REMOTE AUDITS

For NSF International, the health and safety of our customers, auditors and employees has the highest priority. Therefore, in addition to aligning with the legal requirements, we regularly adapt our services to the situations in the market. We have therefore decided to further expand our remote audit service.

WHAT EXACTLY IS A REMOTE AUDIT?

An audit can be carried out remotely for all content and processes that can be reviewed in reasonable technical depth without the physical presence of an auditor. In particular, the operational activities, medical devices and services as well as the associated risks. A remote audit of leadership, management and accompanying processes, such as management evaluation, training, internal audits, and corrective or preventive measures (especially regarding complaints and deviations from previous audits) is usually unproblematic. In the case of product life cycle processes, it is important to check whether a remote audit can provide sufficient depth of evidence from a technical perspective. This has to be decided and justified on a case-by-case basis, depending on the specific process. The remote audit is ideal for auditing technical documentation, since on-site auditing is not necessary.

DIN EN ISO 19011 – Guidelines for auditing management systems refers to remote audit methods, whose application can differ in terms of the extent to which they are used:
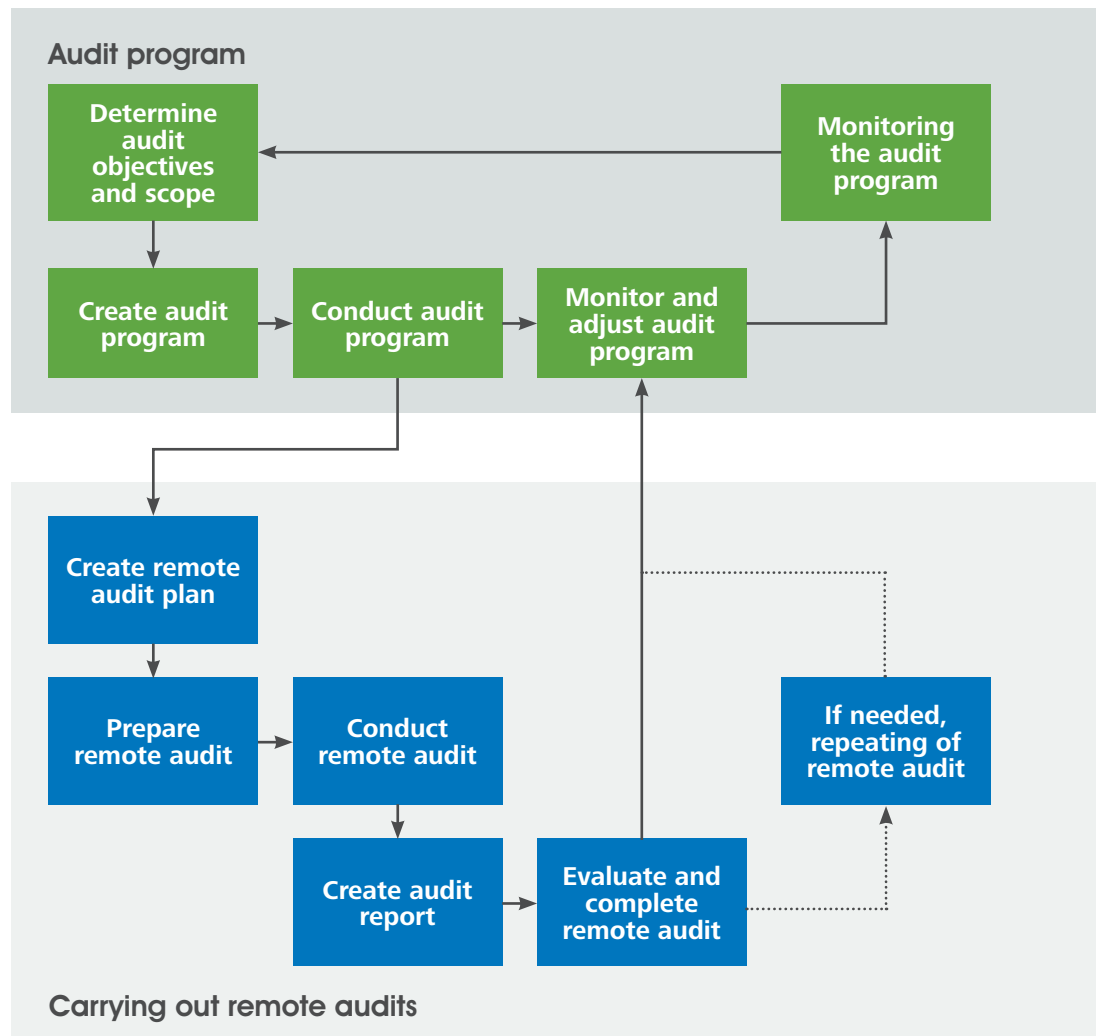
Full remote audit:

The audit takes place in its entirety, from planning to verification of audit follow-up actions, using remote techniques without the physical presence of auditors.

