

 Responsible Office/Division	Document No.: MDSAP AU P0036.001	Page: 1 of 8
	Version Date: 2020/01/13	Effective Date: 2020/01/13
Title: Remote Auditing Pilot Program		Project Manager: Kimberly Lewandowski-Walker, US FDA

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

The purpose of this procedure is to define and document a voluntary pilot program for remote auditing of MDSAP processes and tasks as part of the audit of a medical device organization. The MDSAP Audit Model process that is the subject of this pilot program is the Device Marketing Authorization and Facility Registration process.

2. Scope

This pilot program for remote auditing will allow for the audit of the Device Marketing Authorization and Facility Registration Process to be conducted off-site as part of an MDSAP audit. This approach may facilitate use of new technology and may improve the flow of information between auditors and audited medical device organization when the two parties are not physically in the same location. Additionally, the pilot provides for auditing the linkages from the Device Marketing Authorization and Facility Registration process during the on-site (Stage 2) portion of the audit without creating redundancy with the remote portion of the audit.

This pilot program will not replace Stage 1 audits, as defined in ISO 17021-1:2015: 9.3.1.2; including the portion of a Stage 1 audit that includes the Device Marketing Authorization and Facility Registration Process.

This pilot program will not affect the audit time calculation, as defined in MDSAP AU P0008: MDSAP Audit Time Determination Procedure and calculated using MDSAP AU F0008.2.002 Audit Duration Calculation Form. Audit times will continue to be calculated using MDSAP AU P0008 and MDSAP AU F008.2. This pilot program will not address the Auditing Organization billing practices, including any differences in billed amounts for

Remote Auditing Pilot Program	Document No.: MDSAP AU P0036.001	Page 2 of 7
-------------------------------	-------------------------------------	-------------

on-site and remote audit hours.

This pilot program will not affect the issuance of audit nonconformities or the timeline for post-audit activities, as required in ISO 17021-1:2015: Conformity assessment — Requirements for bodies providing audit and certification of management systems, cl 9.4.5, IMDRF MDSAP WG/N3:2016; Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition, and MDSAP AU P0027: Post-Audit Activities and Timeline Policy.

The expected duration of this pilot program is eighteen (18) months from the date of approval of this procedure. The pilot may be terminated early or extended at the discretion of the MDSAP Regulatory Subject Matter Expert team or the MDSAP Regulatory Authority Council.

The remote audit of any MDSAP processes other than the Device Marketing Authorization and Facility Registration process is outside the scope of this pilot program. If the Auditing Organization identifies a need to conduct remote audits of other processes, the Auditing Organization must contact their Assessment Program Manager to discuss the specifics of the situation before conducting any portion of the audit remotely.

3. Definitions/Acronyms

APM: Assessment Program Manager

DMAFR: Device Marketing Authorization and Facility Registration

Remote auditing: the use of technology to perform a portion of the MDSAP audit of a medical device organization that would normally be performed on-site.

4. Authorities/Responsibilities

Auditing organizations: responsible for oversight of audits that are conducted in accordance with this pilot program, including ensuring adherence to this procedure and all other relevant MDSAP policies and procedures.

Regulatory authorities: responsible for evaluation of the MDSAP audit reports, surveys, and making recommendations for expansion of remote auditing within the MDSAP upon completion of this pilot program.

Remote Auditing Pilot Program	Document No.: MDSAP AU P0036.001	Page 3 of 7
-------------------------------	-------------------------------------	-------------

5. Procedures

Remote auditing of the DMAFR Process can be utilized during this pilot program during Stage 2 Initial, Surveillance, and Re-certification audits.

