



The European Association of
Medical devices Notified Bodies

Team-NB Position Paper

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Version 1

Notified bodies' paper on the application of hybrid audits to quality management system assessments under MDR/IVDR

Disclaimer

Team-NB would like to emphasise that we do not regard this document as final rule or guidance, but rather as our view/expectation for the necessary guidance in absence of such guidance, and reserve to revise or withdraw our position subsequent to further development of the guidance.

Background

Traditionally, quality management system (QMS) audits are performed on-site. However, during the time of the global pandemic, notified bodies implemented procedures to apply alternative methods utilising information and communication technologies (ICT), in alignment with the applicable requirements and guidance such as MDCG 2020--4¹ and IAF MD 4². Additionally, the Notified Body Coordination Group (NBCG-Med) has produced guidance for notified bodies on best practices when applying alternative auditing methods based on ICT³.

This document represents the notified bodies' collective position on the aspects to be considered when employing ICT-based auditing in QMS audits specifically to MDR/IVDR and especially in the context of hybrid audits.

Hybrid audits in the context of legislative requirements

Notified bodies are required to undertake on-site audits of manufacturer's QMS both as part of the initial audit and surveillance audits. In relation to the initial audit, Annex IX section 2.3 of Regulations (EU) 2017/745 (MDR)⁴ and 2017/746 (IVDR)⁵ states:

*The assessment procedure shall include an **audit on the manufacturer's premises** and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors **to verify the manufacturing and other relevant processes.***

In relation to surveillance audits, Annex IX section 3.3 of MDR/IVDR states:

Notified bodies shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management

¹ [MDCG 2020-4](#) Guidance on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions

² [IAF MD 4:2022](#) Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes, Issue 2 Version 3

³ NBTG WG2 A Notified Body's guidance on remote auditing, approved at the 65th NBCG-Med meeting, for internal use by notified bodies

⁴ [Regulation \(EU\) 2017/745](#) of the European Parliament and of the Council of 5 April 2017 on medical devices, as amended by Regulation (EU) 2020/561

⁵ [Regulation \(EU\) 2017/746](#) of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, as amended by Regulation (EU) 2022/112



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system and the post-market surveillance plan. Those audits and assessments shall include **audits on the premises** of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors.

In accordance with these requirements, where quality management system audits to MDR/IVDR are performed using alternative methods based on ICT, at least a portion of these audits must be performed on-site to cover the manufacturing and other relevant processes, i. e. the audit must be a **hybrid audit** defined as follows:

A 'hybrid audit' should be understood as an audit at the premises of the manufacturer or their supplier and/or subcontractor with at least one auditor present at the premises and other members of the audit team participating from elsewhere using information and communication technologies (ICT).

Such hybrid audits undertaken by appropriately qualified staff would satisfy the on-site audit requirements of MDR/IVDR referenced above.

From experience gained during pandemic, hybrid audits, when appropriately planned, are effective and have the following advantages compared to fully on-site audits:

- Hybrid audits may save up to 20-25% of auditor capacities compared to on-site audits⁶, allowing to redirect the capacity saved towards undertaking additional MDR/IVDR audits to aid in the overall MDR/IVDR transition from Directives
- More efficient use and increased availability of subject matter experts
- Increased audit effectiveness for certain activities (assessment of documentation)
- Less time and effort need spent on travelling and accommodation hence reducing travel constraints
- Reducing the risk of travel to high-risk areas (political unrest, pandemic etc.)
- Reducing the risk of burnout for auditors
- Recognising the grown acceptance of telework, hybrid audits are more sustainable and reduce the environmental impact of auditing

Audit requirements

While some aspects of the manufacturer's QMS can be effectively audited remotely, certain aspects should be addressed in the on-site part of a hybrid audit.

Examples of areas to be included in the on-site part of the audit include (but are not limited to):

- Infrastructure
- Work environment
- Production and incoming/in-process/final inspection
- Servicing

⁶ NBCG-Med April 2022 meeting polls report



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- Design transfer to manufacture (if internal testing facilities are involved for verification and validation)
- Warehouse/storage facilities incl. verification of purchased products

Examples of areas which can be effectively audited by using ICT include (but are not limited to):

- Management, e. g. general quality management system requirements, regulatory affairs
- Improvement, e. g. internal audit, management review, corrective and preventive actions
- Human resources, e. g. qualification and training
- Purchasing, e. g. review of supplier files
- Design and development (except design transfer if internal testing facilities are involved)
- Traceability and batch records

Audit team qualification

In the context of MDR/IVDR hybrid audits, the auditor team must meet the qualification criteria specified in Annex VII section 3.2.6 of MDR/IVDR related to site auditors.

The auditor(s) performing the on-site part of a hybrid audit should be qualified for the MDT/IVT codes appropriate to the processes in the scope of the audit which physically occur at the audited facility. In circumstances where it is not possible that the auditor(s) physically present at the audited facility cover all the required qualifications, additional audit team member(s) with the appropriate qualification must support the audit simultaneously through ICT. In this case, the audit duration should consider the additional time needed by the audit team members to review the concerned processes.

Audit planning and duration

As part of the audit planning, notified bodies must consider the manufacturer's capability, and suitability to support hybrid audits (IT systems, paper based vs. electronic QMS documentation and records etc.).

The overall audit duration should be established based on the principles provided in IAF MD 5⁷ and IAF MD 9⁸.

According to GHTF/SG4/N30⁹, approximately 20--30% of the audit duration is allocated to auditing of the production and service controls subsystem. Consequently, at least 25% of the overall hybrid audit duration must be allocated to the on-site portion of the audit. The on-site portion of the audit should be appropriately increased to reflect the increase factors applied in the audit duration calculation that are applicable to manufacturer's production activities that physically occur at the audited facility.

The on-site portion of the audit can be reduced in duly justified cases. Examples include (but are not limited to):

⁷ [IAF MD 5:2019](#) Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems, Issue 4 Version 2

⁸ [IAF MD 9:2017](#) Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485), Issue 3 Version 1

⁹ [GHTF/SG4/N30:2010](#) Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers. Part 2: Regulatory Auditing Strategy (historical). Here: see section 6.6, table 2 on page 12.



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- facilities where no production activities physically occur that would require an auditor to be on-site to review them, e. g. facilities only producing software as medical device (SaMD), where production activities only utilise simple processes or all production activities are fully outsourced (“virtual manufacturer”), and no product is physically handled
- facilities where only administrative activities take place such as human resources management, purchasing or other management processes without physical product handling

However, also in these cases, the on-site portion of the audit must verify the existence of the facility and, as relevant, evidence of product compliance such as purchasing documents, production and inspection records.

In exceptional cases where there is no physical location to visit, e. g. where all company employees work remotely, the audit may be performed fully remotely since there is no physical location to visit; however, it should be confirmed that any physical handling of the product is audited on-site, or that the audited activities do not involve any physical handling of the product.