1 Purpose

This document describes the format and content of a Medical Device Single Audit Program (MDSAP) Surveillance Audit Confirmation Notification.

2 Policy Statements

A Surveillance Audit Confirmation Notification may be issued by an Auditing Organization to confirm completion of an MDSAP surveillance audit activity.

Auditing Organizations (AO's) shall ensure that Surveillance Audit Confirmation Notifications are in the format and contain the information described by this document.

3 Scope

This document applies to MDSAP authorized and recognized Auditing Organizations.

4 Background

A "Certification Document" or "Certificate" is an attestation of conformity to requirements. A certification document can only be issued by an auditing organization following the satisfactory completion of a comprehensive initial or recertification audit.

During Health Canada's transition from the Canadian Medical Device Conformity Assessment System (CMDCAS) to MDSAP, it was decided that in order to minimally impact pre-existing ISO 13485 certifications issued to manufacturers, the MDSAP certification cycle can be synchronised with the pre-existing certification cycle. Consequently, the first MDSAP audit(s) performed at a facility may be a surveillance audit (a non-comprehensive audit).

An MDSAP Surveillance Audit Confirmation Notification may be issued by an auditing organization following the satisfactory completion of an MDSAP audit conducted at a surveillance phase of the certification cycle (before a comprehensive MDSAP audit is completed and a certification document issued).

An MDSAP Surveillance Audit Confirmation Notification may only serve as an attestation of a completed surveillance audit.

An MDSAP Surveillance Audit Confirmation Notification shall not be understood as a certification document or imply valid certification.

The AO shall inform the manufacturer that they cannot use an MDSAP Surveillance Audit Confirmation Notification to demonstrate or imply conformance with all MDSAP regulatory requirements.

5 MDSAP Surveillance Audit Confirmation Notification Format

The MDSAP Surveillance Audit Confirmation Notification must be issued in a letter format using the auditing organization's letterhead.

The MDSAP Surveillance Audit Confirmation Notification must comply with the format contained within the template shown in Annex A.

The MDSAP Surveillance Audit Confirmation Notification shall not be printed on the auditing organization's certificate template.

6 Conditions for issuing an MDSAP Surveillance Audit Confirmation Notification

The MDSAP Surveillance Audit Confirmation Notification may be issued to the audited organization, if:

- an MDSAP surveillance audit has been conducted and completed,
- an MDSAP Regulatory Audit Report has been issued by the MDSAP-authorized auditing organization, and
- the AO received an acceptable remediation plan regarding any identified audit nonconformity

7 MDSAP Surveillance Audit Confirmation Notification content

The surveillance audit confirmation shall include (at a minimum) the following elements:

a) MDSAP logo

b) Title / subject line: "Surveillance Audit Confirmation"

c) Date of issue

d) Auditing organization's legal name and address

e) Name and address of Legal Manufacturer

f) Name and address of the audited facility if different from the Legal Manufacturer

g) MDSAP Report Reference number of the MDSAP Regulatory Audit Report issued to the manufacturer in the format **YYYY-MM-DD-AUR-aaaa-bbbbbb**, found in the footer of the report, where:

- **YYYY-MM-DD** is the audit starting date
- **aaaa** is the four-digit code of the auditing organization
- **bbbbbb** is the six-digit number generated by the Regulatory Exchange Platform – secure (REPs) of the manufacturer

h) Statements that:

- the manufacturer was audited against MDSAP requirements for surveillance audits limited to the audit scope as documented in the associated Medical Device Regulatory Audit Report, including the MDSAP Report Reference number
- the MDSAP Surveillance Audit Confirmation Notification does not imply certification
- the referenced audit report and its attachments should be used to obtain further details regarding the audit outcome

i) Name, title, and signature of auditing organization’s authorized signatory

Annex A – MDSAP Surveillance Audit Confirmation Notification Template

The document is to be printed on the auditing organization's letterhead.

Surveillance Audit Confirmation

< date>

<Legal Name of AO> hereby confirms that

<Name of Legal Manufacturer >

<Address>

was audited against MDSAP requirements for surveillance audits limited to the audit scope as documented in Medical Device Regulatory Audit Report, Ref <yyyy-mm-dd-AUR-aaaa-bbbbbb>.

The audit was conducted at the following facility:

<Facility Name>

<Address>

<To be added if different than Legal Manufacturer Name and Address>

This confirmation does not imply certification. For further details regarding the audit outcome, please refer to the above mentioned Audit Report and its attachments.

<Authorised signature>

<Signatory name and title>

<AO name, address, phone and e-mail, if not included on the letterhead>

Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2014-07-22	Initial Release	Robert G. Ruff, FDA
002	2018-06-21	• Remove mention of MDSAP Pilot • Update background section	Frédéric HAMELIN, Health Canada
003	2018-10-16	• Adjust formatting	Keith M Smith, TGA Hiromi Kumada, PMDA
004	2021-02-08	• Replace DUNS with Facility ID generated by the REPs in section 7	Hiromi Kumada, PMDA

Version004
Approval

Approved: ON FILE Date: 2021-02-08
CHAIR, MDSAP RAC