Table of Contents

1. PURPOSE

The purpose of this procedure is to define and document a voluntary pilot program for hybrid and remote audits of MDSAP processes and tasks as part of the audit of a medical device manufacturer.

2. SCOPE

This pilot program will allow for hybrid and remote audits to be conducted as part of the MDSAP audit and certification process. This approach may improve the flow of information between auditors and the audited medical device manufacturer when the two parties are not physically in the same location.

Stage 1 audits are outside the scope of this procedure. This pilot program will not replace Stage 1 audits, as defined in ISO 17021-1:2015: 9.3.1.2. Stage 1 audits may be performed as desktop audits, remote audits, or on-site audits as determined by the MDSAP Auditing Organization (AO) and in accordance with ISO 17021-1:2015.

This pilot program is not intended to address extraordinary events or circumstances affecting the ability to perform audits on-site (for example, natural disaster or pandemics). However, if an audit is affected by such extraordinary events or circumstances and can be performed according to this procedure, then this procedure could be applied to the audit.

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 Authority Council.

3. DEFINITIONS / ACRONYMS

APM: Assessment Program Manager

Remote Audit method: is an audit performed off-site using information and communication technology (ICT) and performed in real-time directly interacting with the auditee.

Hybrid Audit method: is an audit partially performed off-site using ICT while at least one auditor is on-site during a portion of the audit. The on-site and off-site portions must be performed either simultaneously (fully at the same time or with at least some overlap) or contiguously (one after the other with no major interruptions to the sequence).

On-site and Off-site: refers to the physical location of the Auditor.

Split Audit method: is an audit performed using either the remote or hybrid audit methods that stops for a period of time and then recommences to audit completion. This period time is greater than an overnight or weekend period.

4. AUTHORITIES/RESPONSIBILITIES

Auditing Organizations (AOs): 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 (RAs): responsible for evaluation of the MDSAP audit reports, surveys, and making recommendations for future changes in remote and hybrid audit methods upon completion of this pilot program.

5. PROCEDURES

5.1. Eligibility for remote or hybrid audit methods.

AOs may perform audits contrary to the requirements in this Pilot, however they must document the rationale for the decision, determine the risks and mitigate any unacceptable risks.

An audit may be eligible to be performed by remote audit or hybrid audit methods only if in compliance with the applicable criteria below:

5.1a. Categories of devices:

Remote audit methods may only be performed where the site to be audited is not performing any physical activities for the product realization of medical devices within the scope of the audit. Examples include Software as a Medical Device (SaMD) manufacturers or "virtual manufacturers" that outsource all activities related to medical device manufacturing and distribution.

Remote audit or hybrid audit methods are not to be used for the initial and recertification audits of medical device manufacturers that design and/or manufacture the following device types:

- Life-supporting or life-sustaining devices;
- Implantable devices;
- Devices that come into contact with the central cardiovascular system* or the central nervous system†;
- Devices that emit ionizing radiation and devices and software intended to monitor or control such devices;
- Devices that incorporate a drug or biologic constituent;
- Devices that incorporate human or animal tissues or their derivatives
- IVDs for the detection of cancer, infectious agents, or transfusion-transmitted diseases;
- IVDs for the detection of congenital disorders of the fetus;
- IVDs for blood grouping or tissue typing to ensure immunological compatibility;
- IVDs for near patient testing (point of care or self-test), excluding pregnancy and fertility tests

In order to optimize the access by an audit team to technical experts during the audit of manufacturers of high-risk devices, technical experts may join audit teams through ICT. Technical expert participation off-site cannot be considered in the audit time calculation for initial and recertification hybrid audits, even if they

are qualified auditors.

* The central cardiovascular system means the heart, pericardium, pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta (including ascending, arch, descending, thoracic and abdominal), inferior and superior vena cava, renal arteries, iliac arteries and femoral arteries.

† The central nervous system means the brain, meninges, spinal cord and cerebrospinal fluid.

