

# U.S. FDA Seeks Research for Medical Device Tracking System

The organization's Center for Devices and Radiological Health is requesting input from RFID vendors and end users regarding the effects RFID has on other transmissions in a hospital setting, and on the devices themselves.

By Claire Swedberg

April 23, 2008—The U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH) says it hopes to issue draft specifications by the end of 2008 for a nationwide system that could be employed to identify individual medical devices and supplies, and to make it easier to locate and recall such items.

As it prepares its recommendations, the FDA is now seeking input from the RFID industry, and from end users that have piloted RFID systems in the health-care market, as to the effects the technology has on other transmissions in a hospital setting, and on the devices themselves. That's what Ann Ferriter, issue manager for the CDRH, told attendees last week's RFID Journal LIVE! 2008 conference in Las Vegas.

Almost two years ago, the FDA began investigating how a unique device identification (UDI) system might help automate the collection of information, including the manufacturer, make and model, unique attributes, serial numbers, identifying lot and manufacturing numbers, and expiration dates (see FDA Seeks ID System for Medical Devices and Supplies). In August 2006, it issued a notice seeking comments from the device industry, health-care facilities and device users regarding the current use of UDI systems, the need for a comprehensive, standardized UDI system, what FDA's role should be in the development of such a system and the potential costs and benefits.

At the conclusion of the three-month comment period, the FDA had hoped to draft specifications in early 2007 and put them out for public review and comment, but the agency ultimately failed to meet that goal. The U.S. Congress put additional pressure on the FDA seven months ago by ordering it to establish such a system, but did not specify a deadline (see FDA Works on Draft ID System for Medical Devices, Supplies).

Last week, Ferriter told RFID Journal LIVE! attendees that the CDRH is now seeking research indicating whether there is any RF interference or health risk that could occur from the use of RFID technology in hospitals or other health-care settings. The CDHR, she said, hopes to further examine the potential risks related to RFID use around medical equipment.

The agency is presently studying whether RFID equipment operating at 134.2 KHz, 13.56 MHz, 433.5-434.5 MHz, 902-918 MHz or 2.4 GHz could pose a risk to other electronics in a health-care environment. Ferriter cited pacemakers, which cannot necessarily differentiate between the pulse of an RFID reader and a heartbeat. "We haven't seen any cases of RFID interfering," she said. Other RF-sensitive devices might include infusion pumps, hearing aids, defibrillators and programmable heart valves.

The FDA recognizes the benefits RFID provides the health-care industry in the areas of tracking and visibility, Ferriter said. However, she added, her organization would like to see more studies, particularly those focusing on the use of 13.56 MHz wristbands in hospitals. Addressing the RFID industry, she stated, "I think you do a tremendous amount of research," and appealed to attendees to share their findings with the FDA.

Currently, there is no specific tracking system or serialized identification of medical devices in the United States, says Jay Crowley, senior advisor for patient safety at the CDRH. While prescription drugs are labeled with identification numbers indicating product type, medical devices are not. What's more, the FDA is investigating a pedigree system for pharmaceuticals that would require the drugs' history to include every point along the supply chain (see [All Eyes on FDA for Drug E-Pedigree](#)).

Counterfeiting is a critical concern for prescription drugs, Crowley says. There have also been cases of counterfeiting high-value medical devices, he notes, but such cases are much less common. The greater concern, according to Crowley, is having the ability to quickly identify the location of specific devices in the case of recall. With pharmaceuticals, because the medications carry serial numbers, the FDA can trace the location of a medication that needs to be recalled. "With medical devices, that clarity just doesn't exist," he says.

The FDA may eventually consider the implementation of a similar pedigree system for medical devices, but not in the current plan being drafted. Instead, the agency wants the ability to locate specific items in the event of a recall, and to ascertain an item's manufacturing and expiration dates. "At this point," Crowley says, "we are trying to put the foundation into place. So when it comes time to put a pedigree in place, we'd have a foundation to build on."

To date, Crowley states, no country has a nationwide system for tracking medical devices, though many are looking into such a system in conjunction with the FDA. The agency is currently working with Japan, China, the European Union and several countries in South America to develop a harmonized system with serial numbers that could be recognized internationally.

RELATED\_ARTICLES At present, Crowley says, the FDA is still studying the medical device market itself. "We are trying to address issues such as what an identifying system would look like, how it would work, getting an understanding of supply chain issues." The identification system, he notes, could cover everything from a box of rubber gloves to \$30,000 stents, while the tracking requirements and the technology used to conduct that tracking could vary depending on the item.

"There are a lot of device types that could or should have RFID [technology for tracking]," Crowley explains. However, bar coding is also being considered. "We would like to remain as technology-neutral as we can," he says, though he expects the FDA to recommend a human-readable label with the ID number encoded electronically as well.

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