Preparing for unannounced EU NB inspections – are you ready?

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Unannounced visits from notified bodies are going to be part of life for medtech manufacturers in the EU. But do you know how you would cope if two inspectors walked through the door, expected your staff to host the visit and your testing equipment to be dedicated for their immediate use? Do you know what costs you would have to bear? Here, Gert Bos* and Françoise Schlemmer* of notified body association TEAM-NB explain why it is critical that manufacturers and subcontractors practice and validate protocols for hosting such visits

The long expected EU Commission Recommendation on the audits and assessments performed by notified bodies in the field of medical devices is due to be published on 24 September (after this *Clinica* issue has gone to press), together with the Commission Regulation on Designation of Notified Bodies.

Both documents can be seen as output of the immediate action plan initiated by former Commissioner Dalli following the PIP scandal. Consequently they will have a short transition period of only a few months. Whilst the recommendation includes detailed expectations on evaluation of technical files and design dossiers, regular conformity assessment audits as well as situations around own brand labelling, the most critical element of the document is seen as expected unannounced visits, that are to be added on top of the existing audit structure.

A commission recommendation is a new tool in the EU medical device world. Although it is gently phrased as a request to member states to use the details in identifying their expectations on notified bodies, effectively it can be seen as soft legislation, with a significant legal status. At this stage most of the member states have already confirmed they will endorse the document and follow it as part of their duty to oversee the work of their notified bodies.

Moreover, in support of that effort and, as requested by individual member states, a number of unannounced visits have been performed during the last year.

First levels of harmonization in TEAM-NB's Code of Conduct

As the transition period is short, notified bodies have started to discuss the requirements identified in earlier drafts of the recommendation document in an attempt to harmonize interpretation and implementation prior to the document being published.

The discussions have resulted in a common interpretation that has been provisionally included in the TEAM-NB Code of Conduct, freely available from the association's website at www.team-nb.org; this interpretation will be formalized after the commission's publication of the recommendation.

During the association's upcoming meeting in mid-October it is anticipated that any fine-tuning needed to the provisions once the recommendation has been finalized will result in a revision of the Code of Conduct, to fully match the details of the recommendation. Questions to notified bodies on the topic can be posted on the association's website.

The unannounced visits identified in the document are literally that: visits that are not announced, so a notified body will knock on the door of a manufacturer to whom they have issued CE certificates, or at the premises of their critical subcontractors. But the expectation is also that in addition to being unannounced, they will be unpredictable, which increases the challenges of scheduling them. Such audits will take at least one day and will be performed by at least two auditors.

Frequency dependent on risk and non-compliance factors

The anticipation is that notified bodies will carry out unannounced audits at least once every third year as a basis, unless there are reasons to visit at shorter intervals. The document clearly identifies that notified bodies should increase the frequency of unannounced audits if:

* the devices bear a high risk;
* if the devices of the respective type are frequently non-compliant; or
* if specific information provides reasons to suspect non-conformities of the devices or of their manufacturer.

The code of conduct provides details on how notified bodies should take the above elements into consideration when defining a suitable frequency. It says that, until alternative methods to define higher risk become available, devices that will be perceived as having a high risk if they fall into the highest risk class of the EU medical device directives.

If the following were discovered during regular assessments or audits, they would be indication for future increased unannounced visit frequency:

- concerning post-market feedback that the notified body receives, such as vigilance cases in an unusual high frequency;
- very high complaint rates observed during the regular audit

schedule; and
- very high non-conforming products in manufacturing observed during the regular audit schedule.

As for specific reasons for suspicion of non-conformities of the devices or manufacturer, this could be based on any of the selection criteria above or, for example, other input received through regulatory authorities or news media about possible malfunctioning devices or fraudulence.

The recommendation does not go into detail as to what circumstances should give rise to increased frequency of audits so this matter will need to be further analyzed when the system has been live for a period, and case examples will become available.

