

 Responsible Office/Division	Document No.: MDSAP AU P0029.003	Page: 1 of 5
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Title: Initial Audit and Withdrawal Notification Procedure	Project Manager: Neil A. Mafnas, LCDR, USPHS	

Table of Contents

1. Purpose/Policy
 2. Scope
 3. Definitions/Acronyms
 4. Authorities/Responsibilities
 5. Procedures
 6. Forms
 7. Reference Documents
 8. Document History
- Approval Sign-Off Sheet

1. Purpose/Policy

The purpose of this document is to describe the Medical Device Single Audit Program (MDSAP) notification process when an initial MDSAP audit is scheduled or rescheduled.

This procedure also provides instructions for creating, updating and maintaining facility entries in the MDSAP Master List on the Regulatory Exchange Platform – secure (REPs).

2. Scope

This process applies to all MDSAP participating RAs and all formally recognized AOs, or AOs that have been authorized to conduct MDSAP audits.

3. Definitions/Acronyms

AO – Auditing Organization

RA – Regulatory Authority

REPs – Regulatory Exchange Platform – secure

Master List – Database of all facilities that are participating or have participated in MDSAP.

Initial Audit and Withdrawal Notification Procedure	Document No.: MDSAP AU P0029.003	Page 2 of 5
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Campus –

Either:

- a. A group of facilities within a maximum range of one kilometer, OR
- b. A group of geographically close facilities (within 60-minute drive), if not more than one of these facilities would require a facility-specific Regulatory Authority-issued certificate (such as the issuance of a GMP Certificate (ANVISA) or a Registration Certificate (PMDA))

In either case, the facilities in the group shall be operated by the medical device organization under a single QMS. The management for, and the activities within, the group of facilities must correlate to the realization of the finished medical devices included in the scope of certification

Notes:

- A group of buildings sharing the same street address (same street and number) is seen as a single facility and not as a campus.
- A campus may include multiple facilities with Regulatory Authority-issued facility identifier (e.g. FEI issued by the FDA).

4. Authorities/Responsibilities

Auditing Organization:

Designate a person(s) to serve as the AO Client Manager role in REPs.

AO Client Manager Role:

- Creates new facility requests in the Master List
- Updates and maintains accuracy of facility data in the Master List
- Submits withdrawal requests of facilities from the Master List
- Point of contact for Master List inquiries from the RAs

Regulatory Authorities:

Designate a person(s) to serve as the RA Master List Manager role in REPs.

RA Master List Manager Role:

- Reviews and approves new facility submissions from AOs
- Reviews and approves facility update requests from AOs
- Modifies facility data entries
- Updates and maintains RA specific facility identifiers

Initial Audit and Withdrawal Notification Procedure	Document No.: MDSAP AU P0029.003	Page 3 of 5
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5. Procedures

5.1 Initial Audit Notification and New Facility Request Submission

Auditing Organizations (AOs) must submit an initial MDSAP audit notification to the Regulatory Authorities (RA) by creating a new facility request in the REPs Master List for each facility that participates in MDSAP.

New facility submissions and updates to existing facilities in the Master List are routed to the RA Master List Manager group for review and approval. Detailed instructions for creating, modifying and submitting facilities to the REPs Master List can be found in the REPs User Guide.

After the AO has entered a contract with the facility to be audited under MDSAP, the AO Client Manager shall create a new facility request in REPs within three (3) calendar days of entering the contract.

Each audited address that is listed under the MDSAP certificate is to be entered as a separate facility in the Master List unless the address meets the definition of a **campus** as defined above.

5.2 Campuses

If a group of facilities meet the definition of a campus, each address of the campus is to be entered under the "Address(es)" section of the new facility request form. One of the addresses is required to be identified as the primary address of the campus.

5.3 Facilities Audited by More Than One AO

For facilities that are audited by more than one AO, each AO is responsible for creating and maintaining their own separate facility entry in the Master List.

5.4 Updating and Maintaining Facility Data in the Master List

The AO Client Manager is responsible for maintaining the accuracy of all facility data in the Master List. At a minimum, the Master List data should be verified for accuracy annually.

Within five (5) days of becoming aware, the AO Client Manager is responsible for updating facility information if any of the following items have changed:

- Initial audit start and end dates
- Facility Name
- Other Trade Name(s)
- Address changes (including campus address additions and deletions)

Initial Audit and Withdrawal Notification Procedure	Document No.: MDSAP AU P0029.003	Page 4 of 5
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- Jurisdictions
- MDSAP Scope of Certification
- Certificate holder information
- Facility Contact Person

5.5 Withdrawals

When a participating facility elects to no longer participate in MDSAP, the AO Client Manager shall submit a withdrawal request of the facility from the Master List in REPs. Withdrawal requests shall be submitted by the AO Client Manager within seven (7) business days of the AO receiving the withdrawal notification from the facility.

5.6 Transfers of Facilities Between Auditing Organizations

Facilities that elect to transfer from one AO to another AO is considered a withdrawal from the original AO and the new AO must submit a new facility request. When submitting the withdrawal request, please note in the comments field the AO that the facility is transferring to.

6. Forms

6.1 N/A

7. Reference Documents

7.1 REPs MDSAP User Guide

8. Document History

Initial Audit and Withdrawal Notification Procedure	Document No.: MDSAP AU P0029.003	Page 5 of 5
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Version No.	Version date	Description of Change	Author Name/Project Manager
001	2014-11-20	Initial Release	LCDR Neil Mafnas, FDA
002	2015-09-22	On page 4; Japan's e-mail address was added due to its participation to MDSAP Pilot.	Liliane Brown, FDA
003	2018-10-15	Fully revised due to REPs launch	Michael Chan, FDA Hiromi Kumada, PMDA

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Approval

Approved: On file Date: 2018-10-15
CHAIR, MDSAP RAC