UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICES ADVISORY COMMITTEE

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DEVICE GOOD MANUFACTURING PRACTICE ADVISORY COMMITTEE

+ + +

March 2, 2022
9:00 a.m.

Via Microsoft Teams Videoconference

PANEL MEMBERS:

Yadin David, Ed.D., P.E.	Chair
Jeri Culbertson, DNP	Member
Lisa Dimmick, M.S.	Member
Gordon Gillerman	Member
Chiaoyun (Benson) Kuo, Ph.D.	Member
Alisha Loy, LSSBB, CRCST	Member
Elise Owen, M.B.A., PMP	Member
Robert Phillips, M.B.A., RAC	Industry Representative
Scott Sardeson, RAC	Industry Representative
Jarrod Collier, M.S.	Designated Federal Officer

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INDEX

INDEX

M E E T I N G

(9:05 a.m.)

DR. DAVID: Good morning. I would like to call this meeting of the Device Good Manufacturing Practice Advisory Committee to order.

I am Dr. Yadin David, the chairperson of this Advisory Committee. I'm a biomedical engineer with Biomedical Engineering Consultants, LLC, actually practicing at the clinical environment at the point of care, so the profession is referred to as clinical engineering. I'm also holding an adjunct appointment at the University of Texas School of Public Health. It is my honor to chair this Advisory Committee and I'm looking forward to a productive meeting.

I note for the record that the members present constitute a quorum as required by 21 C.F.R. Part 14. I would like also to add that the Advisory Committee members participating in the today's meeting have received training in FDA device law and regulations.

For today's agenda, the Committee will discuss and make recommendations on the current good manufacturing practice requirements for medical devices under 21 C.F.R. Part 820, the Quality System Regulation, to align more closely with an international consensus standard for medical devices used by other regulatory authorities.

Before I begin, I would like to ask our distinguished Committee members and FDA attending virtually, to introduce themselves. Committee members, please turn on your video cameras and if you can unmute your microphone when I call your name, I'll appreciate that. I'll start with the list of Committee members. And please feel free to correct my pronunciation of your name if I mispronounce it and I apologize for that in advance. Please state the area of expertise, your position and your affiliation.

I'll start with Jeri Culbertson. Jeri.

DR. CULBERTSON: Hello. Yes, hi, my name is Dr. Jeri Culbertson. I am a registered nurse and I work in the healthcare industry as an infection preventionist, both in the hospital setting and as a consultant for infection prevention. I also oversee the duties of sterile processing in our facility, as well.

DR. DAVID: Thank you, glad to have you.

Lisa Dimmick.

MS. DIMMICK: Good morning, I'm pleased to be here today. My name is Lisa Dimmick and I work at the U.S. Nuclear Regulatory Commission. I am a health physicist and my areas of expertise are with radiotherapy devices and therapy treatment planning systems.

DR. DAVID: Thank you, glad to have you.

Gordon Gillerman.

MR. GILLERMAN: Good morning and thank you for the opportunity to participate from government. I'm the director of the Standards Coordination Office at the National Institute of Standards and Technology. NIST is a part of the Department of Commerce. My expertise is standardization, conformity assessment, and in my earlier part of my career I was a medical device product safety engineer.

DR. DAVID: Thank you.

Chiaoyun Benson Kuo.

DR. KUO: Good morning, glad to join. I'm Benson Kuo, I'm a faculty member in the Department of Regulatory and Quality Sciences at the University of Southern California. I'm directing a regulatory consulting center at USC.

DR. DAVID: Beautiful, thank you.

Alisha Loy.

MS. LOY: Good morning, I'm Alisha Loy. My specialties are quality management

system design and I am a Lean Six Sigma Black Belt. I work as a quality and operations manager for central sterilizing services at the University of Iowa Hospitals and Clinics, and I am an adjunct clinical instructor for the University of Iowa College of Public Health. Thank you for the opportunity to join today.

DR. DAVID: We're pleased to have you on this Committee.

Robert Phillips.

MR. PHILLIPS: Yes, good morning. I'm Robert Phillips, I'm the head of quality and regulatory for Siemens Healthineers in North America, and I've been in the medical device industry for about 25 years and have expertise pertinent to this Committee in international standardization and regulations, as well as quality systems. Thank you.

DR. DAVID: Thank you, Gordon (sic).

Scott Sardeson.

MR. SARDESON: Good morning, everybody. My name is Scott Sardeson, I'm the Director of International Regulatory and Quality Compliance at 3M Company in the Health Care Business. My credentials are I'm also the convener for ISO 13485 standard on ISO/TC 210/Working Group 1, and I've been in the industry for about 30 years, from R&D, quality and regulatory.

DR. DAVID: Excellent. Looking forward to hear from you later in the discussions.

Now we'll move to members of the FDA that are virtually here.

Ki-esha (ph.) Thomas.

MS. THOMAS: Good morning. Good morning, hi. It's Keisha Thomas. That's okay, I know it's the accent. Good morning, I'm Keisha Thomas. I am the Acting Associate Director for Compliance and Quality in CDRH's Office of Product Evaluation and Quality. I have been in CDRH for almost 20 years at this point. I've been working in this industry and field for 23 years. I'm also one of the technical SMEs that helped actually draft the proposal that we're

talking about today.

