Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.
6. An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labeling, is not considered a manufacturer.
7. To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

(GHTF/SG1/N055: 2009)

4.0 Guidance for Implementation

4.1 Report Language

For the MDSAP, all audit reports shall be available in English.

It is preferable that report authors prepare reports using the grammatical form of "active voice" using first person (with the identification of the first person when there are multiple authors) and the past tense. Active voice ensures that the focus of a sentence is on the correct subject, reducing ambiguity and improving clarity. First person ensures the specific individual responsible for an audit activity or audit finding can be identified.

4.2 Report Content

4.2.1 Information about the Manufacturer

The following items should be included in the report:

(A) Manufacturer's Name and Address

The report should include the name and full address of the manufacturersubject to the audit.

Note: it is recommended that the manufacturer's name and address is consistent with what appears on a certification document, and if applicable any regulatory authority registration.

(B) Audited Facility's Name and Address

The report should include the name and full address of the audited facility subject to an audit plan. If this audit plan covers several facilities, then the name and full address of each facility shall be recorded in both the audit plan and the audit report.

Note: Regardless of the number of facilities audited, each audit plan has a corresponding audit report.

(C) Manufacturer Identification Number

If assigned by a regulatory authority, the manufacturer's identification numbers for the site audited should be included in the audit report. The audit report shall clearly reference the manufacturer and the relationship of the audited facility to the manufacturer.

(D) Corporate Structure of the Manufacturer

The report should comprehensively explain the corporate structure and the relationship between the corporate's entities in the context of their QMS, and the associated scope of manufacturing activities and devices.

(E) Contact Person

The name and contact information of the organization's point of contact should be included in the report.

(F) Last audit

The report shall include the date of the last audit of the audited facility, and any identifier for the corresponding audit report. If this is the initial audit of the organization, this must be stated in the report.

(G) Description of the audited facility

A description of the audited facility should include:

- The name and title of senior management of the audited facility including the most responsible individual for the audited facility
- The name and title of the senior manager responsible for the quality management system at the audited facility.
- the approximate number of employees
- number of shifts
- number of buildings, if applicable
- an overview of the activities and processes
- identification of outsourced activities

If there are multiple facilities audited, the following should be considered:

- When there is one audit plan and one audit report, the activities for each facility shall be clearly described in the audit report
- Certain recognizing regulatory authorities may require that separate reports are issued for each audited facility

For surveillance audit reports the description of the audited facility may be limited to those parts that fall within the scope of the audit.

(H) Scope of MDSAP Certification Documents

The report should include the applied for or existing scope of MDSAP certification documents of the manufacturer . This includes activities and a list of the generic medical device groups or families that are included in the scope of MDSAP certification documents. The report may refer to an appendix when the scope of certification documents is extensive.

(I) Identification of Critical Suppliers

The report shall include a list of critical suppliers, their legal name, full address, product or service provided, and if applicable, any changes of critical suppliers since the previous audit. The list may be an appendix to the report.

(J) Jurisdictions

The report should include the list of jurisdictions taken into account for the audit, i.e. jurisdictions to which the manufacturer is seeking or maintains marketing authorization.

4.2.2 Information about the Audit

The audit report should describe in adequate detail the nature of the audit performed and the following items:

(A) Audit Type

The report should identify the type of audit performed (for example, initial audit, surveillance, re-audit/re-certification audit, and special audit) See IMDRF/MDSAP WG/N3

(B) Audit Criteria

The report should list the audit criteria. For audits performed per the MDSAP, this would normally include, as a minimum, the applicable regulatory requirements for the participating regulatory authorities.

(C) Audit Objectives

The report should list the audit objectives. This includes, as a minimum, the objectives set in IMDRF N3 9.2.4, 9.3.2 and 9.4.1.

(D) Audit Scope

The report shall describe the activities and processes that form the scope of the audit.

(E) Audit Dates

The audit report shall include the dates of the on-site audit, for each audited facility within the audit plan.

(F) Identification of the Audit Team

The report shall identify all members of the audit team (name, title, affiliation) and describe their respective role (e.g. team leader, technical expert, etc.), the identity of any interpreter and their affiliation, and the identity of any observers present.

(G) Audit Language

The report shall indicate the language or languages used during the audit.

