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April 28, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2015-D-4852: Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff

To Whom It May Concern:

The Advanced Medical Technology Association ("AdvaMed") appreciates the opportunity to provide comment on the Food and Drug Administration's ("FDA" or "Agency") Draft Guidance for Industry and Food and Drug Administration Staff: Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices ("Draft Guidance").[1] AdvaMed represents manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatment. Our members range from the smallest to the largest medical technology innovators and companies.

AdvaMed appreciates the Agency's interest in providing guidance regarding medical device interoperability. We believe the Draft Guidance represents an appropriate first-step in describing the pre-market submission issues that manufacturer's should address. Our specific comments with respect to the content of the Draft Guidance can be found in the attached document. Below we provide several general comments for the Agency's consideration.

1. Scope of the Draft Guidance

Types of Products. We believe it is appropriate to better clarify the scope of connected devices to those that exchange information. The physical connection of multiple devices does not necessarily mean that they are intended to be interoperable (*e.g.*, printer cable ports). The Draft Guidance, however, provides the same recommendations regardless of whether the interoperable medical device is designed by the same manufacturer to function together as a part of a limited system (*e.g.*, an implantable pacemaker and an external programmer, or a monitoring hardware device and corresponding mobile medical application), or is designed to

[1] Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff (Jan. 26, 2016), *available at* http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm482649.pdf.

work with devices from other manufacturers through the use of standards or published protocols. We recommend FDA provide information in the Draft Guidance to account for these different situations. While many of the principles (*e.g.*, risk management, verification and validation testing) apply to all devices, there may be instances in which it is not necessary (or even counter-productive) to follow the Draft Guidance when the devices are part of a limited system. For example, the manufacturer may produce devices that are only interoperable with specific devices sold by the same manufacturer. Accordingly, FDA should clarify that the Draft Guidance does not apply to devices that are part of a limited system.

Types of Interfaces. We recommend FDA limit the request for information concerning electronic data interfaces only to those that impact the device's safety or effectiveness. Devices may contain many interfaces (some in excess of one-hundred) that would not necessarily impact safety/effectiveness or interoperability. It would not be necessary for FDA to review information on these non-safety/effectiveness interfaces in order to make an approval or clearance decision. However, the requirement to include such information would significantly increase the manufacturer's documentation requirements without a positive impact to safety and effectiveness. Accordingly, FDA should clarify that the Draft Guidance does not apply to electronic data interfaces that do not impact the device's safety or effectiveness. In addition, the Agency should place greater emphasis on the use of FDA-recognized consensus standards, including those related to human factors testing (*e.g.*, IEC 62366-1, IEC 60601-1-6, and AAMI HE75).

Types of Configurations. The Agency should clarify the extent to which it intends manufacturers to assess risks associated with an interoperable device that may be connected by a user to multiple devices within their own healthcare system. Assessing risk may be straightforward when a device is connected to only certain types of software or other devices, but that is not always the case. As more devices adopt "plug and play" capabilities, a healthcare institution could connect software and device types that may not be envisioned by the device manufacturer. It is important to specify in the Draft Guidance that this a shared responsibility and there are situations that are beyond the manufacturer's control, which are outside of providing clear labeling that describes the intended configuration and operation.

2. FDA Should Provide a Transition Period

Generally, the Draft Guidance presents a reasonable approach to interoperability but would require many manufacturers to implement changes to their documentation architectures and systems. Given that, we recommend the Agency consider a reasonable transition for adoption of the specific approaches included in any final guidance, as updating procedures and associated documentation, when implemented in accordance with good documentation practices, is a lengthy procedure.

3. The Draft Guidance Should Address Issues that Arise Later in the Product's Life-Cycle

The Draft Guidance does not specifically require addressing future issues that may arise, but it could be inferred that a manufacturer would be expected to be able to perform such an assessment. We recommend that FDA explicitly state that future system level safety considerations may be unknown but that interoperability, like all performance aspects of a device, need to be considered throughout the life-cycle of the product.

* * *

AdvaMed would like to thank the FDA for its consideration of these comments. Please do not hesitate to contact me at 202-434-7224 or zrothstein@advamed.org if you have any questions.

