Onsite or offsite audits? That's the question.

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On January 11, 2021, the EU Commission has published a notice in the Official Journal of the EU on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system (QMS) assessment.

These sections in the Regulations are relevant for manufacturers and Notified Bodies, as they lay down QMS requirements, that need to be assessed by a Notified Body as part of the conformity assessment procedure conform Article 52 of the MDR and Article 48 of the IVDR. As clarified in this notice, the audits by the Notified body need to be performed "on the manufacturer's premises".

The publication of this notice provides the industry and the Notified Bodies the strongly needed options to proceed with the activities towards implementation of MDR and IVDR requirements. This is for the benefit of the patients, as without this option, and Covid-19 still not being under control, availability of medical device and in-vitro diagnostics will be seriously affected.

There are however some items that require special attention, as not all is automatically ready and up and running by publication of this notice. So, let's take a closer look.

As regulatory professionals are aware of, control over the activities of Notified Bodies is with their Competent Authority. The notice identified the options the Competent Authorities have under the MDR and IVDR to penalize non-compliances with requirements.

From this starting point, the notice describes the extraordinary situation that did arise due to Covid-19, hindering Notified Bodies to perform the audits properly, e.g. on the premises of the manufacturer (or its suppliers and/or subcontractors). As a consequence, MDR certification cannot proceed resulting in a decline of available devices on the EU market. This threat of insufficient medical device availability resulted in a strong request for a solution by the industry and Notified Bodies. This need was recognized by the MDCG and was also supported by a majority (but not all) of the Member States.

Based on the principle of proportionality, the EU Commission further removed the obligations for penalties for the situation that Notified Bodies are not performing onsite audits at the premises. The regulators consider this situation, in several sections in their notice, to be a "temporarily allowed non-compliance situation". This will effectively allow Notified Bodies to continue their MDR assessments, by introducing the options for online / offsite audits, as they have been doing the last months for MDD/IVDD related audit activities.

Of course, there are very strict conditions identified under which the offsite audits can take place. This non-compliance situation should, for example, last as short as possible, and only when onsite audits are not possible due to Covid-19. Also, the Notified Body will need to assess and justify this non-compliance on a case to case basis. Finally, the Notified Body shall not go beyond what is required to ensure continuous availability of safe and performant devices. In other words, a process will need to be established by each Notified Body on how to document that justification of performing the required audit "not on the premises".

How should that process work? Well, also there more information is provided in the notice: It should be risk based! Practically that means that an assessment must be documented on e.g. what devices are involved, what activities are performed at the to be audited site, what the track record is from previous audits, planning and amount of days for onsite follow-up audits. Based on that information, the Notified Body will need to justify the performance of the offsite audit. All these activities will needed to be documented and shall be available to the authorities.

Then there are tasks defined for the Competent Authorities on controlling these activities, all to ensure safe and functional devices remain / will be introduced in the market. Whatever measures their Notified Body(ies) take, all will be communicated to the EU commission, including the impact on the period of time of validity of certificates (expiry dates).

Although this notice is good news, some potential bottlenecks can be derived from the provided information. First, will there be coordination and consensus between Competent Authorities on the criteria for an acceptable justification? As stated in the notice apparently not all Competent Authorities were in favor.

Secondly, as the non-conforming situation of performing offsite audits is linked to the local Covid-19 situations, there might be differences in local governmental Covid-19 restrictions, resulting in some Notified Bodies going back to onsite audits, while others can't yet. Let's see how that develops.

Lastly, for start-ups in the industry, the Covid-19 situation raises extra hurdles: hose looking for clinical trial data are severely hampered by studies not starting. They were already hindered by fully booked Notified Bodies not accepting new customers, and the lucky ones, getting their contract, do not have an audit track record yet. How could such cases become valid criteria for allowing an offsite audit?

For those who are interested in the follow-up: Team-NB will be publishing a guidance shortly with further detailing on the implementation of the notice.

Nevertheless, having the EU Commission publishing this notice demonstrates that they listened to concerns raised by the stakeholders. This can only be seen as a positive signal to all stakeholders. With the notice published, let all parties now focus on our joint responsibility and rolling plan to guarantee patient access to medical devices!

About the Author

I am a principal consultant in the medical device industry with a vast experience in EU and USA regulations. After 8 years in the medical device industry in R&D and manufacturing, I worked more than 7 years at Notified Body KEMA Quality / DEKRA. As Sr. Project manager and account manager I was responsible for quality system audits and dossier reviews under EU Medical Device regulations. Additionally, as product expert FDA 510(k) 3rd party accreditation program, I was responsible for the internal review process and performed file reviews myself, including contacts with the FDA. Over the years, my client database developed to include large accounts and small startup companies in the technology

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