DR. DAVID: Beautiful, looking forward to hear from you.

Melissa Torres.

MS. TORRES: Good morning. I'm Melissa Torres, Associate Director for International Affairs at CDRH. I, like Keisha, am one of the technical SMEs that helped write this rule. I've been with FDA for about 17 years and have done a variety of roles at the Center. Thank you.

DR. DAVID: You're welcome.

Kimberly Lewandowski-Walker.

CAPT LEWANDOWSKI-WALKER: Hi, I'm Kimberly Lewandowski-Walker. I've been with the government for approximately 24 years. Twenty of those I've been with FDA in a variety of roles at both our Office of Regulatory Affairs, our field office, as well as CDRH. I'm currently a member of the team for the Medical Device Single Audit Program, and I was one of the people that helped draft the rule with Keisha and Melissa.

DR. DAVID: Thank you, Kimberly.

Anne Reid.

MS. REID: Good morning. My name is Anne Reid, I am with the Office of Regulatory Affairs, the Office of Medical Device and Radiological Health Operations. I've been with FDA for 31 years and my office in ORA has the compliance and inspection staff. Thank you.

DR. DAVID: You're welcome.

And our Designated Federal Officer, Jarrod Collier.

MR. COLLIER: Good morning, everyone. My name is Jarrod Collier, with the FDA, and I am the Designated Federal Officer for today's Advisory Committee meeting. Thank you.

DR. DAVID: Thank you, all. Did I miss anyone? We have great, great members on

the Committee today, I appreciate the time you're taking to join us, and good representation of the FDA personnel. Thank you, all.

And with that, I would like to move to Jarrod Collier, the Designated Federal Officer for today's Device Good Manufacturing Practice Advisory Committee, who will now make some introductory remarks.

Jarrod.

MR. COLLIER: Thank you, Dr. David. And good morning, everyone.

I will now read the Conflict of Interest Statement.

The Food and Drug Administration is convening today's meeting of the Device Good Manufacturing Practice Advisory Committee under the authority of the Federal Advisory Committee Act of 1972. With the exception of the Industry Representatives, all members of the Committee are special Government employees or regular Federal employees from other agencies and are subject to Federal conflict of interest laws and regulations.

The following information on the status of this Committee's compliance with Federal ethics and conflict of interest laws covered by, but not limited to, those found at 18 U.S.C. Section 208 are being provided to participants in today's meeting and to the public.

FDA has determined that members of this Committee are in compliance with Federal ethics and conflict of interest laws. Under 18 U.S.C. Section 208, Congress has authorized FDA to grant waivers to special Government employees and regular Federal employees who have financial conflicts when it is determined that the Agency's need for a particular individual's services outweighs his or her potential financial conflict of interest.

Related to the discussions of today's meeting, members of this Committee who are special Government employees and regular Federal employees have been screened for potential financial conflicts of interest of their own as well as those imputed to them, including those of their spouses or minor children and, for the purposes of 18 U.S.C. Section 208, their

employers. These interests may include investments; consulting; expert witness testimony; contracts/grants/CRADAs; teaching/speaking/writing; patents and royalties; and primary employment.

For today's agenda, the Committee will discuss and make recommendations on the current good manufacturing practice requirements for medical devices under 21 C.F.R. Part 820, the Quality System Regulation, to align more closely with the international consensus standard for medical devices used by other regulatory authorities.

Based on the agenda for today's meeting and all financial interests reported by the Committee members, no conflict of interest waivers have been issued in accordance to 18 U.S.C. Section 208.

Mr. Robert Phillips and Mr. Scott Sardeson are serving as the Industry Representatives, acting on behalf of all regulated industry. Mr. Phillips is employed by Siemens Healthcare, and Mr. Sardeson is employed by 3M Health Care Business.

We would like to remind members that if the discussions involve any other products or firms not already on the agenda for which an FDA participant has a personal or imputed financial interest, the participants need to exclude themselves from such involvement and their exclusion will be noted for the record.

FDA encourages all other participants to advise the Committee of any financial relationships they may have with any firms at issue.

A copy of this statement will be available for review and will be included as part of the official transcript.

Before I turn the meeting back over to Dr. David, I'd like to make a few general announcements.

In order to help the transcriber identify who is speaking, please be sure to identify yourself each and every time that you speak.

Transcripts of today's meeting will be available from Free State Court Reporting, Incorporated.

Thank you all very much, and at this time I will turn the meeting back over to Dr. David.

DR. DAVID: Thank you, Jarrod, and following your instruction, I'm Yadin David and I am now continuing with the agenda to the opening remarks from Ariel Seeley. I will call on Ariel Seeley from the FDA to make introductory remarks.

MS. SEELEY: Good morning. Thank you all for taking the time to be here today. My name is Ariel Seeley and I'm the Associate Director of Regulatory Documents and Special Projects in the Office of Policy here in FDA's Center for Devices and Radiological Health. I would like to welcome all of our distinguished members of the Device Good Manufacturing Practice Advisory Committee, as well as our FDA speakers.

Today has been a long time coming. For all that were involved in issuing the proposed rule to amend FDA's Quality System Regulation, and for those who were watching from the sidelines, today is a big day. I will keep my remarks brief so that we can get started.

