

MDSAP Transmittal Number: AO 2020-10
[Superseding MDSAP Transmittal Number 2020-07]

Transmittal Date: 2020/12/31

Title: Further Extension and Expansion of Temporary Extraordinary Measures related to MDSAP audits during covid-19 quarantine orders and travel restrictions – alternative audit arrangements

Purpose: The spread of Covid-19 globally has resulted in the imposition of quarantine orders, travel restrictions and other sanitary measures that are affecting the ability of AOs to perform MDSAP audits on site. This document further 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. On-site audits may be substituted with alternative audit arrangements only where travel restrictions and social/physical distancing as result of the pandemic prevent on-site audits from occurring.

Definitions

Desktop Audit: audit performed remotely by reviewing documentation.

Remote audit: audit performed off-site using information and communication technology (ICT.)

Hybrid audit: audit partially performed off-site using ICT while at least one MDSAP qualified auditor is simultaneously on-site during a portion of the audit.

Surrogate Audit: audit partially performed off-site using ICT while at least one non-MDSAP qualified auditor is simultaneously on-site during a portion of the audit.

Abbreviation

AO: Auditing Organization

RA: Regulatory Authority

APM: Assessment Program Manager (RA individual responsible for the assessment program of the AO)

ICT: information and Communication Technology

Interim Extraordinary Measures

A. IDENTIFICATION AND EVALUATION OF AFFECTED FACILITIES

1. AOs are to identify affected facilities at which timely on-site 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 applying alternative audit arrangements to the facility in accordance with Section C below;
 - d. Evaluate the risk of maintaining or renewing certification using alternative audit arrangements; and,
 - e. Establish a plan for resuming regular on-site 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 will make the records in relation to items 1 and 2 above available to RAs upon request.
5. AOs shall provide copies of policies, procedures and work instructions for the performance of alternative audit arrangements to their respective APM prior to implementation. APMs may provide feedback, as warranted, but will not otherwise approve these documents prior to use.
6. RAs reserve the right to witness audits performed using alternative audit arrangements. To facilitate this, AOs are to provide their respective APM with advance notice of such planned audits.

B. ELIGIBILITY FOR ALTERNATIVE AUDIT ARRANGEMENTS

1. The eligibility of a facility for alternative audit arrangements will be determined based on a risk assessment using the tables in Section H and the corresponding matrix in Section G.
2. It is not permitted to apply an alternative audit arrangement that uses ICT where the facility previously underwent a remote audit that was deemed not effective or where the facility was unable to apply the appropriate ICT.
3. In situations where a facility is ineligible for alternative audit arrangements and an on-site audit cannot be performed, AOs are to consider suspension or withdrawal 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. Certificates renewed in 2020 through a remote audit may have their validity extended for a further 12 months if on-site verification is not possible subject to ongoing surveillance using appropriate alternative audit arrangements.

C. GENERAL REQUIREMENTS FOR ALTERNATIVE AUDIT ARRANGEMENTS

1. AOs are to establish policies and procedures for the performance of alternative audit arrangements.
2. These procedures will define the requirements for technology or tools required for the performance of such audits as well as the documentation to be prepared (e.g. audit plan, audit report, NGE form, etc.)

3. Procedures for alternative audit arrangements are to consider the need to adjust the duration of the audit in accordance with the effectiveness of the technology and methodology employed and proficiency of the audit team and facility in employing this technology and approach.
4. Audits performed using alternative audit arrangements 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 using alternative audit arrangements" and specify the method used (i.e remote, hybrid, surrogate, etc.) As applicable, section 13 of the audit report shall mention as obstacle any technical difficulties encountered during the 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 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 using alternative audit arrangements.
5. AOs shall add a note in the corresponding node of an audit report package submitted in REPs specifying that "the audit was performed using alternative audit arrangements."
6. Prior to undertaking an audit using ICT, the AO shall verify the technological capability of the facility to ensure that such an audit can be accomplished.
7. When planning a SURVEILLANCE audit using alternative audit arrangements, 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 remotely shall be verified on-site (if applicable) and 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 audit performed using alternative audit arrangements, 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. The audit plan for any RECERTIFICATION audit shall cover all applicable audit tasks. Any deviation to the plan, including the partial or ineffective completion of those applicable audit tasks due to the use of alternative audit arrangements, shall be recorded in section 14 of the audit report.
11. If, following a RECERTIFICATION audit using alternative audit arrangements, this audit only partially covered the applicable audit tasks, or doubts about the effectiveness of the audit exist, and the outcome of the audit nonetheless enables the AO to renew the certification, then the renewed certification will have a validity period not to exceed twelve (12) months following the expiry date of the prior certificate.
12. Following a RECERTIFICATION meeting the conditions in C.11, the AO must perform an on-site, hybrid or surrogate [as appropriate considering the risks per

G.3] special audit or surveillance audit to assess those aspects of the QMS that the RECERTIFICATION audit did not reliably assess. As a result of favorable outcomes of that audit, the AO may issue a certificate with a maximum validity period of three (3) years calculated from the expiry date of the prior certificate.