5.1b. Type of audit:

Audit type	**Eligibility for remote audits (see 5.1a)**	**Eligibility for hybrid audits (see 5.1a)**
Initial Stage 2	No**	No**
Special	Yes*	Yes*
Unannounced	No (this can be performed as a hybrid audit)	Yes*
Surveillance	Yes*	Yes*
Recertification	No (unless at least 1 hybrid/on-site audit has been performed in the cycle)	Yes*

* If eligibility criteria in Cl 5.1 are met.
** Unless the site has been audited on-site in the past for another scheme, e.g., EU MDD/MDR and is in good standing.

5.1c. Processes and Tasks:

Some audit processes may not need to be audited on-site to determine the extent to which the requirements for the process have been fulfilled. MDSAP tasks that can be audited fully off-site include those where there is no physical process, and a review of associated documents can cover all requirements. For example, Management, or Device Marketing Authorization and Facility Registration, or Medical Device Adverse Events and Advisory Notices Reporting, or the planning and design input aspects of Design and Development, or Software Design and Development when the software is the product, or a combination of these processes.

Some processes should be audited on-site in hybrid audits. The MDSAP tasks listed below (where applicable) must be audited on-site by an MDSAP auditor or team that is suitably qualified and has the technical competence to assess these

processes:

- Design and Development
  - introduction of new equipment / capability to verify the environment for the verification and validation testing–design changes that may introduce new risks and how the testing demonstrated mitigation of that risk.

- Production
  - Tasks 1-6 which include references to planning, documentation, infrastructure and cleanliness
  - Task 9 if on-site sterilization, aseptic processing or sterilization processes that do not follow an established international standard are used
  - Tasks 10-11,13 related to monitoring and measuring production, equipment controls and calibration
  - Task 16 related to control of the master file for production activities
  - Task 17 control of production records
  - Task 18 controls on traceability related to implantable, life-supporting and life-sustaining devices
  - Task 19 controls for identification of product status
  - Task 20 regarding customer property
  - Tasks 22-23 related to handling of nonconforming product
  - Task 24 related to preservation of product
  - Task 26 and 27 if installation and servicing occur on-site
  - Task 28 related to risk control and mitigation

- Purchasing
  - Task 9 review of purchasing documents
  - Task 10 verification of inspection

5.1d Compliance Exclusions:

Where the last manufacturing site audit resulted in a 5-day Notice (refer to P0027), the use of hybrid and remote auditing methods are not permitted.

5.2. Planning and Limitations

The Auditing Organization (AO) and audited medical device manufacturer must agree to the use of remote or hybrid audit methods.

Off-site auditing using ICT is more suitable for a manufacturer that primarily relies on electronic documents and records. Although not prohibited, it is unlikely that using remote or hybrid audit methods will result in a fully effective audit if used with a manufacturer whose QMS documents and records are primarily paper based.

An AO should determine if remote and hybrid audit methods are suitable for use with respect to the context of the medical device manufacturer being audited. The following should be considered:

- the manufacturer's compliance history and information from post-market surveillance and vigilance activities,
- the outcomes of previous audits at the audited facility,
- the audit team's knowledge of the audited facility.

Audit times are to be calculated using MDSAP AU P0008 and MDSAP AU F0008.2.

This pilot program will not address the AO's billing practices, including any differences in billed amounts for on-site and off-site audit hours. The time of the off-site portion of the audit should align with the calculated time for the specific MDSAP process and tasks as described in MDSAP AU P0008.

The audit plan for the audit must indicate the following if off-site auditing with ICT will be used:

- a statement specifying which processes will be audited off-site as part of this pilot program and which will be audited on-site,
- the methods and technology to be used during the off-site audit (e.g., WebEx, Microsoft Teams),
- the identification of the auditor(s) who will conduct the offsite and on-site portions of the audit,
- the identification of the personnel from the medical device manufacturer organization who will participate in the off-site and on-site portions of the audit

Split audits, where the audit is interrupted by a period greater than 1 week are not permitted.

On-site audits that are planned to supplement the off-site audit should focus on

elements that cannot be effectively verified off-site, including aspects related to manufacturing, and any other infrastructure-dependent activities taking place at the audited facility (such as testing labs, incoming verification controls and warehouse storage controls).

