Remote auditing for QMS registration to ISO 13485

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Executive summary

During the pandemic, the world has had to adapt regular routines in many ways. Auditing medical device manufacturers' quality management systems (QMSs) to ISO 13485:2016, as well as the Medical Device Single Audit Programs (MDSAP), has been no different.

Due to travel restrictions and risks associated with COVID-19 transmission, registrars have had to change their normal practices for on-site audits. This has brought with it an increase in the use of remote audits. This option supports our customers by minimizing the risk of visitors introducing the virus to their sites while maintaining compliance with regulations by continuing their audit program.

This paper will inform you about:

- Your options for on-site and remote auditing, and situations where an on-site audit is still required
- What IT systems will be required for a remote audit
- The impact of the remote audit
- How to best prepare for the remote audit

On-site versus remote auditing

Remote audits have historically been used less commonly than on-site audits because they have been seen as less effective than having an auditor present at the manufacturing facility. However, due to the coronavirus pandemic, many registrars have utilized the contingency planning procedures available to justify remote audits.

Both UL and the manufacturer must agree to the use of a remote audit. In some cases, a fully remote audit will not be possible due to significant changes to the manufacturing site or certificate scope changes. Other times, the manufacturer may not have the communication facilities needed to support it. In these cases, conducting part of the audit remotely may be possible with some aspects conducted on-site. The on-site part may be conducted simultaneously with the main audit, or it may be delayed until later in the year. For multipath audits, some may conduct it remotely while an auditor is on-site for some aspects. These specific arrangements require some discussion with the audit team to organize the best solutions.

Remote auditing can be used only in certain situations and can also be used in combination with part on-site and part remote audits.

- ✓ Remote surveillance audits
- ✓ New certification/renew expiring certification*
- ✗ Significant change to QMS
- ✓ Remote audit/on-site production audit**

** On successful completion of audit certificate is valid for one year. The next audit that will be classified as a surveillance audit must be scheduled no more than 10 months from the remote audit.*

*** Used where video technology cannot support remote audit of production. On-site production completed within six6 months of remote audit.*

IT systems

Remote audit/on-site production audit requirements

Remote audits are conducted using common, real-time communication tools. Some of the other requirements include:

- Ability to access conferencing software such as Microsoft Teams
- Internet bandwidth of 7.5 Mbps minimum
- Access to UL's File Transfer Protocol (FTP) site or an equivalent file transfer site
- Video recording and storage – tour of manufacturing areas for production (options for when video recording devices are not available are discussed below)

UL strongly suggests the use of Microsoft Teams, but the manufacturer's preferred platform may be used if it meets UL's remote auditing security requirements. Experience has shown that internet bandwidth speeds as low as 7.5 Mbps still allow for effective communication, although video communication may be limited.

UL utilizes an FTP site that allows secure file transfers that are too large to transfer by email (greater than 10 MB). The use of the interface is via the internet and transfer of files if via a drag-and-drop interface. Prior to the audit, the auditor will send an email with a link to the UL FTP site. The link will direct you to a login page if you already have an account on UL's client portal, MyUL®, or a new page to generate a password. Other platforms for transferring larger files are available; if you prefer to use a different platform, please discuss with your auditor prior to the audit.

While much of the audit can be conducted from an office using documentation as evidence, production audits do require the auditor to view the manufacturing areas. This can be achieved by using video technology (mobile phones, tablets, etc.). Viewing does have to be real-time, therefore the communication app needs to be present on the video device so the auditor can view and communicate while the video is being recorded. The remote production audit should be recorded and retained for a minimum of one year. If video recordings of the production areas will be used during the audit, test the connection within all production areas that may be toured. Connection black spots within the production areas can cause communication dropout, leading to delays during the audit.

If video recordings of production is not possible, the remaining parts of the audit can be conducted remotely. The on-site audit for production must be completed within six months of the remote audit. Please contact your UL representative to discuss the best options if you are unable to support video communication.

Impact to remote audits

A remote audit generally lasts an extra half day compared to on-site. The manufacturer's quality management system (MQMS) audit fee is adjusted, but as there are no travel time fees and expenses, the cost to the manufacturer is negligible.

