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UNANNOUNCED AUDIT: SURVEILLANCE ACTIVITIES AND POST-CERTIFICATION MONITORING LIKE ANY OTHER?

The entry into force and implementation of Regulations (EU) 2017/745 and 2017/746 were marked by the introduction of high and strict requirements, the main objective of which is to guarantee and strengthen the safety and effectiveness of devices marketed within the European Union. In this context, the activities carried out by Notified Bodies (NBs) as part of surveillance activities and post certification monitoring have been considerably strengthened, in particular with the requirement for NBs to carry out periodic unannounced audits at the premises of manufacturers or their subcontractors.

This newsletter presents the main regulatory requirements relating to unannounced audits, specifies how they are to be carried out, and provides recommendations to ensure that they run smoothly.

A WHAT IS AN UNANNOUNCED AUDIT?

Unlike traditional audits, an unannounced audit is an audit that is carried out without prior notice or any prior communication between the manufacturer and its NB. This feature allows the NB to ensure that the audited processes are observed in their actual state and operation.

An unannounced audit is an additional audit that is carried out in addition to or in parallel with the standard audits carried out as part of the certification cycle.

The aim of an unannounced audit is significantly different from that of standard audits carried out as part of the certification cycle, as the NB will focus on verifying that the device(s) manufactured by the company and covered by an EU quality management system certificate or an EU quality assurance certificate issued under one of the regulations comply with the technical documentation and applicable regulatory requirements. This is therefore referred to as a "product-focused" audit.

During the unannounced audit, the audit team applies the same audit approach and follows the same methodology as for standard audits carried out during the certification cycle, including:

- Establishing an audit plan prior the audit;
- Conducting an opening meeting;
- Conducting interviews with staff;
- Holding a closing meeting;
- Submitting an audit report.

B WHAT ARE THE APPLICABLE REGULATORY REQUIREMENTS FOR UNANNOUNCED AUDITS?

Unannounced audits are not really a new means of surveillance and post-certification monitoring introduced by the regulations. This type of audit was already defined and used as a means of surveillance under the directives on medical devices and in vitro diagnostic medical devices.

In a recommendation published on September 24, 2013[1], the European Commission already encouraged NBs to carry out unannounced audits of manufacturers every three years.

Under Regulations (EU) 2017/745 and 2017/746, the NB is now required to perform a randomly unannounced audit at least once every five years from the date of first issue of the certificate.

The NB may also be required to carry out an unannounced audit following the completion of surveillance activities and post-certification monitoring, such as the analysis of a vigilance report submitted by the manufacturer or the competent authority.

An unannounced audit is an audit that must be carried out at the manufacturer's site(s) or, where necessary, at the site of a subcontractor or supplier of the manufacturer. The subcontractors or suppliers of the manufacturer that are likely to be audited are mainly those involved in the manufacture of the product.

During the unannounced audit, NB is required to take adequate samples from the manufacturing process or from devices produced for the purpose of testing these samples.

These samples are taken from the audited site and/or directly from the market.

Once the samples have been taken, the NB must carry out tests to verify their conformity with the relevant technical documentation.

C HOW DOES THE NOTIFIED BODY CARRY OUT AN UNANNOUNCED AUDIT?

The NB must establish and update procedures within its quality management system to ensure that surveillance and control activities are carried out after certification with manufacturers holding an EU certificate of conformity.

Unannounced audits are an integral part of these activities and contribute directly and significantly to strict market surveillance.

The key stages of the unannounced audit process are as follows:

→ The pre-audit phase

When preparing for the unannounced audit, the NB does not make any contact with the manufacturer prior to the audit. The audit plan is not sent to the manufacturer, and no quotation is sent.

During this phase, the NB will:

1) **Select the samples of devices to be taken.**
   This involves defining and identifying the device(s) on which the tests will be carried out. This selection is made from among the devices covered by the valid EU quality management certificate(s) or EU quality assurance certificate(s).

2) **Define the tests to be carried out and the associated test protocol.**
   Several parameters are taken into account to determine the tests to be carried out, such as the output data from previous audits and evaluations of the technical documentation carried out or any information from vigilance analyses.

[1] *Commission Recommendation of September 24, 2013, on audits and assessments performed by notified bodies in the field of medical devices*

3) **Select a site of the manufacturer or a site of its subcontractors or suppliers to be audited.**
The site where the audit will be carried out is determined taking into account the samples of devices to be taken, the tests to be carried out, the activities carried out on the site, and the infrastructure available.

→ The audit

During the unannounced audit, the audit team will take one or more samples either at the audited site or directly on the market. These samples may be semi-finished products from the manufacturing process or finished products.