Respectfully submitted,

/s/

Zachary A. Rothstein, J.D.
Associate Vice President
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Attachment

AdvaMed Comments

Date: **April 28, 2016**

Document Title: **Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff**

Submitters Name: **Zachary A. Rothstein, JD**

Company: **Advanced Medical Technology Association (AdvaMed)**

#	Line	Comment/Proposed Change	Rationale
	General	We recommend FDA consider incorporating into section IV of the Draft Guidance the following definitions from ANSI/AAMI/ISO 14971:2007/(R)2010 *Medical devices – Application of risk management to medical devices*: • Hazard • Hazardous situation • Risk • Harm	Using consistent definitions will facilitate manufacturer's updating of their procedures and minimize confusion.
	General	We recommend FDA add an appendix for "Other Resources," which could include: • Integrating the Healthcare Enterprise (IHE) • Healthcare Information and Management Systems Society (HIMSS) • IVD Industry Connectivity Consortium (IICC) • Medical Device Plug and Play (MD PnP)	This change would provide a useful resource for both manufacturers and reviewers.
	General	It appears that terminology referencing the "user" is not consistent throughout the Draft Guidance. We recommend FDA use the term, "intended users" throughout the guidance when referring to the "user," unless a more specific meaning or subset of users is appropriate (*e.g.*, line 455: "authorized users").	Several examples include: Line 309: "any user" Line 343: "anticipated users" Lines 695-697: "user"
	148-149	Revise to: ". . . wired or wireless methods that may exist as peer-to-peer connection, on a local network, or through the Internet."	As written, it is unclear whether "local network" includes protocols such as Near Field Communication (NFC) and/or Bluetooth Low

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			Energy (BTLE).
	153	Revise to: "safety of the patient and operator."	This change clarifies that the safety of all users is important.
	165	Revise to: ". . . patient, operator, device or for the system."	This change clarifies that the safety and effectiveness of all aspects of the system are important, including users.
	199	Replace: "performance testing and" with "verification, validation."	We believe this language is more consistent with the Draft Guidance.
	200	Replace: "Public" with "user-available."	We do not believe use of the term "public" is appropriate in this context because the information is for the user.
	206	Revise to: "interoperable medical devices . . . ."	This change provides consistency with other sections of the Draft Guidance.
	211	Define "data schema" or replace, "the data schema" with "Open Systems Interconnection (OSI) layers."	The term "data schema" is undefined; a possible substitution may be "Open Systems Interconnection (OSI) layers." We also recommend FDA reference ISO/IEC 7498-1 when OSI is first used.
	227	We recommend FDA clarify that this Draft Guidance does not apply to IDEs.	IDEs are regulated through other mechanisms and should be considered out-of-scope for this guidance.
	232-236	Revise to: "For purposes of this guidance, an electronic data interface (EDI) is the ~~medium~~ interface by which i~~nde~~~~pendent systems interact and/or~~ a medical device communicates with ~~each other~~ one or more medical devices and/or non-medical products thereby allowing the exchange of information between systems. It includes ~~both~~ the Open Systems Interconnection (OSI] physical layer ~~connection~~ (i.e. USB port, wireless connection, etc.) and ~~the data schema~~ other OSI layers which define~~s~~ ~~the~~ information content. ~~It is a medium by which a medical device exchanges and uses information.~~"	• An EDI is a type of "interface" not a "medium." • There is no requirement for system elements to be "independent" in an interoperable architecture. • The term "data schema" is undefined; a more appropriate phrase is "OSI layers." • The existing definition is unclear as to

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			whether "systems" are composed of medical devices alone or a mix of medical devices and non-medical products.
	239-244	Revise to: "For purposes of this guidance, interoperable medical devices are devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act that have the ability to exchange ~~and use~~ information through an electronic data interface with one or more ~~another~~ medical device~~s, product, technology, or system~~ and/or non-medical products. Interoperable medical devices can be involved in simple unidirectional transmission of data to another device or product or in more complex interactions, such as exerting command and control over one or more medical devices."	• A device could be part of an interoperable medical system and simply transfer information to another medical device or non-medical product. There should not be a requirement to "use" information. • The exchange of information with a "technology" is an ambiguous concept. • The addition of "non-medical products" clarifies that an interoperable system might consist of a mix of medical devices and non-medical products. Further, the term "products" is used in the last sentence of the definition.
	249	Revise to: "Design Considerations for Interoperable Medical Devices."	This change provides consistency with other sections of the Draft Guidance.
	255; 256	Revise to: "Design inputs should include the desired functional and performance characteristics of the electronic data interface."	It is not clear what "interface characteristics" are, separate from functional and performance characteristics that are already included.
	264-265	Revise to: "Design inputs should include the desired functional and performance characteristics of the electronic data interface."	It is not clear what "interface characteristics" are, separate from functional and performance characteristics that are already included.
	275-297	We recommend FDA clarify that the device manufacturer is not required to document each of the aspects in detail unless specifically relevant to the safety and effectiveness of the device.	While manufacturers should consider these aspects during the design and development of their device, they may not always be relevant to the device's safety and effectiveness.
	280-283	Add: "healthcare professionals, clinicians, and third party vendors."	This language expands known users of interoperable devices.
	285	Revise to: "Security and Risk Management Considerations."	This change is consistent with Section C.

