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July 7, 2014

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

***Re: Docket FDA-2014-N-0339***
***"Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework"***

Dear Sir or Madam:

I am writing on behalf of the members of the Advanced Medical Technology Association (AdvaMed) in response to the draft FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework.

AdvaMed is the world's largest association representing 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 treatments. Our members range from the smallest to the largest medical technology innovators and companies. Nearly 70 percent of our members have less than $30 million in sales annually.
Patient safety is our industry's highest priority.

There is no purpose to making medical devices that place patients at unnecessary risk. This philosophy extends, of course, generally to Health IT and specifically to Medical Device software. Consequently, we are particularly interested in the draft FDASIA Health IT Report's risk-based framework and regulatory control proposals. In this letter, we will describe our primary philosophical position and additional explanatory comments addressing some of the specific sections of the report.

**The AdvaMed Position**

Fundamentally, AdvaMed believes that the following broad principles are critical for an effective effort to regulate Health IT.

1. Platform Agnostic.

   Regulation of Health IT should be platform agnostic. By "platform agnostic" we mean that neither the platform used to run Health IT nor any IT hardware that is part of the Health IT should determine whether or how it is regulated nor, if it is regulated, which agency regulates it, e.g., software running on a phone or driving an eyepiece or other medical device display should be regulated the same when they share the same function. The regulatory controls imposed upon the Health IT product's developer should be based upon the risks associated with the device's intended use, not the technology employed.

2. Intended Use.

   Health IT, that by virtue of its intended use as stated by the manufacturer fits the Federal Food, Drug & Cosmetics Act definition of a medical device[1], should be subject to FDA regulation, as it is now. The current test for whether a product falls under the FDA medical devices regulation is whether it meets the Act's definition of a medical device. We believe that Health IT should be handled similarly to other FDA-regulated medical devices.

   Medical devices that are categorized as Health Management HIT and that meet the definition of the regulation above should be considered by the FDA as so low risk that they should not enforce compliance with the regulatory controls including registration and listing, premarket review, postmarket reporting and the quality system regulation for manufacturers of these types of devices.

   Additional FDA authority or law is not needed to establish a new regulatory schema, with the exception of creation of a means to place these Health Management HIT medical devices into a new Class "HMHIT" (Health Management HIT).

   Within this proposed Class HMHIT as well as the entire Health Management Functionality category, it would be expected that a further separation of those products within this new category would be needed to better manage the diversity of products. Therefore there is an understandable need for a scaling level of controls based on the risk and user's dependence on the product.

[1] A device is: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

3. Exempt Low Risk Health IT Medical Devices.

   We applaud FDA's decisions to exempt low risk Health IT medical devices from active regulation. Issuance of the Mobile Medical Application guidance in September 2013 brought clarity to many aspects of the regulatory schema, e.g., manufacturers of smartphones will not be regulated. The more recent posting of an MMA exemption example (June 11, 2014) and issuance of the draft MDDS guidance (June 20, 2014), in our opinion, correctly remove unnecessary regulatory burdens to Health IT medical devices that will receive data downloaded from actively regulated medical devices and/or display, store or transmit patient-specific medical device data. These decisions bode well for future Health IT risk evaluations and decisions. It will be important, however, to maintain certain expectations, as defined in the FDASIA report, to ensure that the products marketed in this space maintain the needed level of quality, safety, and effectiveness. We agree with the need for these products to be manufactured and designed with a clear set of quality principles and standards. We also agree that an appropriately defined certification process for certain products would also support this goal. Any such system should recognize compliance with FDA quality system regulations in lieu of an additional system, should an FDA-regulated company decide to address in this manner. An alternative to FDA's adverse event reporting process will also be vital to patient safety in the event of a product failure.

4. Guidance and Regulation in Partnership.

   The FDA needs to be nimble in establishing and modifying regulatory controls to respond to the rapidly evolving Health IT industry products. In this ever changing environment, FDA needs to be able to share new risk evaluations and regulatory decisions with industry and the public in a timely manner; Communicating key regulatory decisions with industry and the public via issuance of guidance documents and posting notices on the Agency's website is a useful and productive first step in the process. We encourage FDA to continue doing so. However, to ensure a predictable and consistent set of regulatory requirements, it is critical that FDA follow through with changes to classification regulations where necessary, e.g., 21 CFR 880.9(c), 21 CFR 880.6310, 21 CFR 892.2010, and 21 CFR 892.2020. The updating of these regulations and establishing a Class "HMHIT" for Health IT medical devices that are not be subject to FDA regulation will reduce industry uncertainty and foster the Health IT innovation desired by all. This approach is both flexible and sustainable. Generally we believe FDA and ONC needs to take a proactive approach in avoiding duplication or redundancy of regulations.

