NBCG-MED 2024-1

Application of hybrid audits to quality management system assessments under MDR/IVDR – operational elements

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This document has been produced by NBCG-MED – Notified Bodies Coordination Group established in accordance with Article 49 of MDR / Article 45 of IVDR, and reflects the consensus position of notified bodies designated under:

- ***MDR** (Medical Devices Regulation) – Regulation (EU) 2017/745*
- ***IVDR** (In-Vitro Diagnostics Regulation) – Regulation (EU) 2017/746*

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Development and adoption note

This document has been initially developed and adopted by notified bodies as Team-NB position paper "Notified bodies' paper on the application of hybrid audits to quality management system assessments under MDR/IVDR" [1].

In this version, the document has been **updated** taking into consideration the comments of the Notified Body Oversight subgroup of MDCG[2] and **adopted** as NBCG-Med position. This is the first version of the document after its adoption as NBCG-MED position. This document is available in the dedicated section of the European Commission's website[3].

1. 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 2020-4[4] and IAF MD 4[5].

This document has been developed following the advice from the MDCG to further elaborate on operational elements of 'hybrid audits' including the identification of aspects to be audited on the auditee's premises, as included in MDCG 2022-17[6]. This document represents the notified bodies' collective position on the aspects to be considered when applying ICT-based auditing methods ('hybrid audits') specifically to quality management system audits under MDR/IVDR.

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[1] Team-NB is the European association of notified bodies for medical devices, Team NB (team-nb.org).

[2] MDCG (Medical Device Coordination Group) is an expert group established under Article 103 of MDR and as referenced in Article 98 of IVDR.

3 European Commission / Public Health / Home / Medical Devices - Dialogue between interested parties / Overview (health.ec.europa.eu) website, subsection Notified Body Coordination Group.

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

[5] IAF MD 4:2023 Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes.

[6] MDCG 2022-17 MDCG position paper on "hybrid audits".

2. 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 MDR/IVDR 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 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** as defined in MDCG 2022-17:

A 'hybrid audit' should be understood as an audit on the premises of the manufacturer or its supplier(s) and/or subcontractor(s) with at least one auditor present on 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:

- According to notified bodies' estimation, hybrid audits may save up to 25% of auditor capacities compared to on-site audits, allowing to redirect the capacity saved towards undertaking additional MDR/IVDR audits to aid in the overall MDR/IVDR transition from Directives thus enabling more efficient use of auditor capacities
- Less time and effort need spent on travelling and accommodation hence reducing travel constraints
- Reducing the risk of travel to high-risk areas (e.g., political unrest, pandemic, natural disaster)
- Reducing the risk of burnout for auditors
- Hybrid audits are more sustainable and reduce the environmental impact of auditing
- Hybrid audits promote inclusivity

3. Audit requirements

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

Examples of areas that can be effectively audited by using ICT and areas to be audited in the on-site part of the audit include (but are not limited to) those listed in the following table.

The table has been established considering the audit subsystems listed in Annex VII Section 4.5.2 b) and the requirements of Article 10 (9) of MDR/IVDR, as well as Section 6.2 of GHTF/SG4/N30[7], and has been partially adjusted to be compatible with the audit processes of the MDSAP Audit Approach[8], which are included in the following table for information.

Audit subsystem	**Areas that can be effectively audited by using ICT:**	**Areas to be included in the on-site part of the audit:**
Management, including pre-market requirements and product documentation MDSAP Audit Processes: • Management • Device Marketing Authorization and Facility Registration	• Verification that QMS covers all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices • Responsibility of the management • Strategy for regulatory compliance • Identification of the applicable general safety and performance requirements and exploration of options to address them • Risk management • Clinical evaluation • Resource management, qualification and training of human resources • Handling communications with authorities, notified bodies, other operators, customers and or other stakeholders	• Verification of the existence of facility NOTE: The overall on-site part of the audit must, as relevant, verify evidence of product compliance, such as purchasing documents, production and inspection records (see section 5, last sentence)

[7] GHTF/SG4/N30:2010 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers. Part 2: Regulatory Auditing Strategy (historical).

[8] MDSAP AU P0002.008 Audit Approach (revision of 1 April 2023).

Audit subsystem	Areas that can be effectively audited by using ICT:	Areas to be included in the on-site part of the audit:
Corrective and preventive actions, including for post-market surveillance and PMCF MDSAP Audit Processes: • Measurement, Analysis and Improvement • Medical Device Adverse Events and Advisory Notices Notification	• Post market clinical follow-up • Implementation and maintenance of a post-market surveillance system • Processes for monitoring and measurement of output, data analysis and product improvement • Processes for reporting serious incidents and field safety corrective actions • Management of corrective and preventive actions	
Design and development MDSAP Audit Process: • Design and development	• Design and development activities not involving on-site facilities (design transfer should be audited on-site if on-site testing facilities are involved)	• Design transfer to production/ manufacture, if on-site testing facilities are involved in verification and validation
Production and process controls MDSAP Audit Process: • Production and Service Controls	• Traceability and batch records • Process for the UDI assignment	• Planning, product realisation, infrastructure, implementation of device modifications, work environment, warehouse/ storage facilities, equipment calibration, servicing • In-process and final inspection
Purchasing controls including verification of purchased devices MDSAP Audit Process: • Purchasing	• Purchasing activities not involving on-site facilities, such as review of supplier files	• Incoming inspection/ verification of purchased products

4. Audit team qualification

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

The site 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 and have sufficient knowledge as site auditor on the device and the device related technologies as appropriate to the audited activities. 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.

5. 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 5[9] and IAF MD 9[10].

According to GHTF/SG4/N30, 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):

- 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.

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[9] IAF MD 5:2023 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems.

[10] IAF MD 9:2023 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485).