This Advisory Committee is unlike FDA's other Advisory Committees in that it only convenes when FDA proposes to amend its current good manufacturing practices for devices, commonly referred to as the Quality System Regulation (QSR) for Part 820.

As a testament to the original creators of the QSR, FDA has not significantly or substantially revised these regulations since 1996. At that time, FDA established a comprehensive set of requirements for the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, insulation, and servicing of all finished devices intended for human use. The system was flexible enough to cover the multitude of devices regulated by CDRH and, to this day, helps ensure that finished devices

are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act.

Back in 1996, global harmonization was one of the many tenets for the original drafters of Part 820. However, over time, regulatory bodies coalesced around the international standard for quality management systems for devices based on 13485, with the 2016 version achieving broad acceptance by many regulatory jurisdictions around the world.

With its current proposed rule, FDA is announcing its intention to take the next step to further ensure its QSR remains harmonized with current global standards, primarily by incorporating by reference ISO 13485 into FDA's requirements from Part 820. This proposal is consistent with FDA's mission to protect the public health by ensuring devices are manufactured in a manner that assures their safety and effectiveness, and is part of FDA's longstanding involvement in global harmonization efforts.

Overall, global harmonization of regulatory requirements can bring with it great efficiencies such as ensuring favorable marketing conditions, potentially support earlier access to devices, promoting competition and efficiency, and reducing unnecessary duplication of effort.

As this panel discusses FDA's proposed amendment to the QSR, we want to hear from you about the benefits and challenges you see with this proposal. Ultimately, the input you each provide is critical and will assist FDA in its rulemaking process.

I thank you again for your time and your commitment to this issue, and I turn this process over to our Committee Chair. Thank you.

DR. DAVID: Ariel Seeley, thank you very much for the opening remarks.

And I would like to apologize that I overlooked one of the FDA members that have joined us, Karen Masley-Joseph, and would like to call on her to tell us about her affiliation

and practice.

MS. MASLEY-JOSEPH: Thank you, Dr. David. My name is Karen Masley-Joseph. I am with the Office of Regulatory Affairs, of the field offices, the Office of Medical Device and Radiological Health Operations. I have been working at FDA for over 20 years in the medical device and various other positions. I have been working with Keisha and Melissa and Kim and Ariel on the proposed rule, as well as leading our implementation efforts for the field office implementation of this rule as final. Thank you.

DR. DAVID: Thank you for being kind to me, I appreciate that. Sorry again.

We'll move on with our agenda and at this point, we will start the FDA presentation and I would like to proceed and invite the FDA representative, Melissa Torres, to begin.

I will remind public observers at this meeting that while this meeting is open to public observation, public attendees may not participate except by the specific request of the panel chair.

The FDA representative, Melissa Torres, will have 20 minutes to present. You may now begin your presentation.

MS. TORRES: Good morning. My name is Melissa Torres and I'm the Associate Director for International Affairs in the Office of the Center Director at CDRH. This morning, I'll be presenting an overview and background of the proposed quality management system regulation.

As an overview, FDA is proposing to harmonize the current Quality System Regulation for medical devices with the standard ISO 13485, which is used by many other regulatory authorities. To accomplish this, we are proposing to incorporate by reference the 2016 version of ISO 13485, because many of the requirements in the standard are substantively similar to the requirements of the QS regulation.

For those who may not be familiar, ISO 13485 is the standard that outlines the

requirements for a quality management system for medical devices. It can be used by organizations involved in one or more stages of the life cycle of a medical device. This includes the design and development, production, storage, distribution, installation, servicing, and final decommissioning/disposal of medical devices.

The benefits of ISO 13485 as compared to the QS regulation is that the standard has more modernized QMS principles. It also has greater integration of risk management activities and stronger ties to ISO 14971, the risk management standard for medical devices. The QS regulation does not provide that level of specificity as many of FDA's expectations are outlined in the preamble of the Quality System Regulation.

Finally, the requirements in the standard are globally harmonized and used by many other countries, including major markets such as Europe, Canada, Australia, Japan, and many, many others.

Now we'll look at the evolution of QMS requirements for medical devices.

In 1978, FDA issued the CGMP requirements which first created Part 820.

In the 1990s, FDA undertook the revision of the CGMP regulation to add design controls and to be consistent with the requirements for quality systems contained in applicable international standards. At that time, this included ensuring alignment, as much as possible, with ISO 9001:1994 and the committee draft of ISO 13485, quality system medical devices supplementary requirements to ISO 9001.

Moving along, in 1996, FDA published the current Quality System Regulation and at the same time, the ISO committee issued the first version of ISO 13485, which included supplementary requirements to ISO 9001 for medical devices.

In 2003, ISO issued the second version of ISO 13485, which included complete QMS requirements for medical devices. The requirements in this version of the standard were about 80% similar to the Quality System Regulation.

Thirteen years later, ISO issued the current version of 13485. The requirements in this version of the standard are about 90 to 95% similar to those in the Quality System Regulation.

Recognizing the many similarities between the QS regulation and the 2016 version of ISO 13485, FDA began discussing the possibility of being able to utilize ISO 13485 as our own quality management system requirements.

It is also important to note that throughout the evolution of FDA's QMS requirements for medical devices in ISO 13485, FDA has actively engaged in international standards development processes and global harmonization efforts.

