Introduction to Pre-Submission for Integrated Medical Device Systems

May 13, 2014

The Center for Integration of Medicine & Innovative Technology (CIMIT), the Continua Health Alliance, and the Medical Device "Plug-and-Play" Interoperability Program (MD PnP) co-sponsored the FDA (CDRH) Workshop on "Medical Device Interoperability: achieving safety and effectiveness" on January 25-27, 2010.[1,2]

One of the outcomes of the workshop was the formation of the Medical Device Interoperability Safety Working Group or MDISWG[3] (originally called the Prototype Regulatory Submission working group "PRSWG") comprising 20 participants from industry, clinical care, standards development organizations, academia, and regulatory agencies. This group has been meeting regularly, usually on weekly teleconferences, since its inception. The group pursued the use of regulatory science to develop a detailed risk / regulatory model to support regulatory submission discussions related to systems consisting of interoperable components. The intent was to enable FDA and interoperable system manufacturers to use existing regulatory science mechanisms when assessing the risks associated with interoperable systems.

The MDISWG handed off its initial work products to the FDA in the Spring of 2011, for further internal development at FDA and feedback from FDA to the MDISWG. This work reflected the conclusion by the MDISWG that the ICE standard – ASTM F2761-09(13): Integrated Clinical Environment (ICE)[4,5] – could serve as an exemplar approach in a manner consistent with use of good regulatory science as an aid for managing risk in an interoperable environment. A Pre-IDE[6] submission was submitted to FDA in February 2012, and discussed in a productive face-to-face meeting with the FDA in April 2012. The meeting provided additional valuable feedback from FDA. The MDISWG continued to meet, with the goal of developing practical tools useful to industry, clinical care, standards development, and regulatory bodies based upon the regulatory science approach shared with FDA. While not a standards development organization, the MDISWG has provided thought leadership and analysis that has helped to increase the level of industry consensus on the use of the ICE standard as an exemplar approach for systems of integrated medical devices.

The FDA feedback on the Pre-IDE was combined with additional MDISWG input and evolving industry perspectives on the importance of medical device interoperability, resulting in a second pre-submission - Q140327. The pre-submission was sent to FDA by the MDISWG in March

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[1] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm202671.htm

[2] http://www.mdpnp.org/FDA_Workshop.html

[3] http://www.mdpnp.org/MD_PnP_Program___MDISWG.html

[4] 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

[5] http://www.astm.org/Standards/F2761.htm

[6] Investigational Device Exemption I120162; now a "pre-submission", a type of Q-submission

2014 and represents the current perspective of the MDISWG. The MDISWG will be meeting with FDA to discuss their thoughts on the supplement in the coming months.

With the fluid nature of discussions related to interoperability and connected health, we anticipate our thinking will continue to be refined and evolve. That said, this pre-submission supplement represents a snapshot of our thinking and, we believe, is valuable information to share with other interested stakeholders in the community wrestling with these topics. Therefore, although the FDA treats pre-submissions as confidential, we are publicly sharing the document under a Creative Commons License in the hope that you find our thoughts helpful in your own deliberations, and we will provide additional updates as they become available to share. In that spirit, we have opened an on-line discussion area that can be reached from the url below or from http://bit.ly/presubmission.

Kind Regards,

The Medical Device Interoperability Safety Working Group (MDISWG)
(represented by names that are listed in the Pre-Sub and on this
page: http://mdpnp.org/MD_PnP_Program___MDISWG.html

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
03/19/2014   Silver Spring, MD 20993-0002

Scott Thiel
Navigant Consulting, Inc
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United States

Dear Scott Thiel:

The Food and Drug Administration (FDA) acknowledges receipt of your submission. FDA considers this information to be a Q-Submission (Q-Sub). Q-subs include Pre-submissions, informational meeting requests, submission issue meeting requests, study risk determinations, and requests for Determination and Agreement Meetings. It has been assigned the following document control number:

        Q-Submission Number: Q140327   Received: 03/18/2014   Dated: 03/14/2014
        Device: Interoperable Medical Devices

Your Q-Sub will receive the same confidentiality as provided for IDE applications under 21CFR 812.38 of the IDE regulation (21 CFR PART 812). FDA will not disclose the existence of your submission, unless its existence has previously been publicly disclosed or acknowledged, until FDA approves a marketing application for the device subject to this submission.

It is our goal to provide feedback on your submission within 90 days, whether in the form of a meeting, teleconference, letter, or email. If you have requested a meeting, we will contact you in approximately 3 weeks to schedule the meeting.

FDA's Center for Devices and Radiological Health (CDRH) is committed to educating industry on relevant premarket and postmarket policies and regulations for medical devices. CDRH's latest innovative educational tool is CDRH Learn, which consists of a series of training modules that are intended to provide an information resource that is comprehensive, interactive, and easily accessible. CDRH Learn can be accessed at: <http://www.fda.gov/Training/CDRHLearn/default.htm>

Any future correspondence regarding this submission should be identified with your Q-Sub number and be submitted to the above address.

