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Frequently Asked Questions

Unannounced audits for manufacturers of CE-marked medical devices

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	Theme	Question	Answer
1	Regulations	What is an unannounced audit?	Unannounced audits are additional audits for which Notified Bodies (NBs) do not announce the date to manufacturers. This means the auditors commissioned by the notified body will arrive on the sites to be audited and proceed to the audit without giving the manufacturer prior notice. This type of audit comes in addition to the initial, surveillance or renewal audits of the three-year certification cycle. European Commission Recommendation 2013/473/EU defines their objectives and procedures for execution as from September 24, 2013. They have to be performed at least once every three years, last at least a whole day, and should be conducted by a team of at least two auditors. They may take place on the premises of the manufacturer, of critical subcontractors, or of crucial suppliers.
2	Regulations	Are unannounced audits part of a new requirement?	No, the three European directives on Medical Devices (90/385/EEC, 93/42/EEC, 98/79/EC) have provisions for the possibility of an NB to proceed to unannounced audits. All NBs have conducted a number of unannounced audits since CE marking procedures were implemented. These audits were usually triggered by a specific cause (e.g.: vigilance data, need for an on-site verification, failure to reply of the manufacturer, repetition of compliant situations, etc.) The European Commission Recommendation of 24 September 2013 now states these audits will have to be performed systematically, for each manufacturer, throughout the certification cycle. It specifies their procedures for planning and execution as well as the need to set up a contract between the manufacturer and the NB.
3	Regulations	Where can I read the original Commission Recommendation regarding unannounced audits?	The Commission Recommendation of 24 September 2013 on the audits and assessments performed by NBs in the field of medical devices (2013/473/EU) is available on the European Commission website at the following address: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013H0473&rid=3

4	Regulations	Why does LNE/G-MED perform unannounced audits?	The ANSM (National Agency for the Safety of Medicine and Health Products) is the French competent authority that has accredited LNE/G-MED (0459) as a Notified Body. It is also responsible for its surveillance. Pursuant to the European Commission Recommendation, and on request of the ANSM, LNE/G-MED must define an implementation plan for unannounced audits. Other competent authorities have made similar requests to all NBs. According to LNE/G-MED, this systematic provision is likely to strengthen confidence in the current regulatory framework.
5	Regulations	Does this Recommendation apply to all European Notified Bodies?	Yes, this Recommendation applies to all Member States. The Notified Body Operations Group (http://www.nbog.eu/) is currently working on setting up guidelines for performing the unannounced audits. It is also important to note that this Recommendation is one of the measures of the Dali plan established in 2012 to reinforce the European regulatory framework regarding medical devices (http://europa.eu/rapid/press-release_IP-13-854_en.htm). Gradually implementing the Recommendation's provisions is a type of preparation for economic operators and NBs to comply with the future Regulations on MDs and IVDMDs.
6	Contract	Does my current contract contain a clause regarding unannounced audits?	YES. LNE/G-MED integrated the possibility to perform unannounced audits in its contracts: Article 3, paragraph 3.3 for MDs, and Article 3, paragraph 3.2 for IVD MDs.
7	Regulations	From a contractual point of view, do these new provisions have an impact on the content of contracts?	We drafted a new contract. It specifies the procedures for applying unannounced audits in accordance with the European Commission Recommendation, as well as the manufacturer's and LNE/G-MED's responsibilities. LNE/G-MED will soon be sending each of their customers the new contract. It is necessary for the manufacturer to sign and send it back so that his certification file can be well-managed.

8	Schedule	When will unannounced audits start?	LNE/G-MED has already performed unannounced audits. From now on, they will be conducted systematically, according to an action plan that takes the European Commission Recommendation into account.
9	Methodology	What are the trigger criteria for an unannounced audit?	There are no such criteria since unannounced audits will be performed systematically, on an at least once-every-three-year basis, for all manufacturers, whatever the product class. Nevertheless, this frequency may be increased if the devices present a high risk, if the type of devices are often found to be non-compliant, or if some information leads LNE/G-MED to suspect a lack of conformity in the devices themselves, or on the manufacturer's premises.
10	Methodology	Do companies receive prior notice (very short notice) for an unannounced audit?	NO. In accordance with recommendations on the audits and assessments by NBs, clause 2 (c), *"… without prior notice"*, our auditors will visit your premises, your critical subcontractors premises, or your crucial suppliers premises **without any prior notice**, and at any time (night and day, depending on your activity). As from now, the manufacturer must implement the provisions needed (on his premises and on his subcontractors/suppliers premises) to be able to host our teams and let them conduct the audit in satisfactory conditions.
11	Scope of application	Do unannounced audits apply to all MDs?	YES. Unannounced audits apply to all MD types covered by one of the directives (90/385/EEC, 93/42/EEC, 98/79/EC), regardless of the conformity assessment chosen by the manufacturer. Nonetheless, this requirement does not apply to Class I MDs (non-sterile or without any measuring function), nor to the IVD MDs not covered by Annex II. Note: Companies which are only ISO 13485 certified are not directly concerned with this measure. They may be, indirectly, if they are a critical subcontractor or a crucial supplier of an MD manufacturer.

