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1. Purpose/Policy

This document provides details for the implementation of the requirements 8.6.1, 8.6.2 (when applicable), and 8.6.3 from the IMDRF/MDSAP/WG N3 (2nd Edition) – *Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition*, as they apply to the Medical Device Single Audit Program.

This document specifies expectations applicable to the Auditing Organization regarding the timeline to complete post-audit activities and to share audit information with the participant Regulatory Authorities.

This procedure also provides instructions for submitting Audit Report Packages on the Regulatory Exchange Platform – secure (REPs).

2. Scope

This procedure applies to all Auditing Organizations in Medical Device Single Audit Program.

3. Definitions/Acronyms

AO – Auditing Organization

RA – Regulatory Authority

REPs – Regulatory Exchange Platform – secure

4. Authorities/Responsibilities

Auditing Organizations:
Designate a person(s) to serve as the AO Submitter role in REPs.

AO Submitter Role:

- Creates audit report packages on the REPs
- Adds documents to audit report package
- Submits audit report packages
- Makes changes and resubmits audit report packages

Regulatory Authorities:
Designate a person(s) to serve as the RA Approver role in REPs.

RA Approver Role:

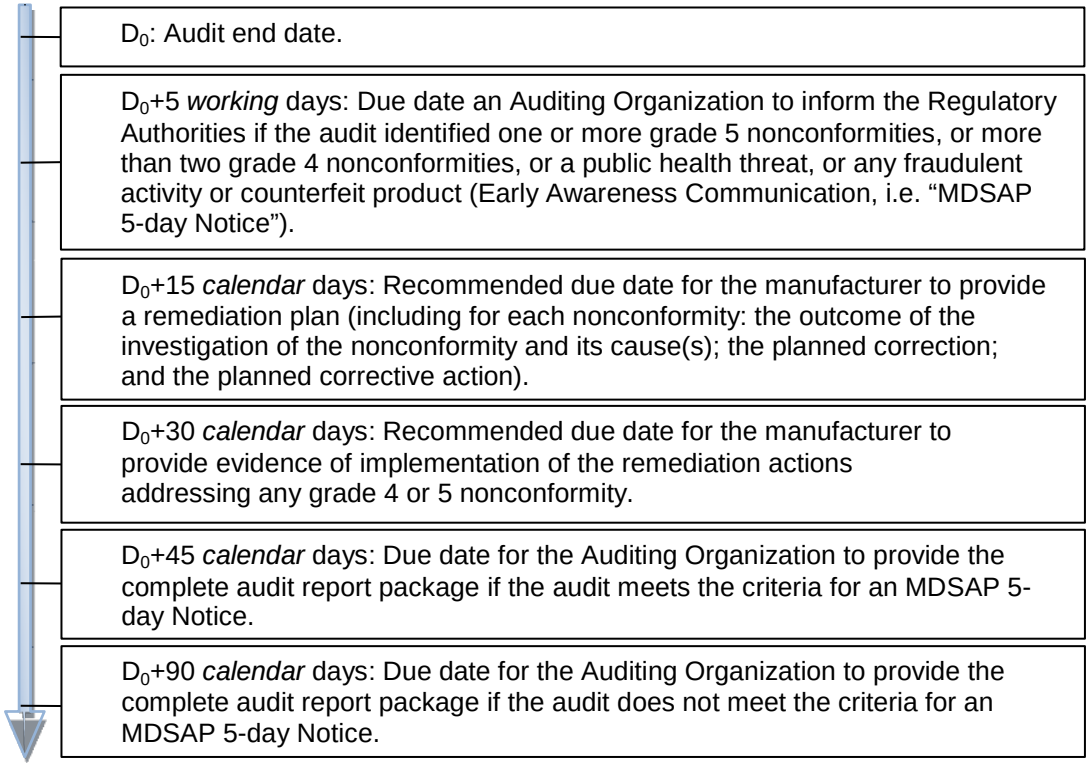
- Manages audit report packages
- Reviews audit report packages
- Can add a final classification
- Can change the status to Update Required

5. Procedures

5.1 Timeline

The following chart specifies the due dates relative to the audit ending date (D0):

- For the manufacturer to provide the Auditing Organization with the results of their investigation of any nonconformity, the correction and corrective action plans, and the evidence of implementation of these actions; and
- For the Auditing Organization to provide the Regulatory Authorities with early awareness communication (MDSAP 5-day Notice) and the complete Audit Report Package.



5.2 Audit Report Package

The Audit Report Package to be shared with the Regulatory Authorities includes:

- The audit report documented on the fillable *Medical Device Regulatory Audit Report Form* MDSAP AU F0019.1. The submitted audit report must be the final version after its review by the Auditing Organization;
- If any nonconformity was open during the audit, the *Nonconformity Grading and Exchange Form* MDSAP AU F0019.2;

- If any nonconformity was open, or left open during the audit, the Nonconformity Reports issued by the Auditing Organization on their corresponding forms, including the remediation plan developed by the manufacturer and the results of the review of this remediation plan by the Auditing Organization;
- The evidence of implementation of corrections and/or corrective actions provided by the manufacturer to remedy any nonconformity grade 4 or 5.
- Any other attachment to the report (listed in section 17 of the report)

Nonconformity Reports should be actively updated until the effectiveness of the corrections and corrective actions proposed by the audited facility or organization has been verified.