5. Accessory to Actively Regulated Medical Device.

   Historically, the FDA has generally regulated products that connect to medical devices by placing them in the same regulatory classification as the medical device. FDA has considered these connected products to be accessories to the medical device. This approach ignores the intended use of the connected product, can overestimate the risk associated with that intended use, and may impose unnecessary regulatory controls.

Recently, the FDA took an important step forward on June 20, 2014 with the issuance of "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices - Draft Guidance for Industry and Food and Drug Administration Staff" which clarified the intention of FDA to consider these MDDS and certain Mobile Medical Application products to be under enforcement discretion.

This regulatory decision is based upon the Health IT product's inherent risk, not upon the parent device's risk. We agree with this decision. We hope that basing regulatory controls upon Health IT product's risk will become the common practice.

6. Three Tier Approach.

   The FDASIA Report proposes a three tiered approach, suggesting there are distinctions between administrative, health management, and medical device Health IT products, and the regulatory schema should reflect those distinctions. We agree. The regulatory schema for these three categories should be based upon the products' risks. We also agree with FDASIA Report authors' acknowledgement of Health IT products that include functionalities associated with more than one of the three categories. There are and will be Health IT products with functionality that fall within more than one of the categories. The Health IT regulatory schema must anticipate these products, and should provide a predictable and efficient means of commercializing these Health IT products. The Health IT should be a continuum of regulatory requirements to avoid redundancy, inconsistency, and unnecessary burden to the industry.

7. Health IT Safety Center.

   Establishing a regulatory schema that encourages continuous learning and improvement is a pivotal component of success. Failure to establish this information sharing forum will shunt the growth of Health IT. The final configuration of the Health IT Safety Center must include subject matter experts from Medical Device and Software companies who will work in collaboration with the three agencies. Currently, however, we do not have enough information to endorse the proposed creation of a Health IT Safety Center.

8. Clinical Decision Support.

   Clinical Decision Support software should be evaluated in the same manner as other Health IT devices, i.e., build a risk-based framework to decide which, if any, regulatory controls should be imposed upon each CDS function.

   We encourage the development of a risk-based framework that examines the user's level of dependence upon the software function in order to determine the Health IT device's categorization. We recommend developing a regulatory schema that takes into consideration: transparency of inputs and clinical rationale, competency of the user, and time to reflect before making a decision, to determine if the user is dependent on the information being provided.

A clear definition of Clinical Decision Support is essential. We offer the following suggestion: CDS definition: "software providing users with clinical knowledge and patient-related information intelligently filtered or presented at appropriate times, to enhance patient care."

9. Health and Wellness.

   The categorization of Health IT products within the scope of the FDASIA report must consider the dividing line between products solely intended for "health and wellness" applications and products with Health Management function.

   Historically, it has been possible to draw a line between health and wellness products and medical devices. This line becomes blurred over time with some Health IT products. Our society encourages its citizens to improve personal health by optimizing diet, exercise, and other lifestyle factors. Health IT products will serve a vital role in educating and motivating people in health maintenance and disease prevention. We encourage the FDASIA work group to establish a predictable, risk-based regulatory framework which clarifies the current regulatory distinction between health and wellness products and medical devices. This will continue to foster the innovation of these important health-supporting products.

10. Global Harmonization.

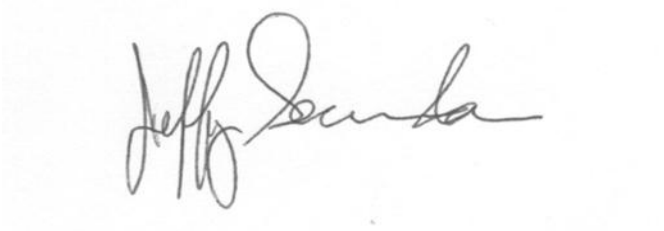
    Historically, a leading inhibitor of medical device innovation has been the lack of global harmonization of regulatory requirements. This lack of global regulatory harmonization may force country-specific verification and validation activities and lifecycle management decisions, which is both costly and complex. This cost and complexity can easily stifle innovation. Building a domestic Health IT regulatory schema upon well-accepted, international consensus standards and technical reports, e.g., ISO 14971, IEC 62304, and IEC/TR 80002-1, should lead to a regulatory environment that protects the public from unnecessary risks while still enabling innovation.