In 2018, this project was announced and placed on the unified agenda. While it has taken us nearly 4 years to publish this proposed rule, the past almost 2 years have primarily been spent dealing with the COVID-19 pandemic. Developing a regulation is a team effort and a small core team of us who worked on writing this rule were also working on COVID-19 priorities.

FDA has long had an interest in the utilization of ISO 13485, and much of the rationale for incorporating by reference the 2016 version of ISO 13485 is highlighted here. We know that regulatory expectations for QMS have evolved since the publication of the current U.S. regulation over 25 years ago.

ISO 13485 is used by many other regulators around the globe as a QMS requirement. Therefore, many global medical device manufacturers already have to meet the requirements of ISO 13485. Moving to ISO 13485 can benefit global medical device manufacturers to have a more globally harmonized QMS and for the most part, comply with a single set of requirements. This also can allow FDA the ability to work closer with regulatory authorities around the globe and facilitate regulatory convergence on QMS.

Through our analysis, we also determined that the requirements in the 2016 version of ISO

13485 are substantively similar to those of the QS regulation. In addition, FDA learned many lessons through programs utilizing 13485, which have demonstrated the feasibility for utilizing 13485 as a basis for our QMS requirements. I will go into a bit more detail about those programs later in my presentation.

FDA has always had an interest in ISO 13485 and as I mentioned previously, we have actively participated in the standards development process for the different versions of ISO 13485.

In addition, we have always sought ways to harmonize utilizing 13485 through programs such as the Pilot Multipurpose Audit Program, the ISO 13485 Voluntary Audit Report Submission Pilot Program, and finally, the Medical Device Single Audit Program.

The Pilot Multipurpose Audit Program was implemented in September of 2006. With this particular program, auditing organizations performed an audit of a medical device manufacturer to satisfy the requirements of both Health Canada and U.S. FDA, utilizing ISO 13485 for Health Canada and Part 820 for the U.S. FDA.

Health Canada and FDA used the experience gained with the PMAP to identify best practices and to be able to promote an enhanced cooperative regulatory approach. This program really allowed us to increase awareness of the advantages of using a multipurpose audit. It also demonstrated the ability to have regulatory cooperation between two countries; in this case, Canada and the U.S. It also led to a reduction in regulatory burden on industry by conducting a single audit for two jurisdictions. These early lessons learned were incorporated into the development of our Medical Device Single Audit Program and was the first step to demonstrating similarities between QMS requirements.

We then moved on to the ISO 13485 Voluntary Audit Report Submission Pilot Program. This program was implemented in March of 2012. In this program, FDA accepted ISO 13485 audit reports in lieu of routine FDA surveillance inspections. This was a precursor

to MDSAP and is no longer active because we have the MDSAP program in full implementation.

We knew that ISO 13485 audits were performed domestically and internationally and that this program could result in a more efficient use of FDA inspectional resources. It also allowed for harmonization with other countries because we were allowing the acceptance of ISO 13485 audits. It also helped demonstrate the similarities between the standard and the requirements of the QS regulation.

The Medical Device Single Audit Program is an internationally harmonized audit program for medical devices. It began as a pilot program in 2014 and went into full implementation in 2017. There are five countries participating in MDSAP, including Australia, Brazil, Canada, Japan, and the U.S.

The program allows for an auditing organization that is recognized by MDSAP to conduct a single audit of a medical device manufacturer to satisfy the requirements of the five participating regulatory authorities. The MDSAP audit model utilizes ISO 13485 as the core QMS requirements and incorporates specific jurisdictional requirements. The lessons learned through this program have really helped set the stage for the proposed QMSR.

The goals in developing the proposed QMSR were to be able to simplify and streamline our QMS requirements. We also wanted to reduce burden on many manufacturers by aligning, as much as we could, FDA's QMS requirements with globally harmonized QMS requirements outlined in ISO 13485. Therefore, we incorporated by reference the 2016 version of ISO 13485 while keeping country-specific requirements at a minimum. We really only focused on the requirements that were deemed necessary to remain in alignment with the Federal Food, Drug, and Cosmetic Act. It was also important to maintain the same level of assurance and affirm QMS and their ability to consistently manufacture safe and effective devices.

The proposed QMSR withdraws most of the requirements of the current Part 820 but retains the scope and a number of the definitions. We incorporated by reference the 2016 version of ISO 13485, but we ensured that we kept U.S. specific requirements at a minimum. Where possible, we proposed to accept the incorporated requirement in 13485 without modification. In some cases, we did have to establish provisions in order to ensure consistency with other applicable FDA requirements. These areas include definitions, clarifying concepts and in some cases, requirements.

The proposed QMSR also includes conforming edits to Part 4, the CGMP for combination products. It is important to note that the conforming edits do not change the CGMP requirements for combination products. They only identify the corresponding ISO 13485 process to the called-out provisions in Part 4.

As you can see, the proposed QMSR is streamlined. There are sections for the scope, definitions, incorporation by reference, the requirements for QMS, clarification of concepts, control of records, and device labeling and packaging controls.

Looking in more detail, the requirements for QMS link additional FDA requirements such as MDR, UDI, corrections and removals, and tracking, as well as applicability of design and development activities.

