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# Commission Allows Virtual MDR and IVDR Audits – Under Strict Conditions

by Amanda Maxwell

Notified bodies may temporarily deviate, where fully justified, from the MDR and IVDR rules for notified body audits of manufacturers' QMS to take place on site. Vital audits can now go ahead.

The European Commission has published *an official Notice* allowing notified bodies to conduct initial audits of medical device quality management systems (QMS) virtually. This applies not only to products that fall under the Medical Device Regulation but also those under the IVD Regulation.

The Commission says these are "temporary extraordinary measures taken in response to the exceptional circumstances of the COVID-19" which should only be used until on-site audits are again possible.

There is now a great deal of pent up demand for these audits so manufacturers who require initial audits should contact their notified bodies to see how soon their products can be prioritized.

The new rule applies also to audits of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.

## EU Rules To Date

Most audits can go ahead virtually for products covered by the current medical device directives (see below), but both the MDR and the IVDR effectively ban virtual audits.

Moreover, the commission published its guidance document, MDCG 2020-4, in April 2020 at the beginning of the pandemic clarifying that that alternatives on-site audits were not allowed in the case of:

- Initial certification audits;
- Unannounced audits; or
- In some other specific instances, such as the verification of specific corrective actions.

Since all audits under the MDR and IVDR are made for these specific reasons, this has halted work towards compliance with the new regulations.

## Lobbying The Commission

Industry has been lobbying hard for a change in its stance since the COVID-19 pandemic started. It has been arguing that otherwise products may miss the 25 May MDR full application date deadline and need to be removed from the market.

But up until summer, the feedback "did not provide evidence that there would be a shortage of devices on the market," according to commission's Maired Finuncane *when she spoke at Informa Connect's virtual MedTech Summit in October*. Finucane is project lead and inspector for joint assessments of notified bodies (medical devices).

The position taken by the commission's Medical Device Coordination Group (MDCG), along with member state support at the meetings in October and December 2020, helped to sway the commission.

In its 11 January notice, the commission now recognizes how COVID-19 and the short-term forecast makes "the situation more serious and increases the need to possibly take temporary extraordinary measures in specific cases when the inability of notified bodies to conduct on-site audits could raise the risk of shortages of vital devices."

## Notified Bodies Overcome Commission Resistance

Notified bodies also helped influence the outcome. Not only had manufacturers been warning that the one-year delay to the MDR date of application to 26 May this year would not be enough time if virtual audits were not allowed, notified bodies were warning that that their workload pushed further down the line, resulting in major bottlenecks over the next few years if the work is not more evenly spread.

In a bid to persuade the commission to update its guidance, notified bodies had been filling in surveys to show the commission and competent authorities how robust virtual audits are, and how many times they had been witnessed by authorities. These were a key factor in the outcome.

## Commission Not Entirely Convinced

The EU is already some 10 months into managing the COVID-19 pandemic, and the commission has long resisted allowing virtual initial audits.

Back in October, Medtech Insight reported that it was starting to waver as demand build up for it to allow initial virtual audits. It has taken nearly three months for it to bow to this pressure. (Also see "*Permitting Initial Virtual Audits Under The MDR: Commission Decision Hangs In The Balance*" - Medtech Insight, 19 Oct, 2020.)

So, it will come as no surprise to hear that the commission sets many conditions in its notice limiting the circumstances under which these audits can be performed.

It even voices that it is not entirely convinced how necessary these new measures are. The EU body makes it clear that its decision has been a knife-edge one that brings with it new responsibilities for monitoring and oversight.

“Given the difficulties to fully quantify the extent of the problem in advance,” the commission states in its notice, “namely the need to recourse to extraordinary temporary measures in order to ensure continuous availability of devices and prevent the potential risk of shortages, it is vital to carefully follow how these measures are applied in practice.”

It is therefore calling on all member states to systematically notify the use of these “temporary extraordinary measures” and submit information (presumably to the commission, although this is not clear in the notice), about:

- Virtual audits conducted by individual notified bodies, including for surveillance assessment purposes, along with information to justify the use of such measures;
- Identification of the notified body, the types of devices affected, and the manufacturers;
- The period of time for which certificates issued by notified bodies in accordance with these measures will be affected by non-compliant procedures concerning audits not performed on site.

## Virtual Audits Under Medical Device Directives

While virtual audits have been banned under the MDR and IVDR in the case of initial and unannounced audits, and in instances such as the verification of specific corrective actions, the *MDCG 2020-4* guidance clarified the following rules for virtual audits under the medical device directives that currently apply.

In general, initial certification audits, or audits to extend the scope of certification under the Directives, should not be performed using these temporary extraordinary measures. However, the guidance says notified bodies may apply these extraordinary measures on a case-by-case basis for such audits in cases where devices are considered relevant to ensure medical care, especially if clinically necessary during the period of COVID-19 restrictions.

This means that alternatives to on-site audits could be carried out as part of the medical device conformity assessment in the following cases:

- Surveillance audits under the medical device directives;
- Audits conducted for re-certification purposes under the medical device directives;
- In cases where a manufacturer submits a change notification to a notified body that would typically require on-site audit or verification; and
- In cases where a manufacturer terminates (voluntarily or involuntarily) its contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device(s).

Where alternatives to on-site audits are performed, notified bodies should have documented procedures detailing the alternative temporary measures and define criteria for implementing such measures (e.g. a procedure for “force majeure”). They should examine the viability of alternatives to on-site audits on a case-by-case basis and carry out a risk assessment. They should also consider the manufacturer’s compliance record.

They should consider technologies to be used during such audits and address the impact of the alternative measures on the audit duration.