Once the sample(s) have been taken, tests will be carried out in accordance with the test protocol defined in the audit preparation phase.

These tests are carried out:

- On the audited site when the facilities and equipment available on-site allow the tests to be carried out as defined in the protocol. In this case, the tests are carried out by authorized personnel of the manufacturer, its subcontractor supplier, under the supervision of the audit team.

OR

- At an external, independent testing laboratory. In this case, the samples taken by the audit team are sent to the relevant laboratory.

Regardless of where the tests are carried out, the results of the tests carried out shall be evaluated by the audit team or another person authorized by the Notified Body.

During the unannounced audit, the audit team will also carry out a traceability exercise on all or part of the manufacturing process. This exercise is carried out to verify that practices comply with the relevant technical documentation and applicable regulatory requirements.

→ The post-audit phase

At the end of the audit, the audit team will submit an audit report to the manufacturer, including when the unannounced audit has been carried out at the site of its subcontractor or supplier. If the tests were carried out at the audited site, this audit report shall include the results of the tests carried out and their evaluation by the audit team, as well as any non-conformities identified, if applicable. Where the tests are carried out in an external and independent testing laboratory, the results of the tests carried out and their evaluation by a person authorized by the Notified Body shall be forwarded at a later date.

As the manufacturer is responsible for the safety and performance of its products, any non-conformities identified during the audit of its subcontractor or supplier shall be reported directly to the manufacturer. The manufacturer is therefore responsible for taking the necessary action to resolve them.

D WHAT MEASURES CAN MANUFACTURERS PUT IN PLACE TO HELP THE UNANNOUNCED AUDIT CARRIED OUT BY THEIR NB RUN SMOOTHLY?

The manufacturer must take all necessary measures to enable its NB to carry out all post-certification surveillance and control activities that are applicable and essential for the maintenance of its certificate(s).

The unannounced audit is no exception to this rule and must be able to be carried out under normal conditions of reception and safety for the audit team.

To ensure the smooth running of the unannounced audit and to reduce the risk of hindrance or obstacles to the performance of this type of audit, the following measures may be put in place by the manufacturer:

1) **Inform its NB of the periods when the sites covered by the quality management system are closed.**
This information is essential to enable your NB to prepare for the unannounced audit in the best possible conditions and contributes to its success.

2) **Inform company personnel that, as part of post-certification surveillance and monitoring activities, the NB is required to conduct an unannounced audit at least once every five years.**
Communication with personnel encourages goodwill toward the audit team and promotes adaptability, both of which are essential to the smooth running of the audit.

3) **Inform subcontractors and suppliers involved in the device's life cycle that the NB may carry out an unannounced audit at their site.**
It is essential that your subcontractors and suppliers are fully informed and aware of this type of audit and that they allow and authorize its performance.

Conclusion

Unannounced audits are one of the main surveillance and control activities carried out after certification under Regulations (EU) 2017/745 and 2017/746. Although unannounced, this type of audit is carried out by the notified body on a systematic basis and at a minimum frequency.
All manufacturers holding an EU quality management system certificate or an EU production quality assurance certificate must be prepared and organized to enable this audit to be carried out smoothly, during which sampling and testing must be carried out by the audit team.
Awareness of the various stakeholders, including subcontractors and suppliers, of the unannounced audit carried out by the Notified Body remains a key factor in its success.

To go further

TRAININGS FOR AMERICA REGION

European Medical Device Regulation (EU) 2017/745
2-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

European in Vitro Diagnostic Device Regulation (EU) 2017/746
2-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

Post Market Surveillance and Vigilance
2 half-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

TRAININGS FOR OTHER REGIONS

Internal audit and supplier audit for medical device manufacturers
SA24 | 2-day training session | On demand

Compiling technical documentation under European Medical Device Regulation (EU) 2017/745
SA57 | 1,5-day training session | On demand

Apply the requirements of European Medical Device Regulation (EU) 2017/745 on medical devices
SA56 | 2-day training session | On demand

→ CONTACT GMED TRAINING CENTER

GUIDE

Application for certification under Regulation (EU) 2017/745

This guide presents the key stages of the certification process under Regulation (EU) 2017/745 set up by GMED. It guides you through the certification process and explains how to apply to GMED, obtain a quote and submit a formal application for certification of your quality management system and/or devices. This document also describes the different conformity assessment activities, the final review and decision-making stages, and post-certification surveillance and control activities.

The conformity assessment procedures corresponding to your activities, risk class and device type are described. The documents to be submitted as part of the formal certification application for each of these procedures are also detailed.

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