D. PARTICULAR REQUIREMENTS FOR HYBRID AND SURROGATE AUDITS

1. The on-site portion of a hybrid or surrogate audit is to occur simultaneously with the remote portion of the audit, but can be of shorter duration than the remote portion.
2. During a hybrid or surrogate audit, the on-site portion should focus on aspects related to the production activities taking place at the audited facility, and other elements that cannot be effectively verified remotely, as well as audit trails identified by the remote auditors.
3. To be eligible as a surrogate auditor, an individual must commit to the MDSAP code of conduct, respect all criteria necessary to preserve the impartiality of the AO, and be proficient with the use of ICT in the context of an audit.
4. Preference is given to qualified ISO 13485 auditors as surrogate auditors. AOs may use individuals with alternative equivalent competence (e.g. facility inspectors competent in the technology and products in question) with appropriate documented justification.
5. The surrogate auditor should have the technical competence required to audit the facility in question with respect to the devices and technologies employed.
6. During a surrogate audit, the surrogate auditor acts as the “eyes and ears” of the remote audit team using ICT. Depending on the audit plan, it may be necessary or desirable to deploy more than one surrogate auditor. It is not permitted to use more surrogate auditors than remote MDSAP qualified auditors in the team.
7. When a surrogate auditor is acting as the “eyes and ears” for a remote auditor, the surrogate auditor does not contribute to the calculation of audit duration (e.g. the surrogate auditor’s time does not count towards the calculation of audit duration.)
8. In situations where the surrogate auditor is a duly qualified technical expert AND auditor that is also auditing activities within his/her scope of expertise (e.g. a medical microbiologist evaluating aseptic processing), the time the surrogate auditor dedicates to the audit of those activities in his/her field of expertise may count towards the determination of total audit duration for those audit activities.

E. REPORTING REQUIREMENTS FOR AUDITS IN PARTS OR SPLIT AUDITS

1. AOs are to avoid splitting audits into separate activities whenever possible. If this is inevitable due to unforeseen circumstances, the following requirements should be used in preparing MDSAP audit reports.
2. Where a planned audit activity is separated into parts, it is permitted to issue a single audit report if the following conditions are met:
 - a. the report submission due date is based on the dates of the first part of the audit activity
 - b. no 5-day report is required at the conclusion of the first part

- c. an NGE is issued at the conclusion of the first part and nonconformity response timelines are respected
 - d. the second audit activity is performed within 1 month of the completion of the first audit activity
3. Where an audit activity split into parts cannot be reported in a single audit report, the AO shall provide two separate audit reports with the second audit report a compilation of both audits.
 4. When a certification decision is to be supported by an audit performed in parts, that certification decision shall be made taking into account the outcome of all parts of the split audit.

F. ACCOUNTING FOR RESIDUAL TIME

1. In situations where a surveillance audit performed with alternative audit arrangements resulted in outstanding items to be verified at the next audit as described in C.7 above, and the duration of the audit was not in accordance with P0008, the AO may opt to:
 - a. Perform a regular on-site recertification audit in accordance with program requirements where the previous audit was a second surveillance audit
 - b. Perform an on-site early recertification audit in accordance with program requirements where the previous audit was a first surveillance audit and the combined duration of the second surveillance audit and the residual items from the first surveillance audit are equal to or greater than the duration of a recertification audit.