12	Methodology	How are unannounced audits carried out for a manufacturer who has chosen an OBL/OEM economic model?	Since an OBL manufacturer is a manufacturer first, in the regulatory meaning of the term, the unannounced audit may be performed on the premises of the OBL manufacturer, but also on the premises of his critical subcontractors or crucial suppliers.
13	Methodology	How often are audits performed for manufacturers who produce MDs of different classes (Classes IIa, IIb and III)?	As for manufacturers of MDs of different classes, the frequency of visits is determined by the class that presents the highest risk. LNE/G-MED will perform unannounced audits efficiently so as to cover as many MDs of the range as possible on the same day. Nevertheless, if the range to be covered proves too wide, the unannounced audit will last longer.
14	Methodology	Is there one unannounced audit per certificate issued, or one audit per legal manufacturer?	The scope of unannounced audits will include all the MDs covered by the CE marking certificates issued by the NB. A sampling will be carried out among these MDs to verify that legal obligations are respected on a daily basis by reinforcing the evaluation of the coherence between the provisions in the quality system and the data in the technical documentation. The NB will inspect a recently-made product sample, preferably a device derived from the manufacturing process going on during the audit, to verify its compliance with the technical documentation and legal requirements. The NB will also verify the traceability of all the components and materials essential to the device, as well as the traceability system of the manufacturer. In addition, the NB will proceed to or order a test on the product, if need be. Testing will be systematically performed on MDs for which an EC type examination or a design examination certificate has been established, according to a sampling defined by the European Commission Recommendation.
15	Scope of application	Does this Recommendation only apply to European manufacturers?	NO. This Recommendation applies to ALL manufacturers who place products on the European market, regardless of where they were produced or where the companies are located.

16	Methodology	How often will unannounced audits be performed?	The frequency defined in Annex III of the European Commission Recommendation is of at least one visit every three years. This frequency will increase if MDs present a high risk (Class III MDs, Active Implantable MDs and Annex II list A IVD MDs), if the rate of non-compliance and/or complaints was high in the previous audit reports, and if some information leads to suspect a lack of conformity on the MD or on the manufacturer's premises.
17	Methodology	How long does an unannounced audit last, and how many auditors are commissioned?	In accordance with Annex III of the European Commission Recommendation, an unannounced audit lasts: - At least one day, on-site (8 hours), - With at least two auditors. The duration and/or resources will be adapted depending on the staff, the number of products certified, the complexity of the devices, or the production operations implemented.

18	Definition	How is it possible to know if a subcontractor is considered as critical, and a supplier as crucial?	The European Commission Recommendation specifies a critical subcontractor or a crucial supplier must be audited *"if this is likely to ensure more efficient control… in particular if the main part of the design development, manufacturing, testing or another crucial process is located with the subcontractor or supplier"* (clause 2, point c and Annex III, point 2). This new terminology first appeared in this text, and the definition established until then was that of the *"critical supplier"* (whose definition is provided in the NBOG 2010-1 Guide http://www.nbog.eu/resources/NBOG_BPG_2010_1.pdf): ***"2.2 Critical supplier*** *A critical supplier is a supplier delivering materials, components, or services that may influence the safety and performance of the device.* *Note: In the context of the audit of medical device manufacturers, a critical supplier is a supplier of a product or service, the failure of which to meet specified requirements could cause unreasonable risk to the patient, clinician or others, or could cause a significant degradation in performance. This can include suppliers of services, which are needed for compliance with QMS or regulatory requirements, e.g. internal audit contractors or Authorised Representatives."* One of the possible interpretations to consider is a **critical subcontractor** ensures all or part of the MD's design, or performs all or part of the manufacturing processes, or carries out all or part of an activity in relation to regulatory requirements (e.g.: post-market data collection), and a **crucial supplier** provides finished devices, or key subassemblies essential to the performance of the MD, or critical raw materials.
19	Definition	Under what form must the manufacturer describe his critical subcontractors and crucial suppliers?	The manufacturer must provide the NB with the list of critical subcontractors and crucial suppliers according to his risk management system. This list is reviewed during the planned audits of the certification cycle.