11. Third-Party Organizations.

    We believe third-parties can serve an important role. The key areas are the development of consensus standards, design guidelines, and independent certification programs; each supported by inclusive and transparent processes. Any such certification program should also recognize compliance with FDA quality system regulations in lieu of an additional system should an FDA-regulated company decide to address in this manner. We believe third-party organizations can serve the role efficiently and robustly; the regulatory schema should leverage these third party resources. We suggest that it is important to adhere and be certified to appropriate process standards that reflect the necessary quality management principles supporting the categorization of Health IT in the risk framework (Administrative to Health Management to Medical Device) based on scientific evidence.

We appreciate the opportunity to offer these comments, and look forward to working with FDA, ONC, and FCC to refine the risk-based regulatory framework. If you have any questions or would otherwise like to contact me, I can be reached at 202-434-7224 or jsecunda@advamed.org.

Respectfully submitted,



Jeffrey Secunda
Vice President, Technology and Regulatory Affairs
Attachment

**AdvaMed Comment Form**

**Date: 7 JUL 2014**

**Document Title: FDASIA Health IT Report; Docket FDA-2014-N-0339**

**Submitters Name: Jeffrey Secunda** **Company: AdvaMed**

| # A | Page/ Section/ Paragraph/ Line | Type: Technical Editorial | Proposed Change | Comment: Rationale/Justification for Change |
|---|---|---|---|---|
| 1 | Pages 4 and 17 | Technical | With regard to the statements at the top-right of page 4, "…the creation of a Health IT Safety Center…be created by the ONC, in collaboration with FDA, FCC, and the Agency for Healthcare Research and Quality (AHRQ), with involvement of other Federal agencies, and other health IT stakeholders…" It is recommended the ONC consult with the Software Engineering Institute (SEI) at Carnegie Mellon University in Pittsburgh, PA during the development of this center. | The SEI can contribute valuable support to help answer the question(s) posed on page 17 of the report, such as, "How do we assure stakeholder accountability for adoption of quality management principles?" and "Is there a role for a non-governmental, independent program to assess stakeholder adherence to quality management principles?"<br>The SEI and has been in place for over four decades. It would serve health IT stakeholders well to enable the ability to leverage this foundational knowledge and expertise the SEI has achieved. Their current repository of lessons learned, information, tools, processes, and data may be valuable for the ONC to use as a basis for standards, best practices, tools, and continuous improvement for health IT.<br>An overview of the goals and capabilities of the SEI is found here: http://www.sei.cmu.edu/about/ |
| # B | Page/ Section/ Paragraph/ Line | Type: Technical Editorial | Proposed Change | Comment: Rationale/Justification for Change |
| 2 | Document as a Whole | Technical | N/A, general comment applicable to the regulation of products that fall within each category outlined in the report. | To promote innovation and preclude regulatory inefficiency, the FDA should be the only agency that approves "medical device health IT functionality". Government agencies should publish clear statements of jurisdiction applicable to "administrative health IT functionality" and "health management health IT functionality" as well as products with "administrative health IT functionality" and/or "health management health IT functionality" in combination with "medical device health IT functionality". |