G. ALTERNATIVE AUDIT ARRANGEMENTS

1. AOs are afforded a range of alternative options to on-site audits where on-site audits cannot be performed
2. AOs are to select the option with the highest level of reliability and scrutiny possible. In order of decreasing reliability, these are:
 - On-site audit
 - Hybrid audit
 - Surrogate audit
 - Remote audit
 - Desktop audit
3. AOs are to use the risk classification in section H to identify the appropriate minimum permissible alternative audit arrangement using the following table:

Audit Type	Low risk	Medium risk	High Risk
Stage 1	Remote	Remote	Remote
Stage 2	Remote	Remote	Hybrid
Surveillance (following on-site audit)	Remote	Remote	Hybrid
Surveillance (following remote audit)	Remote	<ul style="list-style-type: none"> • Surrogate or better (if previous audit) 	Hybrid

		<p>was remote recertification without an on-site follow-up)</p> <ul style="list-style-type: none"> • Remote (if previous audit was a surveillance) 	
Recertification (following on-site surveillance audit)	Remote	Remote	Hybrid
Recertification (following remote surveillance audit)	Remote	Surrogate	Hybrid
Recertification follow-up after remote-only recertification	Remote	Surrogate	Hybrid
Follow-up audits (to close NCs)	Desktop	Surrogate	Hybrid
Unannounced audits	Remote	Surrogate	Hybrid
Transfers	Remote	Remote	Hybrid
Scope changes (adding regulations, products, etc.) and significant changes	Desktop	Remote	Surrogate
Moves/relocations/facility expansion/facility addition	Remote	Surrogate	Hybrid

H. RISK CLASSIFICATION

1. To use the table in section G, AOs are to classify the planned activity according to the audit type, the facility's compliance history, the medical devices produced, and the technologies employed at the facility.
2. In the context of this risk classification, the concept of a lower risk medical device is employed as follows:

Lower risk medical device:

- a. Generally speaking, lower risk medical devices are identifiable by their lower risk classification as part of marketing authorisation. For example:
 - i. Australia: Class I, Im and Is (except sterilised in-house) and IIa
 - ii. Brazil: Class 2
 - iii. Canada: Class 2
 - iv. Japan: Class 2
 - v. US: Class 1 and some Class 2
- b. For greater clarity, lower risk medical devices are generally designed and manufactured using simple processes

- c. For greater clarity, the following devices, regardless of their regulatory risk class, are excluded from the definition of lower risk medical device:
- i. Life-supporting or life-sustaining devices;
 - ii. Implantable devices;
 - iii. Devices that come into contact with the central cardiovascular system* or the central nervous system†;
 - iv. Devices that emit ionizing radiation and devices and software intended to monitor or control such devices;
 - v. Devices that incorporate a drug or biologic constituent;
 - vi. Devices that incorporate human or animal tissues or their derivatives
 - vii. IVDs for the detection of cancer, infectious agents, or transfusion transmitted diseases;
 - viii. IVDs for the detection of congenital disorders of the fetus;
 - ix. IVDs for blood grouping or tissue typing to ensure immunological compatibility;
 - x. IVDs for near patient testing (point of care or self-test), excluding pregnancy and fertility tests
 - xi. Sterilization processes that do not follow an established international standard;
 - xii. Aseptic processing; and,
 - xiii. Sterilization processes performed in-house.

* 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.

3. AOs are to use the following tables to classify the risk of the proposed activity.

	Low	Medium	High
Stage 1	All stage 1 audits are eligible for remote auditing. Risk classification is therefore not applicable		

	Low	Medium	High
Stage 2	<ul style="list-style-type: none"> • Manufacturers of SaMD • Virtual manufacturers that do not take 	Manufacturers that do not fall within the low risk category but have an existing regulatory certification (e.g. MDD,	Manufacturers falling outside of the low and medium risk categories must have an on-site initial audit

	<p>possession of the product</p> <ul style="list-style-type: none"> • Virtual manufacturers that do not perform any activity on the product and where no special storage conditions are needed • Manufacturers of lower risk medical devices with an existing ISO 13485 certified QMS 	MDR, IVDR) in good standing with the AO	
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	Low	Medium	High
<p>Surveillance following an on-site audit</p> <p>And</p> <p>Recertification following an on-site audit</p>	Manufacturers falling outside of the high risk classification are eligible for a remote audit		<ul style="list-style-type: none"> • Manufacturers with a 5-day notice during the previous audit • Manufacturers where the previous audit indicated safety risks • Manufacturers where the previous audit indicated that nonconforming product had been released • Manufacturers with a history of a high number of nonconformities suggesting a lack of operational control