Partial remote audit:

Auditors are physically present at the site for some aspects of the audit and perform other scopes by remote techniques.

Remote audit for monitoring the measures:

Verification of the implementation and effectiveness of the follow-up audit measures or a post-audit is carried out using remote technology.

Audit program

Determine audit objectives and scope → Create audit program → Conduct audit program → Monitor and adjust audit program → Monitoring the audit program

Create remote audit plan → Prepare remote audit → Conduct remote audit → Create audit report → Evaluate and complete remote audit → If needed, repeating of remote audit

Carrying out remote audits

WHAT DO I HAVE TO CONSIDER FOR REMOTE AUDITS?

There is of course a difference between personally meeting auditors on site and being audited remotely without the physical presence of auditors. DIN EN ISO 19011 points out that the audit program should ensure that the use of remote audit methods is appropriate and balanced. For audits of notified bodies, in justified cases - and such with the current pandemic - a special regulation can be applied outside the regular certification cycle for upcoming audits. Different special arrangements are recognized depending on the audit objective. In April 2020, a Notified Bodies Guideline (MDCG 2020-4) was published to address remote audits during the COVID-19 pandemic and travel restrictions.

Remote audits can also supplement or replace conventional audit methods during "normal" operations to save on travel costs and time for arrival and departure. In addition, potential risks associated with on-site audits, such as contamination of work areas or security risks for auditors, can be reduced. In view of the increasing number of technical solutions, there are many possibilities for integrating computer-aided audit procedures into existing audit programs. Remote audits are particularly useful if a company has several locations or if on-site auditing is associated with problems, such as travel restrictions, or if there are health or product-related risks. As with on-site audits, effective remote audits require very detailed planning and preparation. This particularly concerns the provision of a functional, reliable and secure technical infrastructure in conjunction with the necessary competence of auditors and inspectors. Data protection and data security requirements must be taken into account in the planning stage and then implemented by all parties involved.

Make sure that you not only check your internet connection, but that you are also familiar with the software solutions, especially with the management and editing of documents and records. Also consider the requirements of your quality management system, such validating computer software, training, control of (electronic) documents and records. NSF has tested remote audit procedures, and can replace established procedures for on-site audits with appropriate remote techniques:

On-site audit	Remote audit
Personal interview/conversation	Interview/conversation via video conference
Filling out checklists individually	Filling out checklists collaboratively
Evaluation of technical documentation on site	Desktop audit of available documentation
Evaluation of confidential technical documentation	Inspection of approved document parts via video conferencing or document management systems (via VPN)
Company inspection, for example in production or laboratories	Interactive virtual inspection via live streaming
Process monitoring	Observation of the video transmission of processes

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OUR SERVICES

Our auditors, consultants and technical experts support you in the implementation of your audit programs or in the preparation, implementation and follow-up of remote audits by your notified body or competent authorities.

Participation in a remote audit can be done via PC, tablet or even smartphone. The only requirements are an internet connection and a standard internet browser. No special software on your part is required for the participants.

We can offer the following services for remote audits:

> Implementation of internal audits or supplier audits as remote audits

> Trainings, workshops and mock remote audits

> Development of processes, forms and checklists for remote audits in accordance with DIN EN ISO 13485 and DIN EN ISO 19011

> Creation of audit programs and individual process-specific audit plans

> Selection and evaluation of a secure and user-friendly IT infrastructure, including supplier evaluation and validation of software

> Preparation and support of remote audits as lead auditor or expert in the audit team

> Preparation and support of remote audits by customers (supplier audits), notified bodies or competent authorities, including reasons for postponements

> Development of audit strategies

> Evaluation and processing of deviation reports

> Planning, monitoring and evaluation of corrective actions

> Implementation of remote audits for monitoring measures

DIGITAL AND ONLINE CONSULTING

We are also digitizing our proven consulting services so that you can access our expert knowledge at any time, regardless of location, and we can continue to support you efficiently.

Digital consulting means that our services are computer-aided using established and secure software solutions. Together, documents and records can be evaluated, digitally completed and signed via secure connections on tablet, laptop or PC.

Our online consulting, on the other hand, is still conducted via video conferencing systems, whereby you meet with our consultant in a virtual consulting room, regardless of location. It is suitable for initial discussions, presentations, recurring project appointments, answering short questions and contract negotiations.

To provide you with the best possible support for all normative and regulatory tasks and questions, we now offer you the possibility of booking these services by the hour.

For further details on remote audits or for a non-binding offer, please contact us.

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