All auditors, irrespective whether they are on-site or off-site must be sufficiently qualified in accordance with the AOs competence management requirements and IMDRF MDSAP WG/N4 and shall be selected during the audit planning phase.

The audit team members (technical experts, auditors, and lead auditors) must all meet the competence requirements defined in IMDRF MDSAP WG/N4.

The lead auditor must participate at both the opening and closing meetings regardless of whether they are held off-site or on-site.

5.3. Preparation for using hybrid and remote audit methods

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

- video-conferencing;
- web-based meeting systems with screen sharing capability (for example and in no particular order, Microsoft Teams, Zoom, WebEx, Adobe Connect;
- teleconferencing in conjunction with e-mail and file sharing tools;
- 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 manufacturer and the auditor(s). Technology enabling the auditor to take control of the navigation of the document should be preferred whenever available.

The following steps should be undertaken by the auditor(s) to prepare for off-site auditing:

- request information from the medical device manufacturer, to be submitted before the start of the off-site audit, if necessary.
- ensure that the technology for the off-site audit is agreed upon and tested by the Auditing Organization and the medical device manufacturer. For example:

  - ensuring that video-conferencing is functioning, and both the medical device manufacturer and the auditor(s) have relevant accounts established and are able to log-in,
  - ensuring the web meeting invitations are sent with ample time to ensure each party involved in the off-site portions of the audit are able to log-in,
  - ensuring telephone conference lines are reserved, etc.
- prepare a contingency plan for any communication failures
- have direct phone numbers of the relevant audit participants at hand during the audit
- ensure IT experts are available to both the manufacturer and the audit team for quick troubleshooting of any issues
- ask the manufacturer to have an on-site scanning support for paper documentation
- do a confirmation test in advance so that all persons involved in the audit are sufficiently aware of and have adequate command of the ICT being used to support the off-site auditing activities.
- confirm the availability of appropriate workspace for the off-site portions of the audit.
- confirm that the appropriate personnel from the medical device manufacturer are available for the off-site portions of the audit.
- confirm that documents pertaining to the audit of the processes that are to be audited off-site are readily available and may be readily exchanged, before, during and after the audit. E.g., within the video-conferencing software platform or via cloud-based storage.
  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.
- consider the ability of the technology to enable the use of translators or interpreters when necessary.

The above steps should be undertaken before the off-site portions of the audit with sufficient time to resolve any technological issues prior to the planned audit start time. Contingency steps should be planned for an event related to technical issues that would inhibit the performance of the audit. For example, if bandwidth limitations occur in a group meeting, the auditor may ask the attendees to turn off their cameras if not required for auditing. Methods to re-establish a lost connection should be discussed ahead of time. It may be useful to have a backup communication device readily available, and connection and contact information printed out, in the event of technical issues with the main device.

Some aspects of the audited activities can be reviewed by the audit team as part of a preliminary documentation review. A preliminary documentation review may be performed to improve the audit team's orientation and understanding of the

scope of the manufacturer's facility and its activities and allow better selection of samples during off-site auditing.

The preliminary documentation review is not considered part of the audit duration as per MDSAP AU P0008.

The reviewed documentation may include:

- the manufacturer's organization, activities and devices, highlighting any changes (such as the person responsible for regulatory compliance, processes and devices in the scope of certification)
- QMS procedures and documents, highlighting any substantial changes.
    - list of current QMS documents showing revision dates
- information about the audited facility, highlighting any substantial changes regarding:
    - floor plans, including production areas
    - process or product flow charts, including in-process controls and final release
    - processes or activities, including relevant information on critical subcontractors and newly approved suppliers
- list of recent design projects and changes, technical files, and technical documentation
- list of recent production activities (such as production orders, sales volumes, delivery records, installation, and service reports)
- lists of complaints, serious incidents, or adverse events, recalls and field safety actions, corrective actions, and preventive actions
- list of recent internal audits and management reviews

To allow for effective selection of samples during the audit, the manufacturer should make lists of design and development, production, distribution, installation and servicing activities available ahead of the audit. Ideally, the lists are in electronic format allowing searching and filtering (e.g., spreadsheet) and allow unambiguous identification of devices and processes (e.g., arranged by projects, orders, devices, batch, or serial numbers).