(H) Stage 1 Audit Results

When elements of Stage 1 and Stage 2 audits are combined during a single on-site audit of the manufacturer, the report should include a clear description of the stage 1 elements covered during the audit.

(I) Audit Plan

The report should include a copy of the audit plan. The report should document and explain any deviations from the audit plan.

Note: For additional guidance on the content of the audit plan, see ISO/IEC 17021 9.1.2. and Annex F.

(J) Description of Major Changes

The report should describe when an audited activity or process has been subject to a major change. This includes major changes to products or processes, changes to the organizational structure or ownership, changes to key personnel and facilities and to the QMS as a whole. The

description of these changes should include an assessment of whether regulatory requirements have been satisfied, or continue to be satisfied, and whether required regulatory submissions were made when necessary.

4.2.3 Audit Evidence

The audit report should include sufficient audit evidence to support the audit conclusions made in the report. The auditor should document audit evidence, evaluate the evidence against audit criteria and determine a finding, either of conformity or nonconformity. Information regarding the verification of the specific requirements from participating regulatory authorities should be included in the audit report

The Auditing Organization should note that the participating MDSAP Regulatory Authorities will conclude that the Auditing Organization did not audit an aspect or process of the manufacturer's QMS if omitted in the report. If a process of the organization's QMS that is required to be audited by the audit type (e.g. initial, surveillance, re-audit) is not audited, the report should contain the rationale for not auditing the process.

The report should record both findings of conformity and nonconformity. Report authors should refrain from providing specific advice, instructions or solutions towards the development and implementation of a QMS, or from suggesting opportunities for improvement (see IMDRF/MDSAP WG/N3 – 9.1.3).

4.2.4 Audit Summaries

Written summaries of the audit of each of the processes or activities below should be included in the report. The audit summaries should be brief but nonetheless include the following information:

- description of the process or activity audited;
- description of the area (physical or organizational) of the site visited;
- name and title of persons interviewed;
- key documents reviewed (procedures, work instructions, records etc.);
- type and number of documents (documents or records) reviewed, including a qualitative statement of the sample size where appropriate;
- identification of the products or components relevant to the process or activity audited; and,
- concluding statements regarding whether the activity or process under audit is in conformity with the audit criteria.

Note: the inclusion of clause numbers in the concluding statements can assist with demonstrating appropriate coverage.

When an auditor verifies the implementation of corrections and/or corrective actions stemming from past nonconformities, the results of the verification should be included in the audit report, either as part of the Audit Summaries section or under a separate heading.

The report should record any outstanding nonconformity from a previous audit as a repeat nonconformity.

Where the evidence supports a finding of nonconformity, the summary should include a cross-reference to the nonconformity in the form of **[NC #]**

(A) Management:

i. the extent of outsourcing of processes that may affect the conformity of product with specified requirements and verification of the proper documentation of controls in the quality management system;

ii. verification that management reviews are being conducted at planned intervals and that they include a review of the suitability and effectiveness of the quality policy, quality objectives, and quality management system to assure that the quality management system meets all applicable regulatory requirements;

iii. description of the organization's organizational structure and verification as to whether or not the responsibilities and authorities (e.g., management representative) were established;

iv. description of the organization's documents and records control; and

v. verification that the organization has determined the competencies for personnel performing work affecting product quality, including a description of the training procedures and records verified.

(B) Device Marketing Authorization and Facility Registration:

- determination as to whether or not the organization has performed the appropriate activities regarding device marketing authorization and facility registration with regulatory authorities participating in the MDSAP.

(C) Measurement, Analysis and Improvement:

i. determination as to whether or not appropriate sources of quality data have been identified for input into the measurement, analysis and improvement process, including customer complaints, feedback, service records, returned product, internal and external audit findings, and data from the monitoring of products, processes, nonconforming products, and suppliers;

ii. confirmation that data from these sources are accurate and analyzed using valid statistical methods (where appropriate) to identify existing and potential product and quality management system nonconformities that may require corrective or preventive action;

iii. description of the data sources chosen for review during the audit;

iv. determination as to whether or not investigations are conducted to identify the underlying cause(s) of detected nonconformities, where possible; and confirmation that investigations are commensurate with the risk of the nonconformity;

v. confirmation that corrections, corrective actions, and preventive actions were determined, implemented, documented, effective, and did not adversely affect finished devices; and verification that corrective action and preventive action is

