Notified Bodies Recommendation Group

Guidance for the

Interpretation and Implementation of the Commission Recommendation on audits and assessments performed by notified bodies in the field of medical devices (2013/473/EU)

“Testing during unannounced Audits”

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Content

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1.) Introduction

In the context of the European Medical Devices Directives, when involved in the conformity assessment procedure, Notified Bodies should "to *verify the continuous compliance with legal obligations perform unannounced audits in addition to product assessments and quality system assessments*"[1] for medical devices.
Notified Bodies shall do periodic product and/or quality system assessments depending on the conformity route chosen. In addition, Notified Bodies "*may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly*."[2]
On September 24th, 2013 the European Commission published its Recommendation on the audits and assessments performed by notified bodies[3]. *To facilitate the consistent application of the conformity assessment provisions contained in Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC, the notified bodies should apply the provisions of this Recommendation when they perform product assessments, quality system assessments and unannounced audits.*
By providing general guidelines for such assessments and unannounced audits, this Recommendation should facilitate the work of the notified bodies as well as the Member States' evaluation thereof. This Recommendation does not create any new rights and obligations[4].
Rather than the permissive statement in the currently applicable Medical Device Directives, the European Commission has obliged the Member States to advice Notified Bodies to implement the recommendation. As part of that, unannounced audits are to be performed, and may include critical subcontractors and crucial suppliers.

Furthermore, the Commission Recommendation states[4]:
"In the absence of established practice for unannounced audits it is important to determine the practicalities for such audits, as well as to provide advice on the arrangements needed for facilitating these audits".
Annex III to the Commission Recommendation is devoted to the aspect of unannounced audits. Paragraph 3 of this Annex III states: "*The check should encompass a file review and, if necessary in order to establish the conformity, a test of the device."*

In any case Notified Bodies must duly justify the appropriateness and extent of their activities undertaken under the requirements of the Commission's recommendation.[5]

The objective of this NBRG Consensus Document is to contribute to a proper and consistent implementation of the Commission Recommendation by:

- providing a practical mechanism to estimate the frequency of unannounced audits as well as their scope. This mechanism, while respecting the essential element of unpredictability, takes into account the risk class of the device as well as the results from the periodic inspections
- providing guidance on how product testing related to unannounced audit could be performed.

2.) Recommendation on Unannounced Audits[6]

The Recommendation of September 2013 states in paragraph 2 (c) on unannounced audits:

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[1] Commission Recommendation of 24 September 2013 on audits and assessments performed by notified bodies in the field of medical devices (2013/473/EU), "whereas" (5)
[2] See, for example, 93/42/EEC, Annex II, article 5.4.
[3] Commission Recommendation of 24 September 2013 on audits and assessments performed by notified bodies in the field of medical devices (2013/473/EU);
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:253:0027:0035:EN:PDF
[4] 2013/473/EU, "whereas" (11)
[5] See, for example, 93/42/EEC, article 11.10
[6] Commission Recommendation 2013/473/EU
[7]depending on testing modalities within the verification of manufactured products as defined by the notified body

"*To verify the day-to-day compliance with legal obligations, notified bodies should, in addition to the initial, surveillance or renewal audits, visit the manufacturer or, if this is likely to ensure more efficient control, one of its subcontractors in charge of processes which are essential for ensuring compliance with legal requirements ('critical subcontractor') or a supplier of crucial components or of the entire devices (both: 'crucial supplier') without prior notice ('unannounced audits') in accordance with Annex III.*"

The main body of this Annex III is attached in this document as Appendix 1.

3.) Execution, Location and Content of tests

While regular audits are primarily focusing on the Quality Management System as a whole, on process-related documentation such as file review and on verification of the traceability of critical components and materials, unannounced audits supplement the regular audits in order to facilitate Notified Bodies' verification of the day-to-day compliance of the manufacturer concerning the device in question.

Within such unannounced audits, Notified Bodies should focus on verifying whether results of day-by-day device, component or in-process tests match with the specifications defined by the manufacturer of the device. In addition, selective product testing over the entire product value chain can identify potential non-conformities in essential properties - from the raw material level, up to finished goods (e.g. biocompatibility, mechanical stability, sensitivity, specificity, etc.).

During the tests the focus is on relevant aspects of the product e.g. safety and performance as well as the most effective option where and how to perform those. Sample picking for testing outside the manufacturer's premises has to be minimized. In case there is an option to identify non-conformity at a preceding stage of the value chain, e.g. at the component level or at critical subcontractors, this option is the preference in order to save cost and effort.