20	Contract	What happens if the manufacturer, the subcontractor or the supplier refuses the unannounced audit?	In case the manufacturer, his subcontractor(s) and/or supplier(s) refuses to welcome the audit team, the contract between LNE/G-MED and the manufacturer may be breached, resulting in a suspension, or even the withdrawal of certificates. The manufacturer is charged for the travel expenses and the costs incurred for immobilizing the teams.

21	Contract	How much does an unannounced audit cost?	The costs associated with an unannounced audit will be calculated the same way as for cycle audits. This cost depends on several parameters: - The number of days the audit lasts (at least one) - The number of auditors (at least two) - The place where the audit takes place (travel expenses) - Administrative and report fees - Tests performed if any samples are taken - Expenses pertaining to tests* - Safety measures of the auditors On the basis of these elements, it is difficult to estimate how much an audit will cost. As for on-site audits, the daily cost applied will be the normal applicable fee at the time of the audit. As for tests, if they must be performed in a laboratory outside the manufacturer's premises, a quote will be sent according to the elements received by the laboratory performing the tests. The quote must be approved and paid for before tests are performed. The maintenance of the certificate(s) held by the manufacturer depends on the tests performed and their results. * The samples taken will remain the property of the manufacturer. In accordance with LNE/G-MED Terms and Conditions (point 6), *"The customer must make the samples, products or materials required for the service to be provided available to LNE for free (…). They are transported at the Customer's risk and expenses. [Besides], LNE cannot in any case be held responsible for the degradation of samples, only by their being used, or because of the experimentation for which they were supplied".*

22	Contract	Who is charged for the unannounced audits? Can I refuse to pay?	As is stated in the European Commission Recommendation, the costs associated with unannounced audits are paid for by the manufacturer, including the audits performed on the premises of his critical subcontractors/crucial suppliers. In case the manufacturer refuses to pay, the contract between LNE/G-MED and the manufacturer may potentially be breached, resulting in a suspension, or even the withdrawal of certificates. Once the unannounced audit has been performed, the manufacturer receives an invoice detailing the costs associated.
23	Contract	What is the impact of unannounced audits on critical subcontractors or crucial suppliers?	The impact of the manufacturer's critical subcontractors/crucial suppliers' nonconformities will be felt by the manufacturer, as they are responsible for the safety and performance of their products. The manufacturer must define his critical subcontractors/crucial suppliers and review the contractual arrangements between them to ensure LNE/G-MED will have free access to their premises to perform an unannounced audit.
24	Regulations	If critical subcontractors or crucial suppliers are ISO 13485 certified, are they subject to unannounced audits?	The ISO 13485 certification of these crucial suppliers represents part of the evidence the manufacturer provides the NB to prove the efficiency of his subcontracting control system in accordance with regulatory requirements. The NB takes this into account when setting up the audit program. However, given the objectives of unannounced audits as they are defined in the European Commission Recommendation, any critical subcontractor or crucial supplier may be subject to an unannounced audit.

25	Preparation	How can I prepare for an unannounced audit?	If you have not consulted it yet, LNE/G-MED invites you to carefully read the European Commission Recommendation (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013H0473&rid=3) to understand your own role and responsibility, to be compliant, and to implement the appropriate processes within your QMS to be coherent with the Recommendation. The manufacturer's obligations are also defined in the European Commission Recommendation, such as the implementation of favourable conditions for these inspections to be carried out. It should be noted that NBOG Guides are likely to be published in the next few months (http://www.nbog.eu/2.html).
26	Preparation	What elements must the manufacturer make available to LNE/G-MED?	The manufacturer must provide the following elements proposed by LNE/G-MED for unannounced audits to be performed: - Periods of non-production - The list of his critical subcontractors and crucial suppliers - Periods when sites are shut down (whether the premises of the manufacturer, of his critical subcontractors or of his crucial suppliers) - The open invitation letters (required to obtain a visa for performing unannounced audits) for his various sites and those of his critical subcontractors or crucial suppliers