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| 3 | 3/paragraph 1 | Technical | N/A, general comment related to the statement "Overall, we do not believe that regulation should be or needs to be the first approach used to reach this outcome." | AdvaMed agrees with this statement. We believe the report's recommendations related to health IT software quality, consensus standards, and interagency coordination – combined with guidance published by the FDA – are more supportive of innovation than the introduction of new legislation that redefines certain sections of the Federal Food, Drug, and Cosmetic Act. |
| 4 | Page 4/ paragraph 1 | Technical | Change:<br><br>"As such, if a product with health management health IT functionality meets the statutory definition of a medical device,[2] FDA does not intend to focus its oversight on it."<br><br>to:<br><br>"As such, if a product with health management health IT functionality meets the statutory definition of a medical device,[2] the FDA will consult with ONC and other stakeholders (public and private) to determine the appropriate risk-based regulatory approach."<br><br>Note: Similar statements in the document (i.e., paragraph 4.2, Figure 2, paragraph 5.4, paragraph 6) should be reexamined. | AdvaMed is concerned that this statement may cause confusion among manufacturers since the FDA's Guidance on Mobile Medical Applications defines a "Mobile Medical App" as follows (including the footnote):<br>*C. Mobile Medical Application (Mobile Medical App)*<br>For purposes of this guidance, a "mobile medical app" is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)[4]; and either is intended:<br>• to be used as an accessory to a regulated medical device; or<br>• To transform a mobile platform into a regulated medical device.<br><br>[4] Products that are built with or consist of computer and/or software components or applications are subject to regulation as devices when they meet the definition of a device in section 201(h) of the FD&C Act.<br><br><u>The FDA should remain the sole agency responsible for the regulation of products that meet the definition of a "device" in section 201(h).</u> For products with "health management health IT functionality" that meet the statutory definition of a device, the FDA must officially define alternative regulatory schemas |
| 5 | Page 12/ paragraph 4.3 | Technical | Change:<br><br>2) Medical device accessories;<br>3) Medical device clinical decision support software;<br><br>to:<br><br>2) Medical device accessories[X];<br>3) Medical device clinical decision support software[Y];<br><br>Where "X" and "Y" are appropriately numbered footnotes that reference proposed guidance development priorities for CDRH Fiscal Year 2014 (FY2014). (http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/mdufaiii/ucm321367.htm) | Since both of these items are identified in the "B-list" for FY2014 guidance, adding two footnotes is an informative and appropriate addition to the document.<br><br>AdvaMed urges the FDA to publish draft guidance for "Medical device accessories" and "Medical device clinical decision support software" during FY2014. Further, this report and recent legislative activity support a higher priority for these two guidance documents. |

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| 6 | Page 25/ paragraph 5.4 | Technical | The comment addresses the question "How can the private sector help facilitate the development of a non-governmental process for listing selected health IT products? What types of products and information should be included? Should the results of conformity assessments, such as conformance with certain clinical or privacy and security standards, be included?" | AdvaMed strongly supports the use of consensus standards as a means of satisfying regulatory compliance requirements. For conformity assessments that reference certain privacy or security standards, care must be taken to ensure that sensitive information is not inappropriately disclosed. (See AdvaMed comment 32, Docket FDA-2013-D-0616) |
| 7 | Page 27/ paragraph 6 | Technical | The comment addresses the question "What types of CDS functionality should be subject to the health management health IT framework? Which types should be the focus of FDA oversight?" | CDS software that meets the definition of a "device" in section 201(h) of the FD&C Act should be subject to FDA oversight, not necessarily FDA regulation. As indicated in a previous comment, the FDA should remain the sole agency responsible for the regulation of products that meet the definition of a "device" in section 201(h). For products with "health management health IT functionality" that meet the statutory definition of a device, the FDA must define alternative regulatory approaches through new guidance documents or other instruments (e.g., MOUs). |
| 8 | Page 27/ paragraph 6 | Technical | The comment addresses the question: "Are there additional safeguards for CDS, such as greater transparency with respect to CDS rules and information sources that are needed to appropriately balance patient safety and the promotion of innovation?" | Transparency and intended use are both critical considerations for CDS. CDS software should be supported by applicable clinical guidelines and/or peer-reviewed journal articles in order to ensure patient safety. A product's "intended use" should include the consideration of whether it could engender physician dependence in emergency or critical-care scenarios. |
| # C | Page/ Section/ Paragraph/ Line | Type: Technical Editorial | Proposed Change | Comment: Rationale/Justification for Change |
| 9 | Page 4/ Section 1/ First paragraph/ line 3-8 of page | Technical | "…is a product with health management IT functionality meets the statutory definition of a medical device, FDA does not intend to focus its oversight on it. Rather, FDA would focus its attention and oversight on medical device health IT functionality, such as computer aided detection software…." | This approach returns to the mindset presented in the mobile apps guidance that does not remove products from oversight, but rather focus, from FDA's enforcement responsibility. Modifying the current focus of the regulatory agency rather than making a clear determination on product marketing requirements produces confusion and reduces predictability for the industry. . The FDA must provide clear delineations between products that fall under the scope of the FD&C Act and those that do not. For those that do not but still fall under the definition of a medical device, FDA must publish clear expectations that those products must meet prior to marketing, even if this is not the current 510(k) or Class I exempt pathway. |