Parameters	Who conducts Tests		Where*			What		
	Manufac-turer, NB witnessed	NB Test Engineer / 3rd Party	Manu-facturer's premises	critical subcon	NB's / 3rd Party Lab	Raw Mate-rial	Critical Compo-nents	De-vice
Medical Devices / AIMD / IVD	X	O	X	O	O	case dependant		
X = preferably: the preferred option for testing when needed								
O = conditional : alternative options in the event that the preferred testing is not sufficient.								
* = dependent on where technical equipment is available								

Table 1: Content and location of the tests

In case Notified Bodies are in charge of product assessments (either design examination or type test examination); see Appendix 1, paragraph 4) additional specific requirements to device sampling and technical file review apply.

Testing will be performed by the manufacturer at his premises and will be witnessed by the Notified Bodies. Typically, this will include witnessing the regular testing which the manufacturer performs before, during and after production.
Additionally testing could include critical components. The tests could include the preceding stage of the production process, e.g. raw material tests, assuming that the material is safety- and/or performance critical and objective evidence for conformity cannot be demonstrated by other means.
If tests require a specific preparation, such as a controlled test environment, special equipment and trained personnel to operate, the unannounced audit can be extended by another day to ensure proper installation of the equipment on day one and commissioning of the tests on day two. In addition to that, optionally critical subcontractors can be involved. The frequency of unannounced audits at critical subcontractors will be aligned with those as determined for the manufacturer in Chapter 4.).

In case the Notified Bodies do not have sufficient confidence in this 'witnessed regular testing' due to reasoned suspects and/or the manufacturer is not in a position to demonstrate product conformity, e.g. due to a lack of randomly used, special test equipment, tests could be done by qualified test engineers with accredited scope, either at NB's lab or at an accredited third party test lab. Testing will preferably be performed in the presence of a representative of the manufacturer and the NB.

4.) Frequency of unannounced audits

Notified Bodies conduct regular audits every year, normally within a 3 years audit cycle. Any of those regular audits delivers substantial information about the conformity of the manufacturer and could be used as a source to initially assess and regularly reassess the frequency of unannounced audits.
Commission Recommendation 2013/473/EU, Annex III, paragraph 1, states:
Notified bodies should carry out unannounced audits at least once every third year. Notified bodies should increase the frequency of unannounced audits if the devices bear a high risk, if the devices of the type in question are frequently non-compliant or if specific information provides reasons to suspect non-conformities of the devices or of their manufacturer. The timing of the unannounced audits should be unpredictable. As a general principle an unannounced audit should not take less than one day and should be executed by at least two auditors.

Due to the fact, that the degree of conformity of the manufacturer and the device is subject to variations, e.g. due to a process improvement, it is reasonable to assess the necessity for an additional unannounced audit beyond the one stated in the recommendation on a rolling basis. The approximate number of unannounced audits should be based on the following three factors:

a) the devices' classification (representing the devices' risk)
b) the devices' frequency of non-conformities
c) specific information to suspect non-conformities of the devices or of manufacturer's QM System.

The above identified aspects are described in the following in detail:

a.) Risk Level (from device classification)

Class I m, s
Class II a / IVD self-testing (under Annex IV)
Class II b / List B IVD
Class III / AIMD / List A IVD[7]

b.) Frequency of Non-Compliance determined by the NB with data from the manufacturer)

Depending on the Product category, the history of the products in the market and the numbers of units sold, the classification concerning the Frequency of Non-Compliance might differ. Therefore fixed ranges were avoided and default values are just rare or frequent.

Indicators for an evidence-based classification could be:

- post-market feedback that the Notified Bodies receive, such as vigilance cases or field safety corrective actions in an unusual high frequency
- complaint rates observed by the Notified Body during the regular audit schedule.
- non-conforming products in manufacturing observed during the regular audit schedule.
- Incidents with high severity

c.) Reasoned Suspicion

Specific indicators to suspect nonconformities of devices or the manufacturer's QMS could be:

- Any of the indicators listed in b.)
- Other input about possible malfunctioning devices or fraudulent manufacturers received especially through competent authorities or news media.

In conjunction with external or internal Notified Bodies' information and depending on the manufacturer's level of openness, transparency and willingness to cooperate during the regular audit, the Notified Bodies decide and document whether there is reasoned suspicion and decides, if an additional unannounced audit is necessary.

