

MDSAP Transmittal Number: 2020-05
[Superseding MDSAP Transmittal Number: 2020-04]

Transmittal Date: 2020/03/24

Title: Temporary extraordinary measures related to MDSAP audits during COVID-19 quarantine orders and travel restrictions – Remote audits (Revised on 2020/03/24 to clarify item C4 to be section 13 of the MDSAP Audit Report regarding obstacles; and item C11 to be the expiry date of the prior certificate).

Purpose: The global spread of COVID-19 has resulted in the imposition of quarantine orders and travel restrictions that are affecting the ability of AOs to perform MDSAP audits. This document proposes interim extraordinary measures to address the challenges posed by this specific situation. These measures cannot be used in any other context.

Definition

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 and recertification audits, without any extension of the scope of certification. Initial Stage 2, special, and unannounced audits cannot be performed off-site under these measures.
6. RAs reserve the right to witness remote audits. To facilitate this, AOs are to provide their respective APMs 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 C below.
2. 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.

3. Certifications renewed with a remote audit will have a validity period not to exceed six (6) months and be subject to subsequent on-site verification before expiry of the renewed certificate.
4. Remote audits may not be used to expand the scope of certification of a facility or to add new facilities to the scope of a certification.

C. REQUIREMENTS FOR REMOTE SURVEILLANCE OR RECERTIFICATION AUDITS

1. AOs are to establish policies and procedures for the performance of remote audits.
2. These procedures will define the requirements for information and communication technologies 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.

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 six (6) months from the expiry date of the prior certificate.
12. All remote RECERTIFICATION audits will be followed by an on-site verification audit within six (6) months 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 six (6) months or if the verification of the recertification is unsuccessful, the certification shall be suspended.

D. 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 for a period not to exceed ninety (90) days from the date of this transmittal.

Additional guidance contained in the IAF documents [IAF ID3:2011](#) and IAF MD4:2018 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: 2020/03/24

Distribution: AOs

Action Requested: Apply interim measures as necessary

Location of Documents: TGA Connections (restricted access)

Issued by: MDSAP APMs