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1. Purpose/Policy

The purpose of this document is to describe the Medical Device Single Audit Program (MDSAP) notification process and timeframes that an Auditing Organization (AO) shall follow when an initial MDSAP audit has been scheduled or rescheduled. The document also instructs AO's how to properly notify the MDSAP Team when a medical device manufacturer (MDM) withdraws from MDSAP participation.

Timely notification of MDSAP initial audit schedules by an AO will prevent the duplication of inspection/audit activities for MDM's participating in MDSAP. Additionally, adequate notification of situations where an MDM no longer elects to participate in MDSAP will ensure that continued regulatory oversight is maintained by all participating Regulatory Authorities (RA).

2. Scope

This process applies to all MDSAP participating RAs and all formally recognized AOs, or AOs that are seeking MDSAP recognition.

Note: This procedure is not required for notification of surveillance audits, re-audits or special audits.

3. Authorities/Responsibilities

3.1 Auditing Organizations (AO):

- Coordinates MDSAP initial audit schedule/reschedule dates with an

MDM
- Notifies the MDSAP Audit Schedule Point of Contact (ASPOC) about any scheduled/rescheduled initial audits in a timely manner.
- Notifies the ASPOC when an MDM that the AO audits withdraws from MDSAP participation with the AO.

3.2 MDSAP Audit Schedule Point of Contact (ASPOC)

- Notifies each MDSAP RA when an MDM has elected to participate in MDSAP or withdraws from MDSAP.
- Notifies RAs about any scheduled or rescheduled MDSAP initial audits.
- Notifies RAs of MDM sites/locations that withdraw from MDSAP participation.
- Serves as an AOs main point of contact for communication of initial audit schedules/reschedules and MDM MDSAP withdrawals.

3.3 Participating Regulatory Authority (RA)

- Ensures that proper regulatory oversight is maintained for MDM's participating or not participating in MDSAP.

4. Procedures

AOs should complete an "Initial Manufacturer Audit/Manufacturer Withdrawal Notification Form," MDSAP AU F0029.1.001, when notifying the MDSAP ASPOC of a scheduled/rescheduled initial audit or an MDM's withdrawal from participating in MDSAP. The AO shall submit MDSAP AU F0029.1.001 via email to mdsap@fda.hhs.gov by clicking the "Submit by Email" button on the form.

Instructions on how to properly complete and submit the MDSAP AU F0029.1.001 are provided at the end of the form. An AO shall observe the timeframes for submission of the form prescribed in the sections below.

4.1 Notification of Scheduled Initial MDSAP Audits

When an MDM chooses to participate in MDSAP, the AO that will be conducting the MDSAP audits shall submit an MDSAP AU F0029.1.001 form to the ASPOC within three (3) business days after the AO and MDM confirm the initial MDSAP audit request**.** If initial audits are required at multiple locations/sites, the AO shall submit a separate MDSAP AU F0029.1.001 Form to the ASPOC for each scheduled initial audit location.

If the initial audit start and end dates are not confirmed within three (3) business days following the initial MDSAP audit request, the AO shall

provide an estimated schedule date (e.g., May 2017, mid-March 2018, etc.) on the MDSAP AU F0029.1.001 Form. Once initial audit dates have been confirmed by the AO and MDM, the AO shall submit a new MDSAP AU F0029.1.001 Form, within three (3) business days, indicating the confirmed initial audit start and end dates.

4.2 Reschedule of Initial MDSAP Audits

If the MDM or AO requests a reschedule of the initial MDSAP audit, the AO shall notify the ASPOC within seven (7) business days of the reschedule request by submitting a MDSAP AU F0029.1.001 Form. If an MDM has initial audits rescheduled at multiple locations/sites, a separate MDSAP AU F0029.1.001 Form shall be submitted to the ASPOC for every rescheduled initial audit location.

If the rescheduled initial audit dates are not confirmed within seven (7) business days following the reschedule request, the AO shall provide the estimated reschedule date (e.g., May 2017, mid-March 2018, etc.) on the MDSAP AU F0029.1.001 Form. Once rescheduled audit dates have been confirmed by the AO and MDM, the AO shall submit a new MDSAP AU F0029.1.001 Form, within three (3) business days, indicating the confirmed/rescheduled initial audit start and end dates.

IMPORTANT: AOs shall avoid rescheduling an initial MDSAP audit of an MDM if the audit is also a MDSAP witnessed audit and travel has already been confirmed/scheduled by MDSAP Regulatory Authority Assessors.

4.3 Notification of MDM Withdrawal from MDSAP

When an MDM elects to no longer participate in MDSAP, the AO that audits the MDM shall complete the MDSAP AU F0029.1.001 Form and submit it to the ASPOC.

An MDSAP withdrawal notification should also be submitted to the ASPOC by the AO if the MDM elects to seek the services of a different AO.

Withdrawal notifications shall be submitted within seven (7) business days following the MDM withdrawal notification to the AO. If the MDM has multiple locations withdrawing from MDSAP participation, the AO shall list the DUNS number for each location on the MDSAP AU F0029.1.001 Form.

4.4 Notification of MDSAP Regulatory Authority (RA)

The ASPOC shall compile the information received from AO's and

update the MDSAP Participating Manufacturers Master List. The MDSAP Participating Manufacturers Master List shall include the following MDM site information: MDM Name; DUNS number; and complete address.

The ASPOC shall make the MDSAP Participating Manufacturers Master List available for all MDSAP RAs to review. The ASPOC shall distribute the list to all RAs after each update by email or via a secure IT software program/portal.

The email addresses for each Regulatory Authority are as follows:

- Australia: MDSAP@tga.gov.au
- Brazil: MDSAP@anvisa.gov.br
- Canada: QS_MDB_HC@hc-sc.gc.ca
- USA: MDSAP@fda.hhs.gov

5. Reference Documents

MDSAP AU F0029.1.001, Initial Manufacturer Audit/Manufacturer Withdrawal Notification Form

6. Document History

Version No.	Version Date	Description of Change	Author Name/Project Manager
001	2014-11-20	Initial Release	LCDR Neil Mafnas

Version Approval

Approved: Signature on file Date: 2014-11-21