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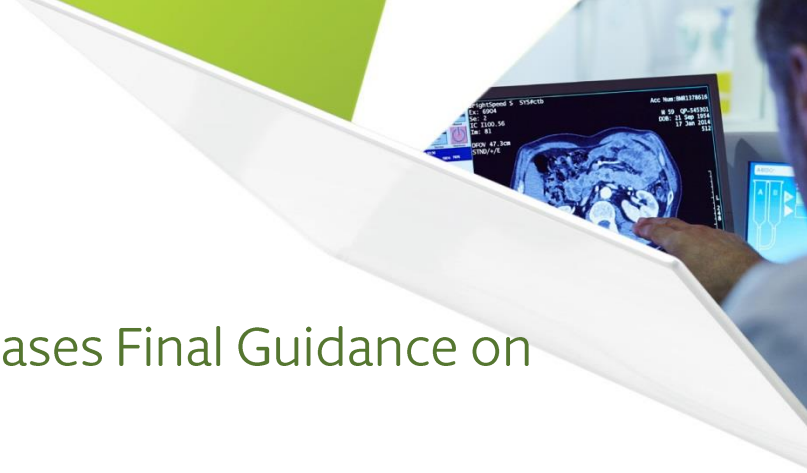

Working Together: FDA Releases Final Guidance on Interoperability

October 3, 2017

On September 6, 2017, the Food and Drug Administration (FDA or the Agency) released its final guidance document, Design Considerations and Pre-Market Submission Recommendations for Interoperable Medical Devices (Final Guidance). The guidance comes at a time when interoperability of medical systems, particularly in a healthcare institution environment, is increasingly important from safety and cybersecurity standpoints. As companies grapple with proactively addressing interoperability challenges, FDA's latest guidance serves as one more resource and guidepost for regulated industry.

The Final Guidance represents FDA's current recommendations for the design, development, and marketing of interoperable medical devices (i.e., those devices that share data and information with other devices and systems). The guidance includes recommendations regarding design considerations, risk management and testing, as well as the content of premarket submissions and device labeling. Like the Draft Guidance,[1] the Final Guidance reflects current FDA practice with respect to requests for information for interoperable medical devices, with a particular emphasis on transparency of information pertaining to the performance and interface characteristics of the interoperable device.

Below we've highlighted several of the key points from the final guidance document.

Design Considerations

The Final Guidance contains much of the same design considerations as the Draft Guidance, with some additional clarification in the following areas:

— Device Purpose and Design. The Agency encourages companies to design their devices with interoperability as an objective but also recognizes that different types of electronic interfaces will require different design considerations, e.g., an interface that delivers electrical pulse for synchronization purposes will have different requirements from an interface that delivers information to an information system. Factors to consider in the design of the interoperable device include the types of devices connected; the type of data exchanged; the use of standards; the need for time synchronization; the method of data transmission, requirements relating to the

[1] See https://www.hoganlovells.com/en/publications/fda-offers-new-recommendations-for-interoperability-of-connected-devices.

transmission of metadata; any contraindications, warnings, or precautions regarding the use of the exchanged information; and any functional or performance requirements.

— Anticipated Users. As in the Draft Guidance, the Agency recommends that companies identify potential users and evaluate how those users will interact with the system. Different types of users may require different information to safely and effectively use the electronic interface and, thus, companies should consider developing instructions specific to different users' needs. Such users are not limited to clinical users or IT professionals, but may also include patients, who may need specific instructions for use of the device in a home setting.

— Risk Management. Consistent with the Agency's trend in other areas of medical device regulation, the Agency emphasizes the importance of risk assessment to evaluate possible error scenarios as well as foreseeable uses and misuses. Although FDA recognizes that medical device interoperability is a shared risk among various stakeholders such as patients and healthcare facilities, it recommends that companies have a defined, systematic process for continuing to evaluate hazards and associated risks on an ongoing basis throughout the lifecycle of the device. Further, the final guidance emphasizes that even under fault conditions; the device should be designed to maintain basic safety and essential performance. The Final Guidance also adds multiple references to the FDA's premarket cybersecurity guidance as part of recognizing how security safeguards may interact (or even create tension) with interoperability aims.