As indicated above, notified bodies may visit premises of critical subcontractors or crucial suppliers if this is likely to provide more pertinent information. In most cases that scenario will be more likely if the main part of design and development, manufacturing, testing or another crucial process such as sterilization is outsourced.

The audits will have a product as well as a production focus. Recently manufactured products will be verified in conformity with the technical documentation and with legal requirements. Such evaluation can also be done with products that are being manufactured or are undergoing quality testing during the audit.

On top of a file review and comparison, the auditors may request specific tests to be performed by the manufacturer during the audit. Such ad hoc tests witnessed by the auditor, as well as tests performed outside of the audit by or on behalf of the notified body, will be undertaken in accordance with testing procedure defined by the manufacturer in the technical documentation or the quality management system.

The check on the conformity of the device should include verification of traceability of critical components and materials used in the production of the device.

The recommendation will include a sampling plan for testing of high-risk devices, based on numbers of different device types and a detailed assessment of the sampling plan requirements is foreseen following the release of the final wording of the Commission Recommendation. Much debate went into the matter, as it will have serious implications on the focus and duration of the audits. The test plans will consider the effect of variants as well. Test plans procedures will be prepared by notified bodies prior to scheduling unannounced visits. In case sampling in the manufacturer's premises is not possible, notified bodies will have to revert to other means of accessing the products.

As for the functioning of the quality management system, notified bodies are expected, during the unannounced visits, to verify at least two critical processes among processes such as: design control; establishment of material specifications; purchasing and control of incoming material or components; assembling; software validation; sterilization; batch-release; packaging;, or product quality control. Amongst the suitable critical processes, the notified body is expected to select one process which has a high likelihood of non-conformity and one which has particular relevance towards safety.

Where needed, notified bodies have been changing the details of their contracts, or terms and conditions. This is to prepare for these upcoming unannounced visits, which are anticipated to start early in the new year, to allow for such events to take place. And as visits might well take place at critical subcontractors, contracts between manufacturers and subcontractors might need similar revisions as well.

The recommendation identifies that all costs for the unannounced visits will be borne by the manufacturer whose CE-marked devices are being inspected. The same is true for costs of device acquisition and testing of devices linked to the inspections. In certain parts of the world that are perhaps unstable politically or where temperatures can fall to extremely low levels, manufacturers currently provide auditors conducting regular inspections with protection measures such as driving them between their hotel and the manufacturing facility or transporting them in special vehicles that can withstand extremely cold weather. When conducting unannounced inspections, the auditors themselves will be able to hire the necessary bodyguards or special vehicles..

Preparation will be key to success

As the system of unannounced visits is essentially different form the well planned pre-scheduled audits, thorough preparation of manufacturers to host such visits will be key to the continued certification of their devices. These audits will disrupt scheduled work, as immediately a number of staff will need to be freed to host the multiple auditor visits, without any delay in the audit being conducted. Protocols will need to be prepared to call in support and escalate to relevant management in case the audit team reports at the front desk. Access to production and warehouse will need to be granted, where procedures on guides to the auditors will need to be initiated immediately. Planned work of essential staff will need to be rescheduled, copies of design dossiers and test protocols to be readily available, test equipment to be used might have to be freed up from planned other testing to support the test plan identified by the audit team.

Critical will also be to ensure at all times critical staff can be available in short time, or replacements identified and brought in place. And if production continues overnight or during the weekend, visit at such times should be anticipated as well. Most difficult to prepare for are the unannounced visits to subcontractors. Clearly at the time of changing subcontractor contracts, the anticipation of unannounced visits should be discussed in such detail that the manufacturer can anticipate the visit to be as smooth as when conducted in their own premises.

Restoring trust in the device world

As the smooth running of audits will help create an environment of transparency within which the audit team can best work, it is recommended that protocols on hosting unannounced visits are practiced and validated. That way the joint operators in the medical device chain will be able to successfully embed this new element of working into their day to day business. And with that, the device industry will be able to improve its reputation towards the public recovering from the effects of the various scandals that occurred in the recent past.

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