The clarification of concepts correlates concepts identified in ISO 13485 to those of FDA.

The control of records section supplements recordkeeping activities in ISO 13485, such as the signature and date, specific documentation required for records of complaint handling and servicing, UDI, and the confidentiality of records.

There are several key considerations with the proposed QMSR. Importantly, the proposed QMSR does not modify which establishments or products are subject to Part 820. It specifically incorporates and references the 2016 version of ISO 13485. We do recognize

that while this standard historically does maintain stability for many years, it will eventually be revised and any future revisions and changes to the standard would need to be evaluated to determine impact to the rule and, if necessary, would need to be addressed through rulemaking. FDA is proposing a transition period of 1 year after the publication of the final rule.

We also have ensured that the standard is free and publicly available. It can be accessed through the ANSI Incorporated by Reference Portal at the website listed on the slide.

Another important consideration is that FDA will retain our inspectional authority. We would like to note that FDA inspections will not result in the issuance of certificates of conformance to ISO 13485, and manufacturers who have ISO 13485 certificates are not exempt from FDA inspections.

There are also many FDA implementation activities that we have to undertake. For example, we will need to update our technology systems. We will need to train FDA staff in the Center and the field on the new requirements. We will also need to replace the current Quality System Inspection Technique with a new inspection model that is aligned with the requirements of the final rule. And finally, we would need to revise relevant regulations and other documents that are impacted by this rulemaking. We certainly have a number of guidance documents and other regulations that reference Part 820 and those would need to be revised accordingly.

Thank you for your attention this morning. I will now turn it over to my colleague, Keisha Thomas, to present on the specific requirements in the proposed QMSR. Thank you.

DR. DAVID: Thank you, Melissa Torres.

This was the first of two presentations by the FDA. We will now proceed to the second FDA presentation and I would like to invite the FDA representative, Keisha Thomas,

to begin. The FDA representative will have 15 minutes to present. You may now begin your presentation.

MS. THOMAS: Hello, I'm Keisha Thomas, the Acting Associate Director for Compliance and Quality in CDRH's Office of Product Evaluation and Quality. Today I'll be going through the requirements outlined in the proposed rule. Previously, Melissa spoke about the content of the rule itself and the organization of the rule. I'll be speaking specifically to some of the requirements themselves. I'm going to start with an overview of similarities and differences.

As you see from this chart, which is included in the proposed rule as a reference guide, it shows how the fundamental alignment of requirements of the Quality System Regulation, the 2016 version of ISO 13485 and the proposed rule align. As you can see, there are four areas where the requirements are not substantively similar where the Agency made planned changes to the regulatory requirements. Throughout this presentation I will go into more detail regarding the areas of difference and discuss the similarities at a higher level.

As you saw by the previous slide, the similarities far outweigh the differences. The requirements overall are substantively similar when taken in totality. The intent of the proposed regulation has not changed, the scope of the regulatory requirements are fundamentally unchanged, and the requirements themselves, as well.

In the areas of differences, most of the differences that you see are where the regulatory requirements differ from or changed in some way. They were done so to ensure that the incorporation of 13485 does not create inconsistencies with the other applicable FDA requirements.

The most notable difference is outlined by the following areas: there's a difference in the title of the proposed rule; there's a difference in the definitions, some definitions;

there's some points of clarification of concepts included; and then there are four areas where there are the most noted requirements changes. We'll start by discussing the similarity.

As far as intent, the Agency is not at all changing the intent of the regulation or who the regulation applies to. The scope is fundamentally unchanged as well, and with risk management you'll notice as we go through this, risk management is listed both under similarities and differences for very specific reasons.

Here it's listed as a similarity in that FDA has always expected risk management activities to begin early in the design and development process and to be integrated throughout a manufacturer's quality management system. Though FDA only identified a prescriptive requirement in one section of the Quality System Regulation, we did discuss the overarching expectation for integrated risk management activities in the preamble of the 1996 rule.

On the right side here you see an excerpt that "FDA expects risk management activities to begin early in the design and development process and be integrated throughout a manufacturer's Quality Management System."

Beneath that, what you see is a chart of the preamble comments presented and categorized according to the regulatory requirements that they align with regarding the Agency's interpretation for risk management requirements.

As we move into differences, many of the differences outlined, as I stated before, are to ensure that the incorporation by reference does not create inconsistency amongst other applicable FDA requirements. With the title, the title, the working title of the proposed rule, "Quality Management System Regulation," is to reflect the incorporation of a quality management standard for medical devices. It's actually been the working title of the proposed rule since the very early development stages of the regulation and seemed to

have gained much traction as we moved forward, so we decided to keep it. I'll go into more detail in the next slides regarding the definitions, clarification of concepts, and the requirements differences that are outlined in the proposed rule.

We'll start with definitions. The changes related to definitions is categorized into five sections: those being withdrawn altogether, those being retained, those being added, terms being clarified, and those that are being retained with modifications where the definition itself has been modified.

We're starting with those that have been withdrawn. The definitions that are being withdrawn do not have a corollary in ISO 13485 because they are not needed to understand and implement the proposed Part 820. Establish definition, that has been totally withdrawn. The Agency felt the term "establish" was no longer needed as the clarification in ISO 13485 of the term "documented" also means it is established, implemented and maintained, and we thought that that was sufficient.