Planning

The Auditing Organization and audited medical device organization must agree to the use of remote auditing to audit the DMAFR process as part of an MDSAP audit. The use of remote auditing during this pilot program will not affect the determination of audit time as defined in MDSAP AU P0008: MDSAP Audit Time Determination Procedure. MDSAP AU F0008.2. Audit Duration Calculation Form can still be utilized to calculate the audit time. The time of the remote portion of the audit should align with the calculated time for the DMAFR process as described in MDSAP AU P0008. The time for the on-site portion of the audit should be the calculated audit time minus the time of the remote portion of the audit. ([calculated audit time] – [time spent on remote audit of DMAFR] = on site audit time)

The audit plan for the Stage 2 audit must indicate the following if remote auditing techniques will be used:

- a statement that the DMAFR process will be audited remotely as part of this pilot program;
- the methods and technology to be used during the remote audit (e.g. WebEx, Adobe Connect, e-mail, teleconference);
- the initials/identification of the auditor(s) who will conduct the remote audit;
- the identification of the personnel from the medical device organization who will participate in the remote portion of the audit

The remote portion of the audit must occur prior to the on-site audit and must be conducted by a member of the audit team that will be conducting the on-site portion of the audit. The remote portion of the audit must occur within ten (10) business days prior to the start of the on-site portion.

Once the audit plan is available, the APM should be notified that an audit is planned that will utilize remote auditing under this pilot program. This notification should take place at least five (5) days prior to the remote portion of the audit. This will allow for witnessing of the remote audit by the participating MDSAP Regulatory Authorities.

Remote Auditing Pilot Program	Document No.: MDSAP AU P0036.001	Page 4 of 7
-------------------------------	-------------------------------------	-------------

Preparation for the remote audit

A variety of technological methods can be used for remote auditing, including, but not limited to:

- videoconferencing;
- web-based meeting systems with screen sharing capability (e.g. WebEx, Adobe Connect);
- teleconferencing in conjunction with e-mail;
- smart glasses (optical mounted head displays);
- other means as appropriate

The use of screen sharing technology is recommended – if available – to help ensure the timely sharing of information between the audited medical device organization and the auditor(s).

The following steps should be undertaken by the auditor(s) to prepare for the remote audit

- request information from the medical device manufacturer, to be submitted before the start of the remote audit, if necessary;
- ensure that the technology for the remote audit is agreed upon and tested by the Auditing Organization and the medical device organization. For example, ensuring that videoconferencing is functioning, and both the medical device organization and the auditor(s) are able to log-in; ensuring the web meetings invitations are sent with ample time to ensure each party involved in the remote audit are able to log-in; ensuring telephone conference lines are reserved, etc.;
- confirm the availability of appropriate workspace for the remote audit;
- confirm that the appropriate personnel from the medical device organization are available for the remote audit;
- confirm that documents pertaining to the audit of the DMAFR process are readily available;
- ensure that any time zone differences are considered;
- query the Regulatory Authority databases to determine the marketing status for the products within the scope of MDSAP certification

The above steps should be undertaken before the remote audit with sufficient time to resolve any technological issues prior to the planned remote audit start time.

Performing the Remote Audit

The remote audit of the DMAFR process must follow the MDSAP Audit Model tasks for the DMAFR process. The audit should be conducted in a manner that resembles an on-site audit as closely as possible.

Remote Auditing Pilot Program	Document No.: MDSAP AU P0036.001	Page 5 of 7
-------------------------------	-------------------------------------	-------------

Audit Trails and Linkages

The linkages from the DMAFR process involving management responsibility for establishing controls to ensure only devices that have received proper marketing authorization are marketed to the MDSAP jurisdictions and that design changes must be assessed for conformity to jurisdictional marketing requirements must be audited during the on-site portion of the MDSAP audit.

The combination of the audit of the tasks in the DMAFR process (MDSAP Audit Model, chapter 2) in conjunction with the on-site audit of the linkages to the Management and Design and Development processes from the DMAFR process will constitute the audit of the DMAFR process.

Audit Report

For the duration of this pilot program, the audit start date in section 1.0 of MDSAP AU F0019.1: *MDSAP Regulatory Audit Report Form*, will be the start date of the on-site portion of the audit. The date(s) of the remote portion of the audit should be recorded in form MDSAP AU F0019.1 in section 11.2 in the narrative section.

