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## StarFish Analysis: Draft Guidance on Interoperable Medical Devices

By Vesna Janic, 26 January 2016

On January 25, 2016, the FDA issued a [draft guidance for connected devices](#) in which information is exchanged and used across the connections and which includes at least one medical device.

This guidance is intended to highlight the following items that medical device manufacturers should consider to provide a reasonable assurance of safety and effectiveness of their interoperable medical devices:

1. Designing systems with interoperability as an objective;
2. Conducting appropriate performance testing and risk management activities; and
3. Specifying the functional, performance, and interface characteristics in a public manner such as labeling.

### Highlights:

Appropriate safety considerations including system level safety considerations that are not taken in to account in the device design can result in unforeseen safety and effectiveness issues for the device or for the system

Implementing appropriate functional, performance, and interface requirements for devices with such interactions is important. One way to achieve this is through use of standardized architectures and communication protocols

Weight units transmission errors - pounds vs kilograms could kill a patient

Manufacturers of interoperable medical devices should perform a risk analysis and conduct appropriate testing that considers the risks associated with interoperability, reasonably foreseeable misuse, and reasonably foreseeable combinations of events that can result in a hazardous situation.

Develop clear labeling to minimize risk

There is a lot of information on how to describe the device

**Verification:**

Verify and validate that when data is corrupted it can be detected and appropriately managed.

See Section 5.4 of ASTM 2761-09 (2013), "Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model."

Contains Nonbinding Recommendations Draft - Not for Implementation

Perform testing to assure that the device continues to operate safely when data is received in a manner outside of the parameters specified. Determine how or if this can be detected and what impact this will have on the rest of the system.

Implement a fault tolerant design and verify its performance.

Establish and specify fail safe states for critical functions (e.g. delivering energy, real-time monitoring).

If conforming to consensus standards, verify and validate that the design meets the intent and scope identified in the standards.

Verify only authorized users (individuals, devices and systems) are allowed to exchange information with the interoperable medical device.

Validate the user(s) interface. Determine that the user(s) are capable to correctly use the interface(s).

[The Draft](#) provides information on how to describe the system, recommends clear labeling to minimize risk, and outlines verification requirements. I recommend reading it.