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	285-288	Revise to: "Manufacturers should assess all risks identified in risk analysis and mitigate to reduce risk as appropriate to their risk management process. This includes risks that arise from others connecting the electronic data interface that allow inappropriate access to the device."	Risks should be evaluated prior to implementing risk control measures to determine whether they require reduction. Risk analysis and risk evaluation are key steps in ensuring a proper balance between risk management and other considerations important to device development, including usability, access, device performance, etc. This change supports a least burdensome compliance expectation.
	288	Add at the end of the sentence: ", or risk of compromising data."	Safety risks may include compromised data.
	290	Revise to: "Verification and Validation Considerations."	This change is consistent with Section D.
	290-293	Revise to: "Manufacturers should establish, maintain, and implement appropriate verification and validation to ensure that their devices with electronic data interfaces work correctly prior to delivery, and (for devices meant to be part of a larger interoperable system) when devices are assembled, installed, and maintained according to their instructions for use." We also recommend distinguishing in the Draft Guidance validation in the hands of the user from computerized system validation (*i.e.*, IQ/OQ).	Lines 290-293 recommend a life-cycle verification and validation focus for all devices, while lines 436-439 apply this concept only to larger interoperable systems (and uses different life-cycle terms). This change provides consistency. We understand the importance of verification and validation of devices with electronic interfaces, but it is difficult to demonstrate when used with non-specified products from different third party manufacturers.
	293	Revise to: ". . . and, in coordination with healthcare providers, continue to operate as intended."	Healthcare providers may have numerous interoperable medical devices in their sites that experience frequent updates, such as having new devices added to their network, or some devices removed from the network. Instead, the functioning of such networks is a shared responsibility between the manufacturer and device operator(s).
	295-297	We recommend FDA clarify that a manufacturer may determine not to	Certain interoperability capabilities of a device

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		publish certain information on product labels due to safety and effectiveness reasons. FDA should provide this information on line 474 of the Draft Guidance.	might be highly desirable by operators but are very complex to implement during the integration and installation process. For safety and effectiveness reasons it may not be appropriate to include information about such aspects in the product's labeling. There may also be instances where the data is intended only for the manufacturer.
	299	The structure of this section, in combination with the following sections, does not easily follow the concept of "Design Input" and "Design Output." We believe a more logical structure would be to consider the purpose, users, and risks as design inputs that drive a potential list of design considerations, labeling requirements and subsequent verification activities.	These changes would help clarify the Draft Guidance.
	309	Revise to: ". . . allow any intended user to connect . . . ."	Only the intended user(s) should be considered.
	312	An item should be added that explains design considerations can be very different for different types of electronic data interfaces. For example, an interface intended to deliver an electrical pulse for synchronization purposes has very different requirements compared to a web service that delivers patient records to information systems.	These changes would help clarify the Draft Guidance.
	324	Add as a new bullet: "The intended uses of the interconnected devices and the data."	We believe this is an important additional consideration.
	359-361	We recommend FDA clarify the phrase: "The verification procedures should be considered as part of the design."	It is not clear from this statement whether FDA expects manufacturers to provide verification procedures for the customer, or whether it is sufficient to have on-site service personnel verify correct operation at installation. It also is unclear how this would apply to over-the-counter or consumer devices.
	350	Revise to: ". . . how the device is intended to be used in the target interoperable system."	Manufacturers should only be responsible for the intended uses of the device in the target interoperable system.

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	378-380	Revise to: "However, FDA recognizes that a manufacturer is only responsible for the intended use of the device, and cannot be responsible for all possible uses outside of the intended purpose of the interface." We also recommend moving this sentence to the end of the paragraph.	Manufacturers should be responsible only for the intended uses of the device.
	394	Add an additional item: "Whether implementation and use of encryption or authentication methods degrades the essential performance of the device."	Dependency on authentication infrastructures may leave the EDI without functionality in the case of failures or resource issues.
	399	We recommend the Draft Guidance define "essential performance" consistent with IEC 60601-1 (which requires compliance with ISO 14971) as: "Performance necessary to achieve freedom from unacceptable risk of a clinical function, other than that related to basic safety, where a loss or degradation beyond the limits specified by the manufacturer results in unacceptable risk. Compromise of the essential performance can produce a hazardous situation that results in harm and/or may require intervention to prevent harm."	The Draft Guidance mentions "essential performance" but does not define the term.
	400	We do not believe the document referenced in footnote 6 adequately addresses "appropriate security features." We believe a better reference is FDA's guidance concerning the Content of Premarket Submissions for the Management of Cybersecurity in Medical Devices.	We believe this guidance provides more relevant information.
	409-411	Revise to: "A manufacturer should evaluate the need to ~~design an interoperable device that can~~ mitigate risks associated with the following specific error scenarios."	Risks should be evaluated prior to implementing risk control measures to determine whether they require reduction. Risk analysis and risk evaluation are key steps in ensuring a proper balance between risk management and other considerations important to device development, including usability, access, device performance, etc. This change supports a least burdensome compliance expectation.
	418-419	We recommend FDA provide clarity on what is meant by a "non-	This addition would provide clarity to the Draft