— Consensus Standards. The Final Guidance places additional emphasis on use of consensus standards, noting that companies should consider consensus standards and should verify and validate that the design meets relevant standards in both intent and scope. FDA continues to evaluate standards and maintains a list of standards recognized by the Agency on its website. Of interest, separately from this guidance, FDA recently recognized AAMI TIR69: 2017 Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems and IEEE/ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence, thereby providing helpful guidance to companies on evaluating the coexistence of device with radiofrequency (RF) emissions. Thus, companies choosing wireless technologies to achieve interoperability may consider use of this testing standard.

Verification and Validation

While not a new concept, FDA continues to acknowledge that the appropriate level of testing will necessarily vary depending on the risks presented, but testing should be sufficient to demonstrate that the electronic interface performs as intended given its purpose and specifications. Specifically, such testing should simulate real-world use of the device and also assure that reasonably foreseeable interactions do not cause malfunctions in other networked systems. Depending on the way in which the device is intended to be used and the environment of use, this may require cooperation with others to prepare testing scenarios.

Labeling

As was in the Draft Guidance, FDA continues to stress the importance of including detailed information in the labeling about the interoperability of the device in order to reduce risks

associated with reasonably foreseeable use and misuse, regardless of whether a premarket submission is required for the device. FDA appears to further expand—even when compared to the Draft Guidance—the type and breadth of information that should be included in the labeling, now suggesting inclusion of a list of data attributes exchanged between the interoperable devices and how any time synchronization is performed. Such information can be included in the packaging of the device, the instructions for use, as well as the company's website. Where and how to provide this information should be part of the company's risk analysis, taking into consideration the anticipated users. FDA emphasizes that labeling should be clear and explicit regarding its interface with other products, e.g., when the device is intended only to be used with certain other devices or when the interface is intended only for use by the manufacturer in software updates or diagnostics.

Contents of Premarket Submissions

FDA's recommendations as to the contents of premarket submissions for interoperable devices have not changed significantly in the Final Guidance. The Final Guidance explains that companies should submit the following information when a premarket submission is required:

- Discussion of each "externally-facing" electronic interface, including its purpose, the anticipated users, and its uses and limitations.
- Risk analysis information including reasonably foreseeable uses, misuses, or combination of events that could give rise to a hazardous situation. The risk analysis should address, in addition to the normal elements, any risk control measures and any risks that may arise from security vulnerabilities—consistent with the FDA's premarket cybersecurity guidance.
- Results of verification and validation testing, which will depend on the device's associated risks, its purpose and intended use, and its anticipated use in the interoperable system.
- Labeling should comply with FDA's previous guidance on the requirements of 21 CFR parts 801 and 809: Labeling – Regulatory requirements for Medical Devices.[2]

Key Takeaways

- Through its Final Guidance, FDA encourages companies to consider safety risks affecting patients and operators of interoperable devices throughout the device lifecycle, specifically in the areas of (1) design consideration, (2) risk management and testing, and (3) provision of relevant user-specific information by means such as labeling.
- FDA makes clear that transparency and sharing of functional performance and interface characteristics with all users is a significant part of risk mitigation.
- The Final Guidance does not specifically address the question of whether the Agency expects companies to provide full risk analyses in future premarket submissions. However, FDA is clearly

[2] Available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf

looking for the submission of risk analysis information that addresses, in addition to the typical elements, measures for reducing unacceptable risks related to interoperability; how devices handle potential issues with the reception and transmission of data (i.e., delays, corrupted data, data provided in the wrong format, unsynchronized or time mismatched data, etc.); and risks potentially arising from security vulnerabilities. The Final Guidance also continues the FDA's increasing recognition of cybersecurity considerations as part of broader design, development, and premarket submission processes.

Companies are expected to comply with the recommendations in the Final Guidance 60 days after the Final Guidance's publication.

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