

MDSAP Transmittal Number: 2020-07
[Superseding MDSAP Transmittal Number 2020-05]

Transmittal Date: 2020/06/03

Title: Extension and Expansion of Temporary extraordinary measures related to MDSAP audits during covid-19 quarantine orders and travel restrictions – Remote audits

Purpose: The spread of Covid-19 globally has resulted in the imposition of quarantine orders and travel restrictions that are affecting the ability of AOs to perform MDSAP audits. This document extends and expands the interim extraordinary measures to address challenges posed by this ongoing situation. The use of these measures is strictly limited to this purpose and cannot be used in any other context. On-site audits can only be substituted with remote audits where travel restrictions or social/physical distancing as result of the pandemic prevent on site audits from occurring.

Definitions

Remote audit: audit performed off-site through the use of information and communication technology. [Synonyms: eAudit, virtual audit]

Interim Extraordinary Measures

A. GENERAL

1. AOs are to identify affected facilities at which timely surveillance and recertification audits cannot be completed in accordance with the audit program.
2. For each facility identified in 1 above, AOs are to:
 - a. Obtain information about the status of the facility, its operations, and quality management system;
 - b. Evaluate the past conformity of the facility;
 - c. Evaluate the possibility of performing a remote audit of the facility in accordance with Section C below;
 - d. Evaluate the risk of maintaining or renewing certification in the absence of an onsite audit; and,
 - e. Establish a plan for resuming regular oversight activities.
3. AOs shall keep records in relation to items 1 and 2 above, as well as of all remote audits performed.
4. AOs shall provide copies of policies, procedures and work instructions for the performance of remote audits to their respective APM prior to implementation. APMs may provide feedback, as warranted, but will not otherwise approve these documents prior to use.
5. The interim extraordinary performance of remote audits shall be limited to Surveillance, recertification audits, significant change audits without any extension of the scope of certification, and transfers between AOs. Initial Stage 2, special, and unannounced audits cannot be performed off-site under these measures.

RAs are considering the possibility of allowing remote audits for a restricted subset of initial Stage 2 audits as they gain experience and confidence in remote auditing practices. No commitment in this regard is made at this point.

6. RAs reserve the right to witness remote audits. To facilitate this, AOs are to provide their respective APM with advance notice of planned remote audits.

B. ELIGIBILITY FOR REMOTE AUDITS

1. Facilities with a good record of conformity may have their surveillance or recertification audits substituted with a remote audit in accordance with Section D below.
2. Facilities with a good record of conformity may undergo remote audits to address changes or transfers between AOs in accordance with Section C below.
3. The following facilities may not have their surveillance or recertification audit substituted with a remote audit:
 - Facilities that require an on-site visit to verify the implementation of corrective actions;
 - Facilities in need of an extraordinary or unannounced audit; or,
 - Facilities with a high number of nonconformities suggesting a lack of operational control.

AOs are to consider suspension of certification as appropriate.

RAs endeavor to apply discretion, as warranted and within their respective jurisdictions, with respect to marketing authorizations supported by certification documents suspended or lapsed because of missed or delayed audits related to quarantine orders and travel restrictions issued in response to the spread of Covid-19.

4. Certifications renewed with a remote audit will have a validity period not to exceed twelve (12) months and be subject to subsequent on-site verification as soon as possible. This extension of the validity of certifications renewed remotely is applicable retroactively to certificates renewed remotely in accordance with Transmittal 2020-05.

AOs are to provide updated information on certifications renewed remotely and the planned dates for on-site verification to their respective APM periodically.

5. Remote audits may not be used to add new facilities to the scope of a certification.

C. ELIGIBILITY FOR REMOTE AUDITS TO ADDRESS CHANGES OR TRANSFER BETWEEN AOs

1. The following table outlines the types of changes that can be addressed through remote audits and any applicable conditions or limitations if the facility is eligible in accordance with B.3 above:

Type of change	Eligibility
Addition of an activity	Generally yes if the activity can be successfully audited remotely.