27	Methodology	What happens if the “key” staff members are not available on the day of the audit?	Pursuant to the certification contract, which includes the elements prescribed in Annex III of the European Commission Recommendation, the audit team that performs an unannounced audit must fulfill its mission in accordance with the objectives and procedures defined. When signing the certification contract, the manufacturer undertakes to implement the provisions needed to provide answers to the auditors' questions. This means he must define procedures regarding temporary replacements and delegations required for the unannounced audit to be performed in satisfactory conditions. By signing the contract, the manufacturer also commits to ensuring his critical subcontractors and crucial suppliers make similar provisions. Any refusal from the staff to cooperate, preventing the audit to be performed in satisfactory conditions, may hinder the maintenance of the certificates (suspension or even withdrawal).
28	Methodology	As a subcontractor/supplier for numerous manufacturers certified by LNE/G-MED, can a grouped unannounced audit be considered?	The scope of unannounced audits is related to the MDs covered by the certificates issued to the manufacturer. This provision remains valid if the unannounced audit takes place on the premises of a critical subcontractor or a crucial supplier. The activity of critical subcontractors/crucial suppliers will be audited to be verified as a whole, and in that sense they may be subject to an audit that would be valid for several manufacturers.
29	Methodology	What happens if an audit by another NB or an inspection by a regulatory authority is already being performed on the day of the LNE/G-MED unannounced audit?	LNE/G-MED is aware this situation might occur and prove quite complex to deal with. In such a case, the feasibility will be assessed on site depending how the joint exercises are performed. The arguments presented by the company for the possible non-feasibility of the unannounced audit will appear in the unannounced audit report. In addition, the manufacturer will be charged for the travel expenses and costs incurred for the audit, regardless if it takes place.

30	Methodology	How is an unannounced audit conducted?	Although the company is not notified of the planning of an unannounced audit by the NB beforehand, the methodology is strictly identical to that of an announced audit within the certification cycle: a mission order will be presented by the audit team to the company audited (manufacturer, critical subcontractor or crucial supplier), and the audit plan will be presented and explained. At the end of the audit, if any non-conformities are found, they will be presented to the company. The samples will be identified during the audit, if need be, and their transport to the place where they will be tested is the responsibility of the manufacturer.
31	Methodology	What are the output data of the unannounced audit?	Auditors will provide an oral report at the end of the audit. A written report will be sent to the manufacturer within the usual period of time provided for as part of the certification cycle. The processing time period will be adapted according to the nature of the non-conformities found and the corresponding risks.
32	Methodology	What happens in case of a critical non-conformity?	Once the unannounced audit has been performed, and the report issued, the usual communication process with the NB is implemented, including what regards critical non-conformities. Then the NB makes a decision according to the result of the unannounced audit, and assesses its influence on the audit programme and on the maintenance of the certification.

33	Methodology	What is audited?	The three annexes in the European Commission Recommendation describe how NBs are to carry out their assessments: - Product assessment - Quality system assessment - Unannounced audits The scope of unannounced audits will include all the MDs covered by the CE marking certificates issued by the NB. A sampling will be carried out among these MDs to verify legal obligations are respected on a daily basis by reinforcing the evaluation of the coherence between the provisions in the quality system and the data in the technical documentation. The NB will inspect a recently made product sample, preferably a device derived from the manufacturing process going on during the audit, to verify its compliance with the technical documentation and legal requirements. The NB will also verify the traceability of all the components and materials essential to the device, as well as the traceability system of the manufacturer. In addition, the NB will proceed to or order a test on the product, if need be. The test will be systematically performed on MDs for which an EC type examination or a design examination certificate has been established according to a sampling defined by the European Commission Recommendation.

