FDA Releases Important MDDDS Rule

In a move with potentially far-reaching implications for hospitals and other healthcare facilities, the U.S. Food and Drug Administration (FDA) has issued a final rule dealing with the regulation of medical device data systems (MDDS).

The rule reclassifies these products as Class I or low-risk devices, which exempts them from premarket review while still subjecting them to quality systems and design control requirements. But, what’s key is that FDA says that any healthcare facility that creates or modifies an MDDS “becomes a manufacturer under the MDDS rule” and is subject to “applicable device regulations.”

Experts say this is noteworthy.

“Hospitals will have to seriously rethink their current approach to acquiring, installing, and modifying new technologies, and take responsibility for their proper functioning,” says Rick Hampton, wireless manager for Massachusetts General Hospital in Boston, MA.

FDA released its rule on Feb. 14 on the regulation of MDDS, which the agency defines as “hardware or software products used alone or in combination that display unaltered medical device data, or transfer, store or convert medical device data for future use.” MDDS products were automatically considered Class III, or high-risk devices. As Class I products, they are subject to less rigorous regulations, but hospitals may wind up

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Implementing IEC 80001 . . .

Expert Sees Role for Manufacturers in New Standard

For manufacturers, their job concerning risk management is usually complete after the product goes to market. But the new standard for the risk management of information technology (IT) networks that incorporate medical devices—IEC 80001—may change that.

The standard calls for manufacturers to give more information—such as a device’s technical specifications for connecting to a network, the intended information flow, and potential hazardous scenarios that could occur from hooking up the device to a network—to hospitals and healthcare facilities.

“One of the key changes for manufacturers is they are now involved in risk management during the use of the product, not just prior to putting it on the market,” said Sherman Eagles, the president of Software CPR, a consulting firm based in Boston. Eagles spoke during an AAMI webinar earlier this winter on understanding 80001, which was adopted by AAMI.

Some manufacturers have been studying 80001 to see how it will affect their process. Elaine Walton, with Sotera Wireless, said that the standard won’t have a large impact.

“We have to generate the basic specifications and risk analysis for our product prior to putting it on the market,” she said.
facing more FDA scrutiny with any modified use of an MDDS.

“The definition of an MDDS describes several systems currently in use in just about every hospital and clinic, many of them developed in-house,” says Hampton.

Agency officials describe the MDDS reclassification as one that would provide a more predictable path to market for manufacturers.

“This rule is a common-sense regulatory approach that provides clarity and predictability for manufacturers of these data systems,” says Jeffrey Shuren, director of FDA’s Center or Devices and Radiological Health.

FDA expects all MDDS manufacturers, including hospitals that modify or create such systems, to establish a compliant quality system and medical device reporting (MDR) system for their devices by Feb. 14, 2012. The rule won’t apply to any devices already on the market unless the manufacturer wants to change the design, according to the rule.

A quality system includes design controls, which is the process a manufacturer uses to design a device, and a risk analysis to ensure the device is safe. The MDR is used to report problems with the device to FDA.

One engineering expert says that the installment of a quality system shouldn’t necessarily be a great burden for hospitals that design their own systems. “Almost all of the quality system is simply good engineering,” says William Hyman, a professor of biomedical engineering at Texas A&M University in eastern Texas. “It is hard to argue or find elements of the quality system that you shouldn’t have to do, that are all burden and no value.”

The burden might come from creating the documentation to satisfy FDA’s requirements, Hyman adds. “I think you can be a quality organization that is doing essentially all of the same things as a quality system, but you still have to demonstrate you are compliant.”

Hospitals will also have to rethink some of their existing policies, namely for risk management. This is where the new standard IEC 80001 can help, says Hampton. The standard addresses the risk management of networks that incorporate medical devices.

“While 80001 doesn’t address all aspects of the quality system and MDR requirements, it does cover many of them,” says Hampton, who helped develop the standard.

A Narrow Definition

While the reclassification from Class III to Class I brings a lower level of regulatory scrutiny, some similar products might not meet FDA’s new definition.

“The definition of MDDS is very specific, and arguably quite narrow,” says Hyman. “There are still a lot of products in this data movement arena that are not MDDS. Therefore they either remain Class III or are something uncertain.”

The FDA rule reads: “An MDDS by itself does not control the functions or parameters of any other medical device. This device is not intended to provide or be used in connection with active patient monitoring.”

FDA says it decided to reclassify MDDS products because they don’t have any new or unique functions, and that controls under Class I are appropriate to ensure safe devices are put on the market.

Hyman says that MDDS manufacturers shouldn’t be too surprised about the final rule, noting that FDA released the proposed rule in February 2008. “If you were ignorant of or otherwise ignoring FDA general requirements then you will have to hustle to come into compliance,” he says. “If you were paying attention, you can’t be surprised.”