	Low	Medium	High
<p>Surveillance following a remote audit</p> <p>And</p> <p>Recertification following a remote audit</p>	<ul style="list-style-type: none"> • Manufacturers that meet all the following conditions: <ul style="list-style-type: none"> ○ The previous remote audit was successfully completed (no 	<ul style="list-style-type: none"> • Manufacturers that meet all the following conditions: <ul style="list-style-type: none"> ○ The previous remote audit was successfully completed (no 	<ul style="list-style-type: none"> • Manufacturers with a 5-day notice during the previous audit • Manufacturers where the previous audit indicated safety risks

<p>And</p> <p>Recertification follow-up after a remote recertification</p>	<p>obstacles)</p> <ul style="list-style-type: none"> ○ No or few nonconformities during previous audit (not grade 4 or 5) ○ Good evidence of ongoing operational control ○ No controlled environments ○ Lower risk medical devices 	<p>obstacles)</p> <ul style="list-style-type: none"> ○ No grade 4 or 5 nonconformities during previous audit ● On-site activities should focus on production activities 	<ul style="list-style-type: none"> ● Manufacturers where the previous audit indicated that nonconforming product had been released ● Manufacturers with a history of a high number of nonconformities suggesting a lack of operational control ● Manufacturers for which the previous remote audit could not be effectively performed
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	<p>Low</p> <ul style="list-style-type: none"> ○ Nonconformities of an administrative or documentary nature (i.e. not involving production activities) ○ Nonconformities that do not suggest a safety risk or the release of nonconforming products 	<p>Medium</p> <ul style="list-style-type: none"> ○ No grade 5 nonconformities ○ No safety risk ○ No release of nonconforming product ○ Number and severity of nonconformities do not suggest a lack of operational control ○ On-site activities should focus on production activities 	<p>High</p> <ul style="list-style-type: none"> ○ All other situations
<p>Follow-up audits to close NCs</p> <p>and</p> <p>unannounced audits</p>			

	<p>Low</p> <ul style="list-style-type: none"> ○ Situations not covered under the high risk category are eligible for remote transfer audits where judged necessary by the AO 	<p>Medium</p>	<p>High</p> <ul style="list-style-type: none"> ○ Transfers with scope changes ○ Transfers where the previous audit reports are not available ○ Transfers where the previous audit included: <ul style="list-style-type: none"> ○ Grade 4 or 5 nonconformities that were not closed by the previous AO ○ A high number of
<p>Transfers</p>			

		<p>nonconformities suggesting a lack of operational control</p> <ul style="list-style-type: none"> ○ Nonconformities that suggest safety risks or the release of nonconforming products
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	Low	Medium	High
<p>Scope changes (adding regulations, products, etc.)</p> <p>And Significant changes</p>	<p>For example:</p> <ul style="list-style-type: none"> ○ Addition of a jurisdiction for a manufacturer with a good history of compliance/conformity ○ Changes in key personnel ○ Changes in key suppliers ○ Changes in ownership 	<p>For example:</p> <ul style="list-style-type: none"> ○ Addition of a product category using existing production technologies/processes for manufacturers with a good history of compliance/conformity and good design controls (including design transfer activities) 	<p>For example:</p> <ul style="list-style-type: none"> ○ Addition of a product requiring new production technologies/processes ○ Addition of a product that incorporates pharmaceuticals, biologics, products of animal origin, or CTOs and their derivatives ○ Addition of a product that requires a new controlled environment

	Low	Medium	High
Moves/relocations/facility expansion/facility addition	<ul style="list-style-type: none"> ○ Expansions of non-production areas ○ Moves/relocations/facility additions where the activities occurring do not directly involve physical products (e.g. admin, RA, design, software, etc.) ○ Moves/relocations/facility additions of storage and distribution facilities without special storage environments ○ Manufacturer of SaMD 	<ul style="list-style-type: none"> ○ Moves/relocations/facility expansions and facility addition of production areas not involving controlled environments or new production/process technologies ○ /relocations/facility expansion or addition of 	<ul style="list-style-type: none"> ○ Moves/relocations/facility expansions and additions involving controlled environments or the introduction of new production/process technologies

	<ul style="list-style-type: none"> ○ Virtual manufacturer that do not take possession of the product ○ Virtual manufacturers that do not perform any activity on the product and where no special storage conditions are needed 	<ul style="list-style-type: none"> ○ Duplication of existing production lines 	<ul style="list-style-type: none"> storage and distribution facilities with special storage environments
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I. 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 2021/06/30 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: 2020/12/31

Distribution: AOs

Action Requested: Apply interim measures as necessary

Location of Documents: TGA Connections (restricted access)

Issued by: MDSAP APMs