In situations where the site was audited entirely remotely (for example, an Australian Sponsor), the audit start date in section 1.0 of MDSAP AU F0019.1: *MDSAP Regulatory Audit Report Form*, will be the start date of the remote portion of the audit. Section 11.2 of form MDSAP AU F0019.1 must indicate that the DMAFR process was audited remotely in the narrative section.

When remote auditing is performed as part of this pilot program, the MDSAP audit report must indicate that the DMAFR process was audited remotely, the date(s) of the remote portion of the audit, the auditor(s) who conducted the remote audit, and the methods used. This information is in addition to the required elements as described in MDSAP AU P0019: *MDSAP Medical Device Regulatory Audit Reports*.

Any nonconformity detected during the remote audit shall be documented and graded in the same manner as if it was detected on-site. The form MDSAP AU F0019.2: *Nonconformity Grading and Exchange Form* shall include the nonconformities detected during both the remote and on-site portions of the audit and presented to the medical device organization's management at the close of the audit.

Remote Auditing Pilot Program	Document No.: MDSAP AU P0036.001	Page 6 of 7
-------------------------------	-------------------------------------	-------------

Certificate

Per IMDRF/MDSAP WG/N3 FINAL:2016 - Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition, paragraph 9.3.2 “The Auditing Organization shall audit all sites that will be recorded on the certificate. Any sites which are relevant to the manufacturer’s quality management system but audited **off-site**, should not be recorded on the certificate”. Therefore, any locations audited only as a remote audit under this pilot program, for example, an Australian Sponsor, should not be recorded on the certificate.

Surveys

During this pilot process, surveys will be available on the MDSAP website to the stakeholders (Auditing Organizations, medical device organizations) that have participated in this pilot. Completion of the surveys will assist the Regulatory Authorities in determining if remote auditing should continue and/or be expanded under the MDSAP.

Evaluation

At the conclusion of this pilot program, the Regulatory Authority MDSAP Subject Matter Expert team will evaluate the submitted surveys. In addition, a sample of at least three MDSAP audit reports that indicate remote audit techniques were utilized for the DMAFR process from each Auditing Organization will be selected for evaluation. The criteria for evaluation will include whether the requirements in this procedure were met in terms of documenting the remote portion of the audit (see the Planning and Audit Report headings of this procedure), and whether the requirements for the DMAFR process as detailed in MDSAP AU P0019: *MDSAP Medical Device Regulatory Audit Reports* were met.

If over 75% of the surveys indicate a positive experience with remote auditing, as evidenced by “strongly agree” or “agree” for the survey questions, and if over 75% of the MDSAP audit reports that indicate remote auditing techniques were used meet the requirements in this pilot program as well as MDSAP AU P0019, further development of remote auditing within the MDSAP will be considered by the Regulatory Authority MDSAP Subject Matter Expert team and Regulatory Authority Council.

6. Forms

MDSAP AU F0008.2: Audit Duration Calculation Form

MDSAP AU F0019.1: Medical Device Regulatory Audit Report

MDSAP AU F0019.2: NC Grading and Exchange Form

Remote Auditing Pilot Program	Document No.: MDSAP AU P0036.001	Page 7 of 7
-------------------------------	-------------------------------------	-------------

7. Reference Documents

GHTF/SG3/N19:2012 - Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange
IMDRF MDSAP WG/N3:2016: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition
ISO/IEC 17021-1:2015: Conformity assessment — Requirements for bodies providing audit and certification of management systems
MDSAP AU P0002 : Audit Model
MDSAP AU G0002.1: Companion Document
MDSAP AU P0008: MDSAP Audit Time Determination Procedure
MDSAP AU P0019: MDSAP Medical Device Regulatory Audit Reports
MDSAP AU P0027: Post-Audit Activities and Timeline Policy

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2020/01/13	Initial Release	CAPT Kimberly Lewandowski-Walker, US FDA

Version 001
Approval

Approved: ON FILE Date: 2020/01/10
CHAIR, MDSAP RAC