Table 2 gives the approximate number of unannounced audits in a 3-year period

Risk group	**Class I s, m**		**Class II a / IVD self testing (under Annex IV)**		**Class II b / List B IVD**		**Class III / AIMD / List A IVD**	
Reasoned Suspicion	none	yes	none	yes	none	yes	none	yes
Frequency of NC: Rare	1	2	1	2	1	2	1	2
Frequency of NC: Frequent	2	2	2	2	2	3	2	3

Table 2: Approximate number of Unannounced Audits per 3-year period

In case the product range of a Medical Device Manufacturer consists of more than one device type the denominators of unannounced audit frequency should be listed per device type and the worst case governs the approximate number of unannounced audits per 3-year period. *"Dimensional size variants should not be regarded as different types unless specific risks are linked to the dimension".*

Based on the acknowledged complexity and differences between manufacturers/ companies and product family risk, Notified Bodies shall share their strategy for unannounced audits (including modifications to audit frequency) with the manufacturer for discussion.

Appendix 1 - Requirements to Unannounced Audits[7]

1. *Notified bodies should carry out unannounced audits at least once every third year. Notified Bodies should increase the frequency of unannounced if*
    - *the devices bear a high risk,*
    - *the devices of the type in question are frequently non-compliant or if*
    - *specific information provide reasons to suspect non-conformities of the devices or of their manufacturer*

    The timing of the unannounced audit should be unpredictable. As a general principle an unannounced audit should not take less than one day and should be executed by at least two auditors.
2. *Notified Bodies may instead of or in addition to visiting the manufacturer, visit one of the premises of the manufacturer's critical subcontractor or crucial supplier if this is likely to ensure more efficient control. This applies in particular if the main part of the design development, manufacturing, testing or another crucial process is located with the subcontractor or supplier.*
3. *Within the context of such unannounced audits, the notified bodies should check a recently produced adequate sample, preferably a device taken from the ongoing manufacturing process, for its conformity with the technical documentation and with legal requirements. The check of the conformity of the device should include*
    - *verification of the traceability of all critical components and materials*
    - *verification of the manufacturer's traceability system.*
    - *file review*
    - *a test of the device, if necessary in order to establish the conformity*

    To prepare the test, notified bodies should request from the manufacturer all the relevant technical documentation including previous test protocols and results. The test should be undertaken in accordance with the testing procedure defined by the manufacturer in the technical documentation which has to be validated by the notified body. The test may also be performed by the manufacturer, its critical subcontractor or crucial supplier under observation of the notified body.
4. *Notified bodies in charge of product assessment[8] should, in addition to the steps foreseen in Sections 1, 2 and 3, sample devices belonging to at least three different device types and, where the manufacturer produces more than 99 device types, devices belonging to at least every hundredth type at the end of the production chain or in the manufacturer's warehouse with a view of testing the conformity of the device types. Variants containing a technical difference which might affect safety or performance of the device should be counted as a separate device type. Dimensional size variants should not be regarded as different types unless specific risks are linked to the dimension. These samples should be tested by*
    - *the notified bodies*
    - *or by qualified personnel under their observation*
    - *on their own premises, or*
    - *on the manufacturer's premises, or*
    - *on the premises of the manufacturer's critical subcontractor or crucial supplier or*
    - *in external laboratories.*

    Sampling criteria and testing procedures should be defined in advance. In particular if a sampling in the manufacturer's premises is not possible, notified bodies should take samples from the market, if necessary with support by the competent authorities, or should perform testing on a device installed at a customer location. To prepare the test, notified bodies should request from the manufacturer relevant technical documentation including final batch testing reports, previous test protocols and results.

[7] Commission Recommendation 2013/473/EU, main body of Annex III. Sometimes interpunction is added to enhance readability.

[8] In accordance with Commission Recommendation 2013/473/EU section 2 (a), product assessment includes design dossier examination and type testing.

5. *Notified bodies in charge of verifying the quality system of the manufacturer[9] should, in addition to the steps foreseen in Sections 1, 2 and 3, verify whether the manufacturing activity ongoing at the time of the unannounced audit is in line with the manufacturer's documentation relevant for the manufacturing activity and that both are in conformity with legal requirements. In addition, these notified bodies should check in more detail at least two critical processes such as*
    - *design control,*
    - *establishment of material specifications,*
    - *purchasing and control of incoming material or components,*
    - *assembling,*
    - *sterilisation,*
    - *batch-release,*
    - *packaging, or*
    - *product quality control.*

    Amongst the suitable critical processes, notified bodies should select one which has a high likelihood of non-conformity and one which is particularly safety relevant.

[9] In accordance with Commission Recommendation 2013/473/EU section 2 (b), quality system verification includes verification of the conformity of the quality system with the quality system related requirements contained in Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC for detecting non-compliances of the quality system and application of Annex II.