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		functional requirement," and add examples.	Guidance.
	445-446	Revise to: "Verify and validate that when data is corrupted, it can be detected ~~and appropriately managed~~."	Interoperability is not meant to confirm that the data is useful; it is only meant to confirm the sending and receiving of data. Data corruption, mismatch, etc. are system software issues that are not related to interoperability.
	447-448	We recommend FDA clarify what is meant by "data parameters."	This addition would provide clarity to the Draft Guidance.
	470	Add a new paragraph: "The recommendations in Section V.B and VI.D about sufficient information for intended user(s) may be helpful in creating appropriate labeling."	Lines 350-374 and 644-706 discuss labeling and should be referenced here.
	475	We believe additional information should be provided about using standard protocol qualification tests.	Section F speaks to the use of consensus standards. Some consensus standards (*e.g.*, BTLE) require protocol qualification tests or certification.
	525	Clarify the phrase: "any electronic data interfaces found on the device."	We believe FDA is referring to data interfaces for devices outside of the system but request additional clarification.
	526-527	Revise to: "The device description should also describe how each interface is meant to be used and/or the limitations of . . . ."	We believe this is a more accurate statement.
	553-554	Revise to: "~~Describe~~ List the API . . . ."	Proprietary APIs are typically specified in order for others to design and develop a product to interface to the API. Specifying an API in detail in a premarket submission would add significant burden without benefiting patient safety.
	560	Replace "Analysis" with "Management."	We believe "management" is a more precise term.
	567 570 572	Replace "mitigations" with "risk control measures."	This change aligns the Draft Guidance with ISO 14971.

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	581	Replace "these" with "applicable."	Risks are not always applicable.
	613	Revise to: "Validate that the device interface performs as intended for all identified device users, including the use of associated labeling."	Lines 659-661 discuss labeling validation, however, the Verification and Validation section starting on line 595 does not mention this topic. The validation of labeling should be treated as an integrated part of the device's overall validation. If this comment is accepted, lines 659-661 should also be removed or updated.
	642	Clarify applicability of this section to "open systems" and/or "closed systems."	Closed systems may use proprietary information and would not normally be disclosed to the public. This information must remain proprietary to maintain the integrity of the system and ensure patient health, privacy, and security.
	661-663	Revise to: "Validation of labeling should include human factors studies that include all identified-users of the data interface during development for on-market release, as appropriate."	Human factors studies for labeling validation may or may not be needed depending on the device. Requiring human factors studies for "all identified potential users of the data interface" would be extremely burdensome, costly, and time-consuming, without benefiting patient safety.
	678	Revise to: "FDA recommends that the following information be ~~included~~considered in the device labeling so that the device can be used safely and effectively for its intended uses:"	This addition would provide clarity to the Draft Guidance.
	680-682	Revise to: "Specify the purpose of the interface including any devices, device types, interface standard/specification or software ~~(including the version of the software)~~ with which it is meant to connect."	We recommend that when a specification for a particular compatibility is made, the Draft Guidance should include "interface standard/specification" as an optional identification. Often devices are developed against an interface standard and as long as the device meets that standard, it is included in the compatible grouping.

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			Furthermore, as proposed, it would be burdensome to update device labeling each time a new compatible version of software is released. This should only be required if the device is only intended to connect with specific versions of the software.
	683-684	Revise to: "Specify whether the data is meant for a specific purpose, and specify intended user(s)."	The current text treats data users as either "specific" or "anyone," which we believe is imprecise.
	690-693	Revise to: "Summary of the ~~testing performed on the interfaces to verify interoperability claims and any~~ activities required by the user to verify safe operation. ~~In the case where testing was performed to an interface specification and verified with a representative device, please specify the representative device used.~~"	Manufacturer testing may involve many different verification and validation methods (unit testing, integration testing, system testing, penetration testing etc.), each potentially involving different representative devices and standards. Including testing information in labeling would be burdensome for manufacturers without a clear benefit (and may be proprietary).
	700	Replace "or" with "and/or."	We believe this is a more accurate statement.
	705	Add: "Non-standard interface requirements and characteristics."	This addition is consistent with Line 173.