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| 10 | Page 11/ Section 4/ Second Paragraph | Technical | "It is also important to note that the systems that healthcare organizations and consumers are purchasing, implementing, and using, often contain functionalities that bridge all three of these categories…..Similarly, some functionalities, such as privacy and security, cannot be placed in a single category." | First, there is a need to provide better clarity on how to regulate products that perform functions that fall in multiple categories. This situation exists for standard medical devices that also perform a non-medical device function but this issue will likely increase with advancing technology where there are more opportunities for connected solutions. This is also particularly important since it is being proposed that there may be a division of responsibility between FDA and ONC.<br>Secondly, the later sentence suggests the need for a wider scope approach to privacy and security since the majority products will be affected by these challenges. |
| 11 | Page 12/ Footnote 35 | Technical | Footnote 35: "Clinical Decision Support (CDS) provides health care providers and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. Because risks are generally low compared to the potential benefits, FDA does not intend to focus its oversight on most clinical decision support. FDA instead intends to focus its oversight on a limited set of software functionalities that provide clinical decisions support and pose higher risks to patients, such as computer aided detection/diagnostic.." | Need clarity on terms:<br>• Intelligently filtered<br>• Enhance health and health care<br><br>Again, and throughout this report, FDA claims that it "does not intend to focus" on certain products. This needs to be defined and a clear line drawn on what FDA will and will not regulate over the longer term. It is also essential that the expectations are clearly and formally defined for those products that the FDA does not plan to regulate.<br>It is currently unclear which products will be transferred to the Health Management classification and which will remain in the Medical Device classification. While examples are helpful in clarifying the intent of the classification structure, it is equally, if not more, important to have a clear description and defining criteria that will place a product in one of the classifications. Clinical decision software, in particular, is a very diverse group of products that can represent a wide variety of risk to patients if poorly designed and produced. |
| 12 | Document as a Whole | Technical | Clarification on: Enforcement Authority | There is a need for clarification on the source for enforcement authority of ONC over the Health Management products in the Health Management Functionality category. It was explained at the FDASIA workshop (May 13-15, 2014) that ONC may receive enforcement authority over this group of products and that those products would no longer fall under the scope of the FD&C Act. It is currently unclear from where the current authority for ONC to regulate or oversee these products would originate. |

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| 13 | Page 15/ Section 5.1 | Technical | Clarification on: Quality Management Principles | One of the recommended infrastructure components for the Health Management class of products is the promotion and use of Quality Management Principles. The use of such principles is essential to the development of reliable, effective products. The use of these types of principles should be required for at least some of the products that fall within the Health Management class of products. Not only is it important for the establishment of trust within that specific product but it is also essential for maintaining confidence in all of the products overseen via this alternate regulatory schema. If the use of basic quality principles is not required but instead established as an optional approach, this has the potential to decrease the likelihood of adoption by clinicians of a larger breadth of products because of a basic lack of quality and reliability. |
| 14 | Page 8/ Column 1/ Paragraph 1 | Technical | Clarification on: Adverse event system<br>"The Workgroup recommended that… and 2) a surveillance mechanism is needed to track adverse events and near misses for certain health IT functionality that is not regulated." | The proposed adverse event system was described at the FDASIA workshop as "non-punitive" in nature and likely separate from the current FDA adverse event process. Clarity is requested in how this alternate system would allow traceability to similar or related issues within the FDA MAUDE database. Often health IT products are connected either directly or in common workflow practice with other medical devices and therefore the ability to perform root cause analysis is dependent on the connection of this relationship. It is also important for the calculation of valuable metrics so that events in health IT can be gathered alongside related medical device events. Lastly, it is clear that the impetus for establishing a non-punitive adverse event reporting system encourages high levels of reporting frequency but it is also important that this activity is balanced with structured surveillance for patterns that suggest a fundamental flaw or developing issue that may need enforcement to be addressed. It is currently unclear how that enforcement would be established. |
| 15 | Document as a Whole | Technical | Clarification on: Standards | What standards organizations will be leveraged for the standards development for interoperability and creation of standardized data exchange to promote safe use of data that is exchanged (p. 9)? Will there be a focus on currently-available standards (HL7, IHE) or are they proposing new development of new standards with alternate standards organizations (NIST)? The scope of impact to the medical device industry will differ greatly depending on the answer to this question. AdvaMed supports the leveraging of existing standards whenever possible to ensure clear, efficient implementation. |