appropriate to the risk of the nonconformities or potential nonconformities encountered;

vi. verification that internal audits of the quality management system are being conducted according to planned arrangements and documented procedures to ensure the quality management system is in compliance with the established quality management system requirements and applicable regulatory requirements and to determine the effectiveness of the quality system;

vii. confirmation that the internal audits include provisions for auditor independence over the areas being audited, corrections, corrective actions, follow-up activities, and the verification of corrective actions; and

viii. confirmation that the organization has made effective arrangements for gaining experience from the post-production phase, handling complaints, and investigating the cause of nonconformities related to advisory notices with provision for feedback into the Measurement, Analysis and Improvement process; and verification that information from the analysis of production and

ix. post-production quality data was considered for amending the analysis of product risk, as appropriate.

(D) Medical Device Adverse Events and Advisory Notices Reporting:

i. determination as to whether or not the organization's processes ensure that individual device-related adverse events and advisory notices involving medical devices are reported to regulatory authorities within required timeframes; and

ii. a listing of the advisory notices applicable to each of the regulatory authorities participating in the MDSAP. The listing should include whether the advisory notice was reported to the regulatory authority in the jurisdiction where the device is marketed.

(E) Design and Development:

i. a brief description of the design and development project(s) selected for review, and the rationale for the selection of the project(s);

ii. description of the records reviewed for the selected design and development project;

iii. verification that risk management activities are defined and implemented for product and process design and development, risk acceptability criteria are established and met throughout the design and development process, and any residual risk is evaluated and, where appropriate, communicated to the customer;

iv. determination that design and development validation data show that the approved design meets the requirements for the specified application or intended use(s);

v. verification that the results of validation includes the presence and completeness of clinical evidence

vi. verification that product and production specifications are fully documented prior to design release or design changes for transfer to production. In particular, where applicable, that:

   a. production parameters derived from process validation / revalidation are reliably transferred to routine production activities, e.g. for a viral inactivation process; for the uniformity of content for medicine/device combinations; for sterilization, requirements for bioburden monitoring, environmental monitoring and controls, dose audits, etc.
   b. for devices containing tissues, cells or substances of animal or microbial origin requirements for breeding/culturing, veterinary checks, sacrificing/harvesting, segregation, transport, storage, testing and handling of material to be incorporated into a device (e.g. ISO 22442 for animal origin) are followed.

vii. for devices containing medicinal substances, requirements for storage, sampling and identification testing of starting materials in accordance with a recognized pharmacopeia (BP, EP, USP) and a Medicinal Code of GMP, for testing of finished devices against a validated test method or recognized pharmacopeia (BP, EP, USP), where applicable, and requirements for maintaining stability are followed.

viii. determination that control of design and development changes, including changes to manufacturing processes affecting the characteristics of the medical devices, are subject to design and development verification and validation, as applicable, addressing the new or impacted risks;

ix. for products where design controls are a permitted exclusion, verification that the organization has available and is maintaining adequate technical documentation to demonstrate conformity to safety and performance requirements and other relevant regulatory requirements.

(F) Production and Service Controls:

i. brief description of the manufacturing, incoming inspection and warehouse areas and production process(es);

ii. brief description of the controls for receiving, handling, storage and distribution of products in the warehouse, including traceability controls;

iii. brief description of the production processes selected for review, and the rationale for the selection of the processes;

iv. description of the records reviewed for the selected production processes;

v. evaluation of records of maintenance, calibration and incoming inspection relevant to the selected production process(es);

vi. verification that the selected process has been validated if the result of the process cannot be fully verified, that the validation demonstrates the ability of the process to consistently achieve the planned result, and in the event changes have occurred on a previously validated process, that the processes were reviewed and evaluated, and re-validation performed where appropriate;

vii. if product is supplied sterile, confirmation that the sterilization process is validated, periodically re-validated, and records of the validation are available, that devices sold in a sterile state are manufactured and sterilized under appropriately controlled conditions, and that the sterilization process and results are documented and traceable to each batch of product;

viii. if product needs to be reworked, prior to rework being authorized, confirmation that the organization has made a determination of any adverse effect of the rework upon the product, verification that the rework process has been performed according to an approved procedure, that the results of the rework have been documented, and that the reworked product has been re-verified to demonstrate conformity to requirements;

ix. verification and description of the utilities (e.g. environmental conditions – air treatment, water treatment, compressed gases) and their validation, maintenance and monitoring status;

x. evaluation of environmental controls inside the production areas (e.g. cleaning of the areas, room qualifications, differential pressure, non-viable and viable particle count, etc.);

xi. evaluation and description of the product release process;

xii. if installation activities are required, verify whether records of installation and verification activities are maintained; and

xiii. verification that servicing activities are conducted and documented in accordance with defined and implemented instructions and procedures.