                                Sincerely,

                                Sheila Brown
                                Nurse Consultant
                                IDE Program
                                Office of Device Evaluation
                                Center for Devices and Radiological Health

14 March 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -
W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention:
Mr. Richard Chapman
Ms. Catherine Li
DHHS/FDA/CDRH/ODE/DAGID/GHDB
Building W066, Room 2526

RE: Pre-IDE for interoperable medical devices

Mr. Chapman & Ms. Li –

Navigant Consulting, Inc. is pleased to submit the attached pre-Submission supplement to you for consideration and discussion on behalf of the Medical Device Interoperability Safety Working Group (MDISWG). This supplement addresses a key aspect related to the regulation of interoperable medical devices and proposes a path for regulation that supports patient safety and innovation, and utilizes regulations as currently codified.

The names of individuals and institutions listed below are the volunteer members of MDISWG involved in generating this supplement. You will note that the group represents a large and varied set of perspectives from the healthcare community. We believe that the approach proposed is representative of stakeholders involved in or using systems in the healthcare system, and who would like to see those systems become more integrated and interoperable.

Please feel free to contact us if you require additional information or clarification on any of the items discussed in this submission. In line with the Agency's desire for more interactive review processes, we are willing to engage in an ongoing dialog concerning the regulatory status of this product. Per FDA's *Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act*, this submission is being submitted in duplicate with one paper copy and one eCopy. Per FDA's *Guidance eCopy Program for Medical Device Submissions*, the eCopy is an exact duplicate of the paper copy.

Kind Regards,

Scott Thiel, MBA, MT (ASCP), RAC
Associate Director
Navigant Consulting, Inc.

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PRE-SUBMISSION SUPPLEMENT TO I120162

MEDICAL DEVICE INTEROPERABILITY:
A PROPOSED APPROACH SUPPORTING SAFETY

14 March 2014

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on behalf of the
Medical Device Interoperability Safety Working Group

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On April 13, 2012, the Food and Drug Administration ("FDA") hosted a pre-submission ("Pre-IDE") meeting with the Medical Device Interoperability Safety Working Group ("MDISWG") to discuss the submission identified by FDA under I120162. During the meeting, FDA representatives shared several areas where they had questions and offered their thoughts on how MDISWG might resolve some of the areas of concern. This pre-submission supplement to I120162 offers a clarification in response to the questions raised by FDA, and expands upon the key concept within I120162 to utilize existing regulations. The comments and pre-submission will eventually be shared openly with the public to assist others in communication (e.g., pre-submission meetings) with the FDA and aid in the overall discussion related to the regulation of interoperable systems.

The information we present in this document is intended to focus on regulatory science, and is not meant for regulatory policy. Specifically, based upon our proposed approach, we are interested in what specific verbiage is necessary in an indication for use statement relative to the types of claims proposed at the end of this document.

Can a modification to an existing system be assumed to be compliant with performance standards if both the original system and the modification component[1] have been cleared (or approved) separately and both are certified[2] products? Historically, systems are based upon proprietary or closed systems with ready identification of responsibilities for assessing safety at a system level. They are vertically integrated by a single manufacturer, and the configuration of the devices in the system is known *a priori*. But in the case of a system comprised of separately cleared (or approved) and certified components, an assumption of compliance cannot be supported solely by each component's regulatory status or certification; someone or something must also verify the assembled system to ensure safety at the system level.

We believe, however, that the desired state is one that readily supports the introduction and removal of devices (e.g., sensors, actuators, software applications [apps]) without re-verification by evaluating all possible combinations of devices.

In order to reach this desired state, a system must be designed at the outset with appropriate architectural and interface principles for partitioning and managing risk to allow for insertion and removal of devices (i.e. Plug-n-Play or "PnP"). Interface specifications and communication rules addressing relevant aspects of privacy and security for the involved devices and their communication and data must be defined and available publicly. The architectural and interface

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[1] "Component" means an essential functional part of a subassembly or of an assembled electronic product, or system and which may affect the safety or effectiveness of the finished product or system.

[2] "Certification" means the manufacturer assures, as described in ISO 15026: 2011 (Systems and Software Engineering – Systems and Software Assurance), the component or system will perform as required by the performance standards when it is assembled, installed, adjusted, tested, and maintained in accordance with the manufacturer's instructions.

principles used to partition and manage risk must also be publically available. Devices meant for use in such a system need to be verified relative to their roles, that is, what the devices are capable of contributing to a system. The devices must be designed to and operate within a known architectural platform.[3]