Upon request from an MDSAP Regulatory Authority, the Auditing Organization is expected to provide updated nonconformity reports within 10 calendar days. It is not necessary for Nonconformity reports to be closed at the time they are shared with the Regulatory Authorities.

5.3 Audit End Date - D_0

The start date for post-audit activities is the audit end date for the audited facility. If any nonconformity is identified during the audit, the Auditing Organization must issue the nonconformity reports at D_0.

If the audit program covers several facilities, this document applies individually to each facility.

5.4 Early Awareness Communication ("MDSAP 5-day Notice")

An Auditing Organization must inform the Regulatory Authorities within 5 working days starting on D_0, if any of the following situations occur when auditing against the Regulatory Authorities' audit criteria.

If the audit team identified:

- one or more nonconformity grade 5, *OR*
- more than two nonconformities grade 4,

the Auditing Organization must inform the Regulatory Authorities by providing a completed Nonconformity Grading and Exchange form MDSAP AU F0019.2.

OR

If, in the course of the audit, the audit team:

- perceives a public health threat, *OR*
- detects any fraudulent activity, *OR*
- detects any counterfeit product,

the Auditing Organization must inform the Regulatory Authorities by providing a written report setting out the circumstances of the perceived public health threat, the detected fraudulent activity or the identification of counterfeit product.

> Note: IMDRF/MDSAP WG/N3 (2nd Edition) – clauses 8.6.2 and 9.5.3 – requires the Auditing Organization to report within 5 working days from when **they become aware** of public health threat, fraudulent activities or counterfeit products to the recognizing Regulatory Authorities. This applies regardless the source of information that makes the Auditing Organization aware of such reportable situation. The present document addresses the cases when such reportable situation is identified during an audit.

If the audit meets the criteria for an MDSAP 5-day Notice, the complete audit report package is to be provided to the regulatory authorities before D0+45 calendar days. In all other cases, the complete audit report package is to be provided to the regulatory authorities before D0+90 calendar days.

5.5 Submitting an Audit Report Package that does not meet the criteria for a MDSAP 5-day Notice in REPs

1. All post-audit documents and communications are to be submitted directly through the Regulatory Exchange Platform – secure (REPs). Detailed instructions for creating, modifying and submitting Audit Report Packages in REPs can be found in the REPs User Guide.

2. The complete Audit Report Package must be submitted in REPs no later than 90 calendar days after the audit end date (D_0+90).

3. When submitting the Audit Report Package to the Regulatory Authorities in REPs, the Audit Report Package must include the contents described in 5.2.

5.6 Providing the Early Awareness Communication ("MDSAP 5-day Notice") and Submitting the Audit Report Package in REPs

1. All post-audit documents and communications are to be submitted directly through the Regulatory Exchange Platform – secure (REPs). Detailed instructions for creating, modifying and submitting Audit Report Packages in REPs can be found in the REPs User Guide.

2. The creation of a draft Audit Report Package in REPs will automatically trigger a notification to the Regulatory Authorities if any of the MDSAP 5-day Notice situations have been identified.

<u>If the audit team has identified one or more nonconformity grade 5, *OR* more than two nonconformities grade 4;</u>

The AO shall create a draft Audit Report Package in REPs and include the *Nonconformity Grading and Exchange Form* MDSAP AU F0019 no later than 5 working days after the audit end date.

OR

<u>If, the audit team perceives a public health threat, detects any fraudulent, or detects any counterfeit product:</u>

The AO shall create a draft Audit Report Package in REPs no later than 5 working days after the audit end date. The AO shall also check one or more of the applicable 5-day Notice checkboxes in Section 1 of the New Audit Report form. The AO must include in the draft Audit Report Package the *Nonconformity Grading and Exchange Form* MDSAP AU F0019 and written report setting out the circumstances of the perceived public health threat, the detected fraudulent activity or the identification of counterfeit product.

3. After the draft Audit Report Package has been created, the remaining required documents described in 5.2 are to be added to the Audit Report Package no later than 45 calendar days after the audit end date (D_0+45) and submitted to the Regulatory Authorities in REPs.

6. Forms

N/A

7. Reference Documents

REPs MDSAP User Guide

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2014-07-18	Initial Release	Marc-Henri Winter, FDA
002	2014-10-14	The threshold for triggering certain activities was erroneously cited within the procedure as two or more grade 4 NCs. The true threshold is more than two grades 4 NCs. Therefore this document was revised to align with the true threshold requirements specified in IMDRF N3.	Robert G. Ruff, FDA
003	2015-07-28	Page 3 – Section 6 “Method for sharing information with regulatory authorities” was updated to add Japan email information for the AOs. (minor update no RAC signature)	Liliane Brown, FDA
004	2016-08-15	Document was revised to reflect ISO changes. Page 1 – section 1. Purpose - was updated as follows: “This document provides details for the implementation of the requirements 8.6.1, 8.6.2 (when applicable), and 8.6.3 from the IMDRF/MDSAP WG/N3 (2nd Edition); throughout the document MDSAP AU F0019.2 version 004 was removed.	Liliane Brown, FDA
005	2018-10-15	Fully revised due to REPs launch	Marc-Henri Winter, FDA Michael Chan, FDA Hiromi Kumada, PMDA

Version 005
Approval

Approved: On file Date: 2018-10-15

CHAIR, MDSAP RAC