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| 16 | Document as a Whole | Technical | Clarification on: Overall Implementation | Is the proposed approach for administrative and health management functionality similar to the EU CE marking conformity assessment? It would seem that this may present a good model for fostering innovation while still maintaining accountability. Similar to how the notified bodies (NB) are responsible for certifying manufacturer's quality system, but the competent authorities still maintain accountability on the notified bodies, and by extension, on the manufacturers. One possibility may be to have the administrative health IT self-declared and the health management health IT may involve a notified body certification (a parallel to devices that Class I (self-declared) and Class IIa or Class IIb (NB involvement) in the European Union. |

| # D | Page/ Section/ Paragraph/ Line | Type: Technical Editorial | Proposed Change | Comment: Rationale/Justification for Change |
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| 17 | Document as a Whole | Technical | General comments to promoting using existing standards. There are a wealth of established Health IT standards and FDA guidance that encompass the breadth of health IT functionality, including medical device:<br><br>ISO 13485: 2003 Medical devices – Quality management systems – Requirements for regulatory purposes<br>ISO 14971: 2007 Medical devices- Application of risk management to medical devices<br>IEC 62304: 2006 Medical device software – Software lifecycle processes<br>ISO 62366: 2007 Applicability of Usability Engineering to Medical Devices<br><br>IEC 80001-1:2010 Application of risk management for IT Networks incorporating medical devices, Part 1 – Roles, responsibilities and activities (addresses both devices and networks )<br>ISO 27799 Health Informatics – Information security management in health using ISO/IEC 27002<br>ISO/TR 27809:2007 Health informatics -- Measures for ensuring patient safety of health software<br>ISO/TS 25238:2007 Health informatics - Classification of safety risks from health software<br>ISO 82304-1, Healthcare Software Systems<br>ISO/IEC TR 80002-02, Medical device software - Part 2: Validation of software for regulated processes<br>ISO/TR 17791:2013, Health Informatics – Guidance on standards for enabling safety in health software<br><br>FDA Guidance, Sept 25, 2013, Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff.<br>FDA Draft Guidance, June 20, 2014, Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices | Quality Management Systems need to allow manufacturers to apply a single process that satisfies the requirements of all agencies. Existing safety and quality-related processes, systems, and standards should be leveraged for patient safety in health IT.<br><br>Health IT should leverage recognized standards for assuring patient safety.<br><br>There are also a significant number of other ISO health IT related standards currently undergoing development and revision by ISO TC 215.<br><br>**Standards currently undergoing development and revision by ISO TC 215** : http://www.nsai.ie/NSAI/files/5a/5aa28cf0-5d29-4ffe-94cf-83629d4e8a84.pdf<br><br>  <br>Adobe Acrobat Document |
| 18 | Page 4/ 1st column/ line 12 | Technical | General comment that patient safety should be expanded to include elements of patient safety such as hazards, security, health information (HIPAA). | The section is ambiguous on elements of safety and to what safety applies. |

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| 19 | Page 10/ 2nd column/ item 2 | Technical | General comment to item 2:<br>"2) Individual health IT components may meet their stated performance requirements, yet the system as a whole may yield unsafe outcomes;"<br><br>Existing standards exist for health IT from a system perspective. Application of these standards would, in part, meet the concern for system safety concerns. | Expect compliance to applicable standards that support system safety, such as:<br><br>IEC 80001-1:2010 Application of risk management for IT Networks incorporating medical devices, Part 1 – Roles, responsibilities and activities (addresses both devices and networks )<br><br>ISO/IEC TR 80002-02, Medical device software - Part 2: Validation of software for regulated processes (draft) may be applicable as well |
| 20 | Page 15,/Sections 5.1 and 5.2 | Technical | Quality management systems already exist that allow flexibility to determine the necessity of individual quality elements and to tailor the development and implementation of quality management processes appropriate for their products and services. | Medical Device manufacturers operate under quality management systems and principles, and can provide the expertise in developing guidance in these areas. |
| 21 | Page 15/ Section 5.1/ second paragraph/ third sentence, and last paragraph | Technical | General comment that "configuration management" along with "customization" to read "customization and configuration management". | Configuration management is a critical element to maintaining customization and configuration changes/change control of Health IT systems |
| 22 | Page 17/ Summary and Conclusion: input to 1st bullet question | Technical | General comment that configuration management, change control, and defect tracking are essential quality management principles that apply to the health IT product lifecycle. | These are critical quality management principles to developing and maintaining Health IT systems. |
| **END OF COMMENTS** | | | | |