For the definitions that we are retaining, the list is here. Those that are being retained are terms that do not appear in ISO 13485, but have been retained because they are necessary for the purposes of Part 820 and are necessary to ensure alignment with the Food, Drug, and Cosmetic Act and its implementing regulations. We have retained the definition of "Act," which has been expanded to now read the Federal Food, Drug, and Cosmetic Act. So it's no longer the term "Act" alone, it will be the Food, Drug, and Cosmetic Act or the FD&C Act.

For management with executive responsibility, what we're doing here is we're retaining the current definition from the Quality System Regulation for management with executive responsibility, but we're replacing it with the term "top management" from ISO 13485.

For the validation of processes term, we are retaining the definition of process

validation from the Quality System Regulation and recognizing it as synonymous with the term "validation of processes," as the term "validation of processes" is the term that is used in ISO 13485. The Agency is recognizing these terms as synonymous but retaining the definition that is currently in the Quality System Regulation.

There are several definitions that we are retaining and there are no modifications and no term changes associated with that. Those terms that are being retained with no change are those for component; finished device; human cell, tissue or cellular or tissue-based products (HCT/P) regulated as a device; design validation; remanufacturer; nonconformity; and verification.

We are also retaining the definition, FDA's definition, of manufacturer. FDA's definition is more comprehensive than that in ISO 13485 and contains a list of functions that, when performed, meet the definition of manufacturer. The comparable ISO 13485 definition does not include this level of detail in its definition. This definition is expanded upon in the notes to the ISO definition, which are guidance and not requirements, but it allows FDA to maintain its original interpretation and to clarify the functions that continue to be subject to Part 820 by retaining the definition that we currently use.

Regarding definitions that we're adding, we are adding one definition that is the definition of customer. Though customer is not typically used by FDA, we've included the definition as it's useful in encompassing many types of individuals and organizations throughout the device manufacturing process and we would like to have that referred.

There are definitions that we are clarifying where they are superseding other terms. We propose not to incorporate these terms or proposing that the definitions supersede the definition of a similar term in the standard.

Device is superseding the term "medical device" as used in ISO 13485. And labeling spelled with one "L" is superseding the term and definition of labeling with two "L's" as

noted in ISO 13485. There are a couple of definitions that we are retaining, but we are modifying in some way.

Rework is a term that we are retaining; however, we are removing the term "device master record" from that definition since device master records are not referenced in ISO 13485. The current record types that are specifically identified in the Quality System Regulation are not specifically identified in ISO 13485. Those definitions or those terms are quality system record, device master record, design history record, and design history file. We are not proposing to retain separate requirements for these record types, as we believe the elements that comprise those records are largely required to be documented by other clauses in ISO 13485.

The second definition that we are retaining with modification is that of product. We're retaining the definition from the Quality System Regulation, but we're adding the term "service" to the definition. FDA's definition includes a list of items considered to be a product that are not included in ISO 13485. We've decided to modify it and add "service" to the definition to clarify that when the term "product" is used, it also means service as it relates to purchasing requirements.

For clarification of concepts, these are slightly different than just definitional changes. For the first area that we are choosing to clarify the concept of, it's organization. ISO 13485 uses the term "organization" to describe the entity who is creating a quality management system that conforms to the requirements in ISO 13485. Instead, FDA is proposing to clarify the term "organization" to also include the meaning of the term "manufacturer."

As for the term "safety and performance," where the standard uses the term "safety and performance," FDA would like readers to construe that phrase to mean the same as safety and effectiveness as outlined in section 520(f) of the Food, Drug, and Cosmetic Act.

We proposed this clarification to avoid confusion and ensure that implementation of a quality management system is aligned with the standard of safety and effectiveness that is listed in the Food, Drug, and Cosmetic Act.

In my previous slide I addressed the clarification and the change of the term "validation of processes."

Now that we're done with the definitions, we can move on and talk about the actual differences in requirements that are noted. As I spoke previously, there were four fundamental areas where we saw differences in requirements and we'll go through them now. Previously, I spoke to the fact that risk management was listed as both a similarity and a difference. I explained why we see it as a similarity and now we'll talk about why it's highlighted as a difference.

It is included as a difference as there is now a greater emphasis on risk management activities with the explicit integration of risk management requirements throughout the requirements of ISO 13485. Some may see this more explicit, more prescribed regulatory requirement as different than what was in the Quality System Regulation. But as I mentioned previously, there has been an expectation from FDA all along that risk management activities be considered throughout the total product life cycle, even though that requirement is not explicitly called out in our requirements. We do not want this more explicit, broader prescription of risk management requirements to be seen and perceived as new requirements.

Additionally, there's a change in traceability requirements. We've added a requirement to ensure that devices that support or sustain life comply with the traceability requirements in addition to just implantable devices, as outlined in Clause 7.5.9.2 in ISO 13485.

There are supplementary provisions that are added to the proposed rule, as well.

Those supplementary provisions are added to provide clarity on the information FDA needs to align with its other applicable regulatory requirements.

