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EU Notified Body Association Takes Steps To Allay EC's Virtual Audit Fears

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Executive Summary
The European Commission has reluctantly allowed virtual audits in the context of new MDR and IVDR. The EU notified body association is helping the collective effort to meet its strict requirements.

TEAM-NB, the EU notified body association, has confirmed that it is drafting a consensus paper to support notified bodies approach their designating authorities with consistent risk assessment criteria for planning remote audits.

The draft is currently in the process of voting among Team-NB and NBCG-Med members with the aim of to finalizing it, Francoise Schlemmer, director of TEAM-NB told Medtech Insight. (NBCG-Med is a body, which among other roles, drafts notified body technical recommendations and creates consensus on matters relating to conformity assessment.)

The TEAM-NB consensus paper will be published once the voting is complete, Schlemmer said, adding that this should be before the end of January.

European Commission's Strict Conditions
The position paper is a response to a recent European Commission notice which allows notified bodies to temporarily deviate, where fully justified, from the Medical Device and IVD Regulations' rules for notified body audits of manufacturers' quality management systems (QMSs) to take place on site.

The majority of audits taking place under the MDR and IVDR are initial audits which are banned under EU law.

While the commission is allowing remote/virtual audits for now in the context of the COVID-19 pandemic, travel restrictions and social-distancing, the notice makes it clear that this is a temporary emergency measure and it is accompanied by a list of conditions to which notified bodies must adhere.

The commission has been very reluctant to allow virtual audits in the framework of the new Regulations, and TEAM-NB's response should help address, at least to some extent, the commission's concerns, by ensuring that notified bodies act consistently in applying risk assessment criteria for these remote audits.

What Notice Says About Risk Assessment
In its notice, the commission says that the designating authorities responsible for notified bodies should ensure that notified bodies, when carrying out their audits and assessments, always act responsibly and apply a risk-based approach.

This approach, it says, requires these authorities to confirm notified bodies always perform a careful review of the manufacturer's technical documentation relating to the status and operations concerning the audits and devices in question.

The activities conducted at the site to be audited, the manufacturer's quality management system

and, where applicable, the level of compliance from previous audits should be taken into due account by the notified bodies. Following this review, a risk analysis should be conducted by the notified bodies, and the results documented and duly substantiated.

It adds that no decision that could jeopardize the technical or clinical validity of a specific activity or the safety and performance of devices should be taken.

Harmonization "Will Never Reach 100%"

Based on the risk assessment of the intended audit, the notified body's planned activity should be classified according to its risk level, Schlemmer noted.

The TEAM-NB director explained that "the legal context is difficult, therefore a certain level of harmonization across member states is necessary." She added: "We respect the fact that this harmonization will never reach 100%."

In writing the position paper, the association's aim is to fully and effectively support the notice's goal to ensure continuous availability of safe and performant medical devices/IVDs, and to help prevent shortages.