34	Methodology Tests	Can the audit team take samples with a view to perform these tests?	In accordance with the European Commission Recommendation (Annex III), a test may be performed on the MD when controlling a sample, if it is required to establish compliance. To prepare for this test, LNE/G-MED will ask the manufacturer to provide all the technical documentation needed, including the protocols and results of the previous tests. The test will be carried out in accordance with the testing protocol defined by the manufacturer in the technical documentation, which will be validated by LNE/G-MED. The test may also be performed by the manufacturer, his critical subcontractor or crucial supplier, under the supervision of the auditors. If the tests are not performed on the premises of the manufacturer, the name of the laboratory(ies) in charge of the tests and selected by LNE/G-MED will be issued to the manufacturer. LNE/G-MED will be the only interlocutor of the third party laboratory. On this account, LNE/G-MED will transmit any information deemed useful by the manufacturer to the third party laboratory. As a principal, LNE/G-MED will directly receive the test report, and then include it in the final report for the manufacturer.
35	Methodology Tests	In case products are taken, how are quantities determined, and where are samples taken: on the premises of the manufacturer, on the premises of the supplier, or from the market?	As for products assessed as part of a design examination or EC type examination (Class IIb and III MDs, AIMDs, IVD MDs of Annex II lists A and B), performing tests is mandatory, and **the number of samples will vary depending on the width of the ranges of MDs or IVDs placed on the market by the manufacturer, but also on the tests to be performed.** For these products, it will be possible to take the samples **from the market**, with the help of the competent authorities if needed. It will also be possible to perform the tests on the products installed **on the customers' premises**, if required.
36	Methodology Tests	Which tests may LNE/G-MED choose to perform on the MDs/components?	The European Commission Recommendation does not specify the nature of the tests to be performed; nevertheless, the manufacturer will have to provide the testing procedures defined in the technical documentation. As a consequence, if this proves necessary, LNE/G-MED may perform or order any type of tests to ensure the MDs routinely manufactured comply with the characteristics defined in the technical documentation: mechanical, chemical, physical/chemical, electrical safety, EMC, biocompatibility tests, etc.

37	Methodology Tests	How does LNE/G-MED manage sample taking from an accounting/financial point of view, in particular for rather costly MDs or components?	These provisions are already provided for in the current LNE/G-MED Terms and Conditions, since the manufacturer must ensure all the required conditions for LNE/G-MED to be able to perform the unannounced audit in satisfactory conditions.
38	Regulations	In case some products are taken to perform the tests, and entrusted to third party laboratories, what are the provisions implemented by LNE/G-MED to manage conflicts of interest and ensure confidentiality? Are the name of the laboratory in charge of the tests and the testing methods selected issued to the company?	LNE will take care of identifying the laboratories which have no conflict of interest for the mission to be accomplished, and will ensure the confidentiality of the data is respected as part of the general provisions in force. The name of the laboratory may be given to the manufacturer; however, LNE/G-MED remains the only intermediary and implements provisions to ensure confidentiality and impartiality are respected.
39	Methodology	If the unannounced audit takes place on the premises of a critical subcontractor or a crucial supplier, who will receive the audit report, including any non-conformity, if applicable?	Since the certification contract is established between LNE/G-MED and the manufacturer to whom CE marking certificates are attributed, the unannounced audit report is sent to the manufacturer. The critical subcontractor or the crucial supplier will have been orally informed of the results at the end of the audit. It is the responsibility of the manufacturer to search for causes and to implement remedial and corrective actions.
40	Methodology	How does the unannounced audit fit into the certification cycle? Do you review the previous or on-going non-conformities?	Since unannounced audits are conducted outside the normal surveillance programme, the LNE/G-MED audit team does not carry out any follow-up of the previous/ongoing non-conformities. Nevertheless, when preparing and performing the unannounced audit, our auditors take into account the cycle audit history. If non-conformities are raised during the unannounced audit, they will be followed up during the next routine audits.
41	Methodology	Does LNE/G-MED notify the manufacturer when the unannounced audit is scheduled on the premises of a critical subcontractor or a crucial supplier?	NO. LNE/G-MED does not notify the manufacturer of an audit planned on the premises of one of his subcontractors or suppliers. However, the subcontractor/supplier may warn the manufacturer LNE/G-MED is present on his premises to perform an unannounced audit.

42	Communication	What are the communication actions organised by LNE/G-MED regarding unannounced audits?	In order to inform their customers, LNE/G-MED will organise webinars that can be downloaded on our website in French and English. This issue will also be dealt with in a Newsletter, and each customer will receive an explanatory letter informing them of the new procedures and associated contractual changes.

For any further information, please do not hesitate to contact us to the following email addresses: medical.gmed@lne.fr or gmedna@lne-gmed.com