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Philips, Hamilton Medical To FDA: QMSR Shouldn't Subject Devices To ISO Traceability Requirements

by Shawn M. Schmitt

The makers of breathing machines said in comments to the US agency that it must address language in its draft Quality Management System Regulation that the companies say would place onerous traceability requirements on most medical devices.

Two makers of breathing machines have told the US Food and Drug Administration that it must address language in its draft Quality Management System Regulation (QMSR) that the manufacturers say would place onerous traceability requirements on most medical devices.

24 May is the deadline for commenting on the proposed QMSR, which will replace the FDA's Quality System Regulation. The QSR has been the bedrock rule for making safe and effective devices in the US since the mid-1990s. The QMSR is a result of the agency's years-long work harmonizing the QSR with international quality systems standard ISO 13485:2016. (Also see "*10 Things You Need To Know About FDA's Proposed Quality Management System Regulation*" - Medtech Insight, 23 Feb, 2022.)

The draft QMSR says in Sec. 810.10 (d) that companies that make devices that "support or sustain life … must comply with the requirements in Traceability for Implantable Devices, Clause 7.5.9.2 in ISO 13485."

That clause, "Particular requirements for implantable medical devices," says required records for traceability include "records of components, materials and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements."

Clause 7.5.9.2 also says "suppliers of distribution services or distributors" must "maintain

records of the distribution of medical devices," among other requirements.

In 18 May comments to the FDA, *Philips*' head of global regulations and standards, Elisabeth George, said the agency should strike from the final QMSR Sec. 810.10(d), as "we do not believe it is the intent of FDA to extend the 7.5.9.2 to all medical devices." Her comments can be found *here* and *here*.

Sec. 810.10(d) "presents a significant issue that could impact ventilators and perhaps other products. In particular, those which incorporate OTS [off-the-shelf] technology such as embedded PCs," George wrote in her letter.

An embedded PC is a computer system that forms part of a larger machine or system.

Meanwhile, the product manager for Hamilton Medical, Matthias Himmelstoss, *wrote in March comments to the FDA* that QMSR Sec. 810.10(d) would create a "risk of unmanageable workload." He also said it wasn't necessary.

"Mechanical ventilators must be regarded as life-supporting or -sustaining devices, and they are constructed out of hundreds of parts – namely, they are monitored and controlled by a special software, which also has to comply to high-standard requirements," Himmelstoss wrote. "But next to built-in software, every part of a ventilator is evaluated in terms of its risk to fail and endanger a patient. This is required e.g. by IEC 60601-1 and related standards."

The international standard *IEC 60601-1* is "Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance."

He noted that "by European law, manufacturers are furthermore required to trend and document all incidents and report this trend analysis to the authorities (Article 88, Regulation (EU) 2017/745)."

Himmelstoss concluded by suggesting that "for non-implantable devices, the process of trend reporting as described in the European regulation is sufficient."

Philips Wants 2 Years For Rule Transition

The letter from Philips' George also urged the agency to rethink its proposed one-year transition time frame for companies to switch from the QSR to the QMSR.

In her letter George proposes "at least two years allowed from the time that the FDA issues this rule and all associated guidance have been updated."

> *"Companies that don't have 13485 certifications will need more time." – Elisabeth George*

The director of the FDA's device center, Jeff Shuren, said earlier this month that the agency thought one year for transition "was enough time" when it was included in the draft QMSR. (Also see "*'If You Know The Answer, Let Me Know': FDA's Shuren Mum On 1 Year Transition For Coming QMSR Reg*" - Medtech Insight, 4 May, 2022.)

Industry advocacy groups including AdvaMed and the Medical Imaging & Technology Alliance told the FDA at a March public meeting on the QMSR that one year wouldn't give some device makers enough time to make the rule switch. Even the convener of the International Organization for Standardization (ISO) working group that oversees ISO 13485 told the agency at the time that some companies, big and small, will need at least an extra year. (Also see "*Industry To FDA: 1 Year Isn't Enough Time To Transition To New QMSR Rule*" - Medtech Insight, 2 Mar, 2022.)

"Companies that don't have 13485 certifications will need more time. And the activities will be easier if all associated FDA guidance documents have appropriate linkages," George wrote. The "timing seems appropriate for those manufacturers that already have compliance to ISO 13485 in place; however, I am concerned that it may be a challenge for small domestic-only establishments."