We have pointed to the ICE standard[4] in our pre-submission as an example architectural design, knowing that all aspects have not yet been created (e.g., interoperability standards such as the planned Joint Committee [AAMI and UL] 2800 standards). A diagram depicting a generic system compliant with the ICE standard is found below.
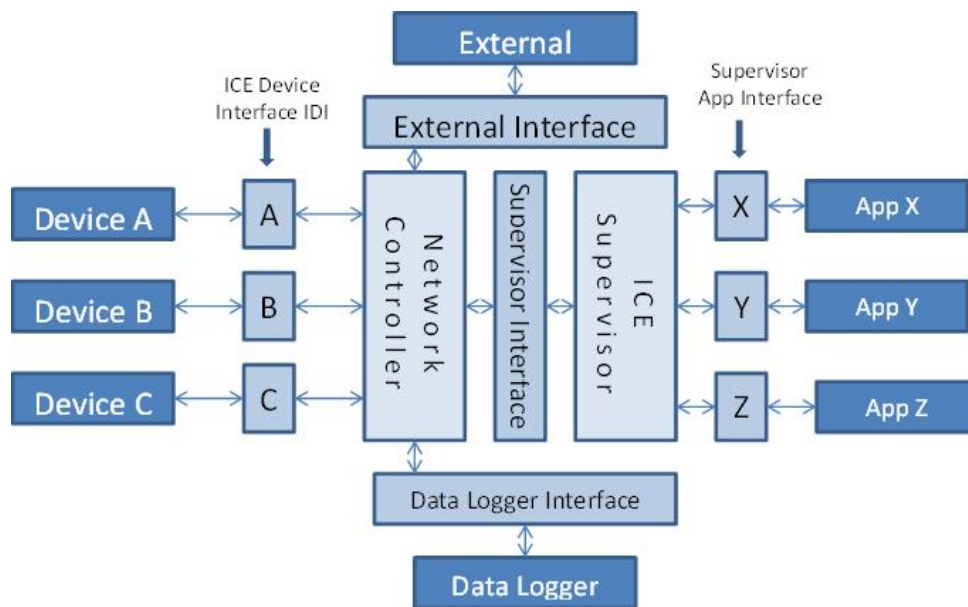

Figure 1: Generic ICE system

The various interface regions (e.g., device, supervisor, data logger, and external) are defined through publicly available interface specifications.[5] The remainder of the platform (i.e. ICE infrastructure) is defined by the supervisor, network controller, and data logger. The supervisor and network controller monitor, manage, and maintain communication among all devices (including apps); they are how the devices know who is connected, what they can do,

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[3] John Hatcliff, Andrew King, Insup Lee, Alisdair Macdonald, Anura Fernando, Michael Robkin, Eugene Vasserman, Sandy Weininger, Julian Goldman. "Rationale and Architecture Principles for Medical Application Platforms", Proceedings of the 2012 International Conference on Cyber-Physical Systems, pp. 3-12, April, 2012.

[4] ASTM F2761 - 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; FDA recognition 13-46.

[5] IEEE 11073 Health informatics - Medical / health device communication standards (as example).

and the health of the communication infrastructure (e.g., available bandwidth, processing power, storage). The devices could be sensors or actuators or a combination thereof, and could provide information indicating what they do (that is, intended use) and, if relevant, how (that is, performance characteristics such as sampling rates).

The app is another device type with a specific role in the system. The app is responsible for a particular clinical function defined by the app manufacturer, i.e. the intended use of the app. The app creates the clinical system through interaction with and use of available devices by indicating required information (for example, physiological parameters) and functionality (e.g., infusion of a solution)[6]. The app also indicates performance characteristics needed from the various devices and the ICE infrastructure, if needed.

Safety of a system defined by an app is realized by the app, the devices, and the ICE infrastructure (ICE network controller, ICE supervisor, ICE data logger), with the app taking the lead role. Each must fulfill its respective responsibility, but the app's role and responsibility are to determine when and if the system is safe.

Compliance testing to standards, often carried out by third parties, can provide justification to trust that a device will interoperate correctly. In similar fashion, apps could be tested by third parties for various use cases to provide evidence that the app is in compliance with its specifications and intended use(s). Furthermore, third-party testing for security, privacy, and communication infrastructure would establish the necessary confidence in the performance of the system. Third-party testing is supplemented with development environments and conformance test suites that device developers can use during development prior to official third-party testing to determine if they correctly implement standards.

By designing a platform for safety through the utilization of a defined and publicly available architecture, such as ICE, and associated communication and security standards coupled with third-party certification testing, we believe the core issue related to ensuring system safety when changing components (in this case, devices) is resolved. Does FDA concur that by using the proposed approach we could generate the type of information needed for the assessment of safety of the system? We are not asking whether FDA would find such a system safe, only whether the approach proposed could generate the type of information FDA would find useful in its assessment activities.

One endpoint we are driving toward is the generation of supportable claims statements (indications for use).   For example, a device manufacturer claims compliance to a set of publicly-available design specifications (standards) and is allowed to market its device for use in an ICE architected environment. An example of such a claims statement might be, "Device A complies to Standards 1, 2, and 3 and can be used with a platform compliant with ASTM F2761-

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[6] http://www.mdpnp.org/MD_PnP_Program___Clinical_S.html

09." An alternative is having an app manufacturer claim an intended use that relies upon a device or devices that meet publicly-available design specifications without having to name the specific brand or model of device(s). In this scenario, we would prefer that the app manufacturer not be required to provide verification data for all possible combinations of devices and device types; rather, we would like to leverage third-party compliance to standards and testing against representative sets of devices as sufficient.

Does FDA believe that development of a system using the standards and approaches we have described is moving in a direction that could facilitate making these types of claims supportable?