For the control of records, what you will see is that in addition to meeting the requirements that are outlined in Clause 4.2.5 of ISO 13485, FDA has also added provisions from the current Quality System Regulation that you see listed here, which is inclusive of those records having the signature and date requirements for records, having the information that is necessary to meet the requirements of Part 803 as it relates to complaints and servicing activities. There is documentation required to meet the unique device identification and UDI requirements under 21 C.F.R. Part 830, and FDA is maintaining the requirements for confidentiality of records that FDA receives because we have an obligation to ensure that any information that we receive is confidential and protected.

These additional requirements or supplementary requirements provide clarity on the information FDA needs to ensure the validity of records and to ensure records are established and maintained in a manner that is useful to FDA and manufacturers.

The other supplementary provision is regarding the controls for device labeling and packaging. Each year, device recalls are initiated related to product labeling and packaging. Since ISO 13485 does not address the inspection of labeling by the manufacturer, FDA has chosen to retain some requirements to strengthen controls related to labeling and packaging activities. We have proposed to retain the requirements from the Quality System Regulation, as these additional requirements are not outlined in ISO 13485. They're intended to strengthen controls for labeling and packaging operations. So in addition to meeting the requirements listed in ISO 13485 in Clause 7.5.1(e), we are also proposing the additional requirements that are listed.

In addition to the supplementary provisions, we have a section of the regulation that applies to applicable regulatory requirements. Those other applicable regulatory

requirements are requirements that we have the authority to ensure that the requirements in 21 C.F.R. 820 comply with other linked and applicable regulatory requirements. Those are the requirements that are outlined here: the unique device identification requirements under 21 C.F.R. Part 830; traceability requirements under 21 C.F.R. Part 821; the reporting to regulatory authorities or MDR requirements under 21 C.F.R. Part 803; and the advisory notices requirements and/or corrections and removals requirements that are noted under 21 C.F.R. 806. And there you also see the corresponding clauses for ISO 13485 associated to be linked to the applicable regulatory requirements.

Lastly, we have conforming amendments. We have made conforming amendments to Part 4 to reflect the amendments to Part 820, the rules, as we incorporate, propose to incorporate ISO 13485. We're not proposing to change the underlying activities required. These amendments do not impact the CGMP requirements for combination products, and we're proposing amendments to Part 4 references to the corresponding clauses in ISO 13485 that are changed as a result of this proposed rule. Outside of that, we don't intend that these amendments to the Part 4 requirements will overarchingly impact the requirements for combination products.

As I've gone through what you see in the proposed rule itself is that the requirements overall are substantially similar to each other. We feel, as an agency, that the requirements provide a similar level of assurance that we had previously.

The changes to align with the statutory or applicable regulatory requirements were necessary to make sure that we retain not only our authority, but we are in line with the laws and statutes that govern FDA.

We are soliciting comments on the proposed regulatory requirements outlined in the proposed rule, those amendments and revisions and additions, as well as the perceived and realistic impacts of the proposed rule.

Thank you. And that concludes my discussion today.

DR. DAVID: Thank you, Keisha Thomas.

This concludes the FDA presentation part of our agenda and we will move now to the industry presentations. The first industry representative, Jamie Wolszon, will now give their presentation.

I will remind public observers at this meeting that while this meeting is open for public observation, public attendees may not participate except by the specific request of the panel chair.

The industry representative will have 10 minutes to present. You may begin your presentation now.

MS. WOLSZON: Hello, everyone. This is Jamie Wolszon, Vice President, Technology and Regulatory Affairs at AdvaMed. AdvaMed stands for the Advanced Medical Technology Association. We represent hundreds of manufacturers of medical devices 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, and we thank you very much for the opportunity to present today on this very important topic. We intend to provide written comments to the docket once we have had time to evaluate the proposed rule in detail.

Topics to be covered today include the following: the importance of international voluntary consensus standards, generally; the specific benefits we view from transition from QSR to ISO 13485; and some specific points for implementation that will help ensure the realization of these benefits that include avoiding a 13485-plus type approach, a sufficiently long transition period, clear rollout, inspections, and the role of risk, each of which I will delve into in this presentation.

Turning to the importance of voluntary international consensus standards generally,

the use of international voluntary consensus standards to meet regulatory requirements has many benefits, including -- and this one is paramount -- that it furthers the efforts to harmonize global medical technology regulations. This is very important. It also introduces efficiencies for both FDA and the medical device industry by reducing unnecessary duplication. It minimizes unnecessary costs and delays in patient access to innovative new devices, and everybody here wants the best interests of the patient.

Additional benefits of international voluntary consensus standards generally include that the open process used to develop these standards encourages participation by a broad group of stakeholder experts. The development includes and ensures a high level of quality.

It is also consistent with U.S. federal law. OMB Circular A-119 and the National Technology Transfer and Advancement Act of 1995 direct U.S. government agencies to use standards developed or adopted by voluntary consensus standards bodies rather than government-unique standards, except where inconsistent with applicable law or otherwise impractical. Use of voluntary international consensus standards also reduces barriers to trade. And signatories of the WTO also have obligations in terms of their use of standards, which also reduces barriers to trade.

Turning from the general benefits of international voluntary consensus standards to the benefits of the transition from QSR to ISO 13485 specifically, AdvaMed strongly supports the proposed transition and we have made several statements in the past showing that support. We strongly believe that the proposed transition will lead to the promotion of global harmonization and reduction of unnecessary burden while ensuring patient safety and public health.