Generally, auditors will organize a remote meeting prior to the audit to help ensure that:

- The communication platforms are functioning as expected
- All parties understand how information will be transferred between them, including test file transfers
- Video recording hardware has been confirmed
- All parties agree on the format of the audit

This meeting generally lasts less than 30 minutes.

Currently, time limit restrictions can impact scheduling for the next audit. The expectation is that on-site audits will reconvene and that the next one will be scheduled within 12 months of the start of this year's audit.

For recertification audits, the certificate will be issued with an initial 12-month validity. Once the next audit is completed on-site, then the certificate will be reissued with a validity of the remaining three-year cycle.

Preparing for a remote audit

Experience has indicated that the combination of communication via internet-based communication tools, file transfer sites/email and video recording devices works smoothly. This is especially true when documents and records are electronic. Where the records are paper-based, we understand that these may take more time to retrieve, as generally they are scanned or photographed to allow the auditor to view. To help mitigate for these delays, some documents should be prepared in advance. While record samples can't be preselected prior to the audit, it is possible to prepare lists of records for commonly requested items.

Suggested items to prepare for audit

This list should be checked against the audit agenda so that only items within the agenda need be prepared.

List of procedures to provide before the audit (at least one week prior)	List of documents to be available before the audit to allow effective sampling
General	
• Product list and code, including relevant where distributed. • List of key suppliers, including name and address of supplier, service/ product supplied and mechanisms of control.	• Organization charts
Management subsystem	
• Quality manual	• Quality policy • List of quality plan updates since previous audit
Management review process	
• Management review procedure • Analysis of data procedure	• List of management review(s) conducted since previous audit
Internal audit process	
• Internal audit procedure	• List and number of internal audits conducted since previous audit • List of internal auditors
Improvement process	
• Complaint handling process • Vigilance procedure • Advisory notice procedure • Feedback process procedure	• List and number of complaints since previous audit with brief description and indication of product(s) • List of reportable events since last audit with brief description and product details • List of recalls since last audit with brief description and product details • List of advisory and field safety notices since last audit • List of feedback since last audit
Corrective action and preventive action process	
• Corrective Action Preventive Action (CAPA) procedure	• List and number of CAPAs since last audit
Design and development process	
• Design and development procedure • Design change procedure • Risk management procedure	• List of design projects completed since last audit • List of design changes since last audit
Production process	
• Production planning procedure • Cleanliness of product or contamination control procedure • Summary of major production processes • Risk management procedure	
Customer requirements process	
• Quote/orders handling procedure	• List and number of sales orders/quotes received since last audit • List and number of distribution records for product manufactured in the last three months

Suggested items to prepare for audit continued

List of procedures to provide before the audit (at least one week prior)	List of documents to be available before the audit to allow effective sampling
Purchasing process, outsourcing	
• Purchasing procedure • Supplier selection, evaluation monitoring and reevaluation procedure	• List and number of key suppliers
Receiving, preservation of product and identification/traceability Processes	
• Incoming inspection procedure • Storage, handling and distribution procedure • Preservation procedure • Traceability procedure	• List and number of incoming inspections since last audit
Control of nonconforming product process	
• Control of nonconforming product procedure • Rework procedure	• List of nonconforming products since last audit (brief description) • List of nonconforming products detected after delivery since last audit (brief description) • List of reworked products since last audit
Infrastructure, work environment/contamination control and calibration process	
• Preventative maintenance procedure • Calibration procedure • Personal Protective Equipment (PPE) procedure	• List of equipment requiring preventative maintenance • List of equipment requiring calibration
Validation of processes for production and service, and quality management system software validation processes	
• Process validation procedure • Software validation procedure	• Validation master plan/list of validations completed since last audit
Installation activities, servicing activities, and customer property processes	
• Installation Procedure • Servicing Procedure	• List of installation/servicing vendors (if applicable) • List of installations since last audit • List of servicing since last audit
Human resourcestraining process	
• Training procedure	
Control of document and record processes	
• Document control/change procedure • Record control procedure	• List of main QMS SOPs, if not included in Quality Manual

Our experience has indicated that remote auditing can be carried out very successfully with a small amount of preparation. Given technical improvements with communication tools — that are now robust and offer the opportunity to interview and observe processes and facilities real-time — the remote audit offers a valuable alternative to on-site audits.

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