5.4. Performing the off-site and on-site portions of the audit

The MDSAP Audit Approach must be followed when using remote audit methods or hybrid audit methods. The audit should be conducted in a manner that follows the sequence and resembles an on-site audit as closely as possible. When using the hybrid audit method, if the off-site portion is not being performed simultaneously to the on-site portion, the off-site portion should be performed first

to provide the greatest opportunity to follow audit trails (linkages).

When using hybrid audit methods, the on-site audit time should be at least 50% of the calculated audit time. A minimum of 25% is allowed, however the AO must document a justification if the on-site audit time is between 25% and 50% of the calculated audit time.

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, cl 9.4.5, IMDRF MDSAP WG/N3:2016, and MDSAP AU P0027.

5.5. Audit Report

The audit start date in section 1.0 of MDSAP AU F0019.1: Medical Device Regulatory Audit Report Form, will be the date the opening meeting commences (regardless of whether this is performed on-site or off-site). The date(s) of the on-site and off-site portions of the audit should be recorded in form MDSAP AU F0019.1 in section 13; if they deviate from the audit plan.

MDSAP audit reports and NGE forms are to be issued as per normal for audits conducted using remote or hybrid audit methods. The audit report shall clearly identify in section 3 (Audit type “Specify” field) that “the audit was performed using alternative audit arrangements” and specify the method used (i.e. remote or hybrid). As applicable, section 13 of the audit report shall mention as an obstacle any technical difficulties encountered during the audit leading to delays or difficult communication. As necessary, section 16 (“Factors encountered that may affect the Audit Reliability” field) shall mention aspects of the audit that did not yield an equivalent level of confidence in the conclusions as an on-site audit would have.

Any nonconformity detected during the off-site auditing 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 off-site and on-site portions of the audit and presented to the medical device manufacturer’s management at the close of the audit.

5.6. Certificate

Sites audited using a remote audit method can be listed on the certificate on the condition that the requirements in Cl 5.1b above are met (i.e. at least 1 audit is on-site or hybrid per audit cycle).

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.

5.7. Evaluation

At the conclusion of this pilot program a sample of audits performed using hybrid and remote audit methods from each Auditing Organization will be selected for evaluation. The APMs will choose witness assessments that review the eligibility criteria listed above, including the use of remote audit methods and auditing high risk device manufacturing sites using hybrid methods. The criteria for evaluation will include whether the requirements in this procedure were met in terms of documenting the off-site portion of the audit (see the Planning and Audit Report headings of this procedure), and whether the requirements for the reporting of the audit of the MDSAP processes and tasks as detailed in MDSAP AU P0019: MDSAP Medical Device Regulatory Audit Reports were met. Additional evaluation criteria may include the impact on audit package submission timelines, feedback from the AO’s, feedback from other stakeholders (for example Manufacturers, Observers and Affiliate Members) and an analysis of nonconformities identified by MDSAP task for each audit type.

Further development of remote auditing and/or expansion of hybrid auditing within the MDSAP will be considered by the Regulatory Authority MDSAP Subject Matter Expert team and Regulatory Authority Council upon review of the sample of hybrid and remote audits reports as detailed above.

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

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
IMDRF MDSAP WG/N4:2021: Competence and Training Requirements for Auditing Organizations
ISO/IEC 17021-1:2015: Conformity assessment — Requirements for bodies providing audit and certification of management systems
MDSAP AU P0002: Audit Approach
MDSAP AU P0008: Audit Time Determination Procedure
MDSAP AU P0019: MDSAP Medical Device Regulatory Audit Reports
MDSAP AU P0027: Post-Audit Activities and Timeline Policy
MDSAP AU P0037: Guidelines on the use of Quality management system-Medical devices – Nonconformity Grading System for regulatory Purposes and Information Exchange (GHTF/SG3/N19:2012) for MDSAP purposes

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
002	2023/03/02	Major update to describe remote and hybrid audit methods and eligibility criteria	Andrew Bathgate, TGA

Version Approval 002

Approved: ON FILE Date: 2023-03-06
CHAIR, MDSAP RAC