



EU Commission Recommendation 2013/473/EU on Unannounced Audits

The EU Commission issued a Recommendation (2013/473/EU) on the audits and assessments that notified bodies (NB) perform for medical devices (MD). This Recommendation outlines the proposed requirements for conducting the unannounced audits, and obligations for both the manufacturer and the NB in the performance of these unannounced audits. **NBs have had the authority to perform unannounced audits according to the MDs directives. The Recommendation 2013/473/EU, however, obligates NBs to perform unannounced audits.**

NB Audits / Assessments

The Recommendation is divided into four parts: the beginning clauses that state the purpose and general guidelines and three Annexes focused to product assessment (I), quality management system assessments (II), and the unannounced audits themselves (III). It also covers the minimum content of NB audits.

Annex I – Product Assessment deals with product assessment, in accordance with the design dossier examination and type examination provisions. The NBs should verify that:

- The product is a medical device (qualification of a product), its classification, and whether it complies with the relevant Essential Requirements.
- The risk management requirements are met.
- The certificate covers the types/variants of devices that the manufacturer intends it to cover, and that the declaration of conformity and the technical documentation match the devices that are assessed.
- The clinical evaluation is up-to-date (MDs).
- The post-market clinical follow-up is undertaken or planned (MDs).
- The performance evaluation is undertaken and post-market follow-up is undertaken or planned (IVDs).

The technical documentation should at least cover the requirements in the GHTF document - Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED).

Annex II – Quality System Assessment deals with the quality system assessments that NBs perform with respect to conformity assessment of MDs. The requirements focus on ways how to verify that the appropriate and required elements to the quality system are in place and functioning as they should. For Class IIa or IIb MDs, the NBs should review the technical documentation on the basis of representative samples. The NBs should verify that:

- Application of the quality system assures the conformity of the devices.
- The product identification system ensures that the NB's certificates, the manufacturer's EC declarations of conformity and the manufacturer's technical documentations unambiguously attributes to certain devices.
- The procedures regarding the design and product development, including any change control procedures, are appropriate to ensure the compliance of the devices.



- The manufacturer has work instructions on the required processes. The Recommendation states that NBs should sample the product documentation to ensure that these work instructions actually work as they are supposed to.
- The manufacturer has adequate controls of traceability and that they can collect the necessary vigilance data systematically. In addition, this vigilance data should result in any necessary improvements of the devices, and that these improvements are initiated.
- The manufacturer's business organization is such that its quality system is allowed to function as required. This includes the control over the manufacturer's subcontractors, which the NB may audit on site. The NB should not engage a manufacturer that does not allow access to all its critical subcontractors, regardless of the relationship between the manufacturer and its subcontractors.

The NB needs to be able to see that the manufacturer's entire quality management system complies with its regulatory requirements and functions as it should, ensuring continual device safety and performance.

Annex III – Unannounced Audits - gives recommendations for the frequency, length, and content of the unannounced audits that NBs perform:

- NBs should conduct at least one unannounced audit every three years that lasts at least one day with at least two auditors. *NBs can perform more unannounced audits if the devices are high-risk, if the devices are frequently non-compliant, and if the NB receives information that points to suspected nonconformities of either the product or the manufacturer.*
- NBs should perform unannounced audits on the manufacturer's critical subcontractors, instead or in addition to, the manufacturer's audits.
- *NBs should sample the products during the unannounced audits, review them and/or test them to ensure that they meet the Essential Requirements. For testing, either the NB may witness the manufacturer testing the product, or the NB may take the product and test it itself in its facilities. To perform the test, the NB requests all the technical documentation, including testing records, from the manufacturer to verify the products' conformity.*
- *NBs should sample the products according to the number of types of devices if the NB also performs the product assessments. Likewise, the NB would verify that the manufacturing activity at the time of the audit conforms to the manufacturer's quality system.*

Manufacturers

The main purpose of the Recommendation is to harmonize the different practices of the NBs. The manufacturers should plan for:

- Contracts with sub-contractors. NBs should have total access to a manufacturer's sub-contractor. Manufacturers should amend their contracts with their sub-contractor in order to allow this to happen, regardless of the length of the relationship between the manufacturer and the sub-contractor. *It is reasonable that if a sub-contractor does not allow a NB to audit its facility, there would be major consequences for the manufacturer.*
- Revise / create any new processes.
- If a manufacturer does not execute adequate control over a sub-contractor's activities, the manufacturer should revisit its relationship or revise its procedures to perform that control.
- New contracts with NBs (amendments that include provisions allowing them to perform unannounced audits), as well as standing invitation letters so that auditors can receive visas to audit different facilities if needed.

It is imperative that these and any other necessary steps are complete if the manufacturer wishes to avoid nonconformities.



NBs will start to systematically perform the unannounced audits at the beginning of 2014. In the meantime, manufacturers can get ready for the upcoming changes by analyzing their products' technical documentation and quality systems to make sure it is continually ready for an audit. 3EC's team is ready to answer questions.

- *European Commission calls for immediate actions – tighten controls, increase surveillance, restore confidence. Press release, 9 February 2012.*
- *2013/473/EU*