This will occur for several reasons. First, the 2016 version of ISO 13485 is very much aligned with the current QSR in Part 820. Second, the standard is widely accepted throughout the globe. Moreover, many within industry already follow the standard.

Additional benefits of the transition specifically from QSR to ISO 13485 include that MDSAP is based on the standard. It also will eliminate the need to maintain multiple quality systems for those companies that sell both in the United States and outside of the United States.

It also sets a great example to encourage other jurisdictions to adopt the standard and not impose their own country unique quality systems requirements, which will also greatly enhance and promote global harmonization. When a major player like the United States FDA sets an example, others will follow.

To fully realize the benefits of the transition, there are several points to consider in implementation. One includes avoiding a 13485-plus type of approach, essentially adopting additional requirements over and above 13485 that are country unique. So to gain these full benefits of the transition, we stress the importance of avoiding a 13485-plus type approach.

A very important point for implementation is the need for a sufficiently long transition period. There must be a sufficiently long transition period to avoid disruption. We recommend at least a 2-year transition period. We note that transition is more challenging for small companies and/or companies only selling in the United States.

Also, the transition needs to take into account how long it takes to rewrite the quality systems and hire needed experts. The reason we suggest a 2-year transition period is we actually understand that this reflects experience of at least one company that has made such a transition, that this is approximately the amount of time that it actually takes in real time to make this transition for the reasons that we mentioned.

We note that for those companies that have already adopted the standard, and we mentioned that many have, they could choose to immediately implement as soon as possible. They would not necessarily have to wait the entire transition period.

Another important point for implementation is rollout. There's a need for a clear rollout, including transition times and, as previously mentioned, we cannot stress enough the importance of a sufficiently long transition time frame. It will be very important to have adequate training of both industry and the FDA inspectional group. And we would like to offer our assistance, we'd be happy to partner with FDA and other stakeholders to assist with that training.

We note that both industry and FDA will need a clear understanding of any requirements that are above and beyond the QSR, for instance, the role of risk.

We also suggest clarification that other provision, such as the adverse event reporting requirements in Part 803, corrections and removals in Part 806 -- a clear statement that they continue to apply for those that might be less familiar with the regulatory scheme. I realize this might seem obvious to this audience, but it has been mentioned that that kind of clarification might be helpful to some people who are less familiar with the FDA regulatory scheme.

Another key point for implementation involves inspections. We seek clarification from FDA that while a company would need to abide by the standard, an ISO 13485 certification is not required. The reason this is important is that our small member companies have informed us that having to pay for an ISO 13485 certification could be costly and a potential challenge for them. We do not believe that FDA intends to require a certification; however, we believe that such clarification would help reassure our small member companies that are concerned about this potential cost.

We also note the importance of harmonizing how FDA conducts inspections with other inspectors, for instance, notified bodies.

And we'd also like to understand FDA's thinking about how FDA intends to leverage existing ISO 13485 certifications. For instance, what value might be conferred to those that

hold existing certificates? So for those companies that do have ISO 13485 certificates, would there be a potential benefit because of those existing certificates?

As previously mentioned, one of the key substantive differences between ISO 13485 and QSR is the role of risk. ISO 13485 places a much greater emphasis on risk throughout the product's life cycle than QSR. We support in many different iterations the importance of a risk-based approach. That being said, it will be important to take this into account as part of implementation. For instance, design and development is a potential challenge for implementation, especially because of the linkages to risk management.

In conclusion, we very much support the proposed transition and we look forward to collaborating with FDA and other stakeholders on implementation to help achieve the full benefits of the proposed transition. We thank you for the opportunity to present today on this very important topic. Thank you.

DR. DAVID: Thank you very much. At this point the standards representative, Peter Linders, will now give their presentation and I was asked to remind the public observer at this meeting that while the meeting is open for public observation, public attendees may not participate except in the specific request of the panel chair.

The standards representative will have 30 minutes to present and I appreciate him coming all the way across the pond from Europe to present this.

MR. VEIZIS: I'm sorry, Dr. David, we might have to wait. We need to first introduce the presentation from MITA, M-I-T-A.

DR. DAVID: Yes.

MR. VEIZIS: I'm sorry.

DR. DAVID: Yes.

MR. VEIZIS: You can introduce Diane.

DR. DAVID: Thank you for the correction.

The second industry representative, Diane Wurzburger, will now give their presentation. And I already state the reminder to the public observer. The industry representative will have 10 minutes to present. You may begin your presentation now.

MS. WURZBURGER: Good morning. My name is Diane Wurzburger and I am Executive of Regulatory Affairs and Quality for GE Healthcare. Thank you for the opportunity to present on this very important topic on behalf of MITA.

The Medical Imaging and Technology Alliance is a division of the National Electrical Manufacturers Association and is the leading organization and collective voice of medical imaging equipment, focused ultrasound, radiopharmaceuticals and contrast media innovators, product developers, and manufacturers. We represent companies whose sales make up more than 90% of the global market for advanced imaging technologies. MITA is also the Secretariat of Digital Imaging and Communications in Medicine or DICOM. Our mission is to reduce regulatory barriers, establish standards, and advocate for the medical imaging industry.

MITA strongly supports the