	Activities that are administrative or documentary in nature (e.g. design controls) are eligible for remote audits.
Addition of a medical device	Permitted if the device represents a similar risk profile as existing devices in the scope and uses existing production technologies and facilities.
Addition of a facility	No. IMDRF N3 explicitly forbids the inclusion of a facility that has not been audited on site on a certificate.
Addition of a regulation	Yes
Expansion of a facility	Generally yes if the expansion is for the existing production environment and technology and does not involve an additional site or facility.
Change in name or ownership	Yes
Change in critical supplier	Yes, if the change does not require an audit of the supplier

2. Remote audits can be used to transfer facilities between AOs if all the following conditions are met:
 - a. The certification of the facility is in good standing and is still within its validity period;
 - b. The facility has a good history of conformity;
 - c. The facility does not require an on-site audit to verify the implementation of corrective actions;
 - d. The transfer of certification does not expand the scope of certification or add facilities; and,
 - e. All relevant audits reports and nonconformities going back to the last certification or recertification audit are available and reviewed.

AOs are to provide updated information on certifications transferred remotely to their respective APM periodically.

D. REQUIREMENTS FOR REMOTE AUDITS

1. AOs are to establish policies and procedures for the performance of remote audits.
2. These procedures will define the requirements for technology or tools required for the performance of such remote audits as well as the documentation to be prepared (e.g. audit plan, audit report, NGE form, etc.)
3. Procedures for remote audits are to consider the need to adjust the duration of the audit in accordance with the effectiveness of the technology employed and proficiency of the audit team and facility in employing this technology.
4. Remote audits shall result in the issuance of MDSAP audit reports and NGE forms as per normal MDSAP audits. The audit report shall clearly identify in section 3 (Audit type "Specify" field) that "the audit was performed remotely". As applicable, section 13 of the audit report shall mention as obstacle any technical difficulties encountered during the remote audit leading in delays or difficult

communication. As necessary, section 16 ("Factors encountered that may affect the Audit Reliability" field) shall mention aspects of the remote audit that did not yield an equivalent level of confidence in the conclusions as an on-site audit would have. Audit report packages uploaded to REPs will include a comment that the audit was performed remotely or virtually.

5. AO shall add a note in the corresponding node of an audit report package submitted in REPs to specify that "the audit was performed remotely".
6. Prior to undertaking a remote audit, the AO shall verify the technological capability of the facility to ensure that such an audit can be accomplished.
7. When planning a remote SURVEILLANCE audit, the AO shall include in the audit plan all mandatory surveillance elements as listed in the MDSAP Audit Model (MDSAP AU P0002.4). Mandatory elements that cannot be verified during the remote or virtual audit shall be listed in section 14 of the audit report as deviations to the plan and added to the next on-site audit with the addition of a commensurate amount of on-site audit time.
8. Beyond the mandatory elements in 7. above, remote SURVEILLANCE audits will primarily focus on activities that can be verified remotely.
9. Following each remote audit, the AO shall adjust the audit program for the facility to ensure that all required oversight is completed during the certification cycle. Audit duration adjustments and, potentially, extraordinary audits may be necessary to accomplish this.
10. Remote RECERTIFICATION audits will cover all the mandatory recertification tasks of the MDSAP Audit Model that can be verified remotely.
11. Any certification renewed using a remote audit will have a validity not to exceed twelve (12) months from the expiry date of the prior certificate.
12. All remote RECERTIFICATION audits will be followed by an on-site verification audit as soon as possible to confirm the conclusion of the remote audit and to perform tasks that could not be completed during the remote audit.
13. Following a successful verification of the RECERTIFICATION, the AO may issue a certificate with a maximum validity period of three (3) years calculated from the expiry date of the prior certificate.
14. However, if an on-site verification audit cannot be performed within twelve (12) months or if the verification of the recertification is unsuccessful, the certification shall be suspended.

E. COMING INTO FORCE AND DURATION OF INTERIM MEASURES

1. These interim measures come into force on the day of this transmittal.
2. These interim measures will remain in effect until 2020/12/31 unless otherwise rescinded.

Additional guidance contained in the IAF document [IAF ID3:2011](#) may be considered by AOs, with the exception of any guidance which contradicts this transmittal.

AOs are encouraged to contact their assigned APM to discuss any situation not addressed in this transmittal.

Approver: Frederic HAMELIN

Effective Date: 2020/06/XX

Distribution: AOs

Action Requested: Apply interim measures as necessary

Location of Documents: TGA Connections (restricted access)

Issued by: MDSAP APMs