(G) Purchasing:

i. description of the supplier evaluation files selected for review, and the rationale for the selection of the suppliers for review;

ii. verification that suppliers are selected for use by the organization based on their ability to supply product or services in accordance with the organization's specified requirements; and that the degree of control applied to the supplier is commensurate with the significance of the impact of the supplied product or service on the quality of the finished device, based on risk;

iii. confirmation that the controls defined for the verification of purchased medicinal substances, or purchased tissues, cells or substances of animal or microbial origin have been implemented by the manufacturer. (e.g. GMP for medicinal substances, ISO 22442 for animal origin); and

iv. confirmation that data from the evaluation of suppliers, verification activities, and purchasing are considered as a source of quality data for input into the Measurement, Analysis and Improvement process.

4.2.5 Findings of Nonconformity

For each nonconformity:

- Identify the requirement against which the nonconformity is raised,
- Make a statement of nonconformity (when a requirement has not been fulfilled),
- Reference the supporting objective evidence in the audit summaries, and
- Assign the grade according to IMDRF/MDSAP WG/N3 – 9.1.2.

If nonconfomrities are documented elsewhere the record should be uniquely identified and cross-referenced in the appropriate audit summaries. When a separate nonconformity form is used by the Auditing Organization that contains the specified information, the form shall be attached to the report.

The audit report should record any unresolved objections by the organization to the issued nonconformities.

Where the audited organization undertakes cause analysis, correction or corrective action before the end of the audit, the report may record these activities; however, it does not eliminate the need to record the nonconformity.

4.2.6 Additional Content

The following should also be documented in the report and may be included in a relevant audit summary or, where suggested, under a separate heading:

(A) Obstacles

The report should record any circumstance where an auditor requested information and the audited organization refused to provide the information or refused to grant the auditor access to premises for audit. The report should record any other obstacles encountered that have the potential to impact the validity of the audit conclusions.

Alternatively, the report may describe these obstacles in section 4.2.7 (D) – Reliability of Audit.

(B) Areas Not Audited

The report should record an explanation when areas that are within the scope of the audit as defined in the audit plan are not audited or not sufficiently audited.

(C) Topics to be followed during the next audit

The report shall document situations which appear to be nonconforming but where insufficient audit evidence was collected or observed, for follow-up during the next audit (see IMDRF/MDSAP WG/N3 – 9.1.3).

4.2.7 Conclusions

The audit report should provide clear conclusions about the conduct of the audit and its overall outcome and results. The conclusions provided in this section should relate to the quality management system as a whole and should cover the following:

(A) Conformity with Audit Criteria

The report should include a brief summary and conclusion regarding the conformity of the quality management system as implemented and addressing each set of audit criteria in 4.2.2 (B) above.

(B) Effectiveness

The report should include a brief summary and conclusion regarding the effectiveness of the quality management system in meeting quality objectives and regulatory requirements.

(C) Confirmation of Audit Objectives

The report should record whether the audit achieved the objectives in 4.2.2 (C) above. The report should explain why the audit did not achieve all of its objectives, if applicable.

(D) Reliability of Audit

The report should outline any factors encountered that may decrease the reliability of the audit. This may include such factors as a shortfall in auditor time, the absence of the required technical competence in the audit team, or any obstacle not mentioned under 4.2.6 (A).

(E) Recommendations

The report should record recommendations made by the audit team with regards to the initial or continuing certification/MDSAP suitability of the quality management system, together with any conditions or observations; as well as any other follow-up actions by the AO including changes to the audit program, changes to the composition of the audit team, or changes to the number of auditor-days projected as necessary for future audits.

4.2.8 Identification and Dating

The final audit report should include the name(s), titles, and affiliation of the author(s) of the report. The report should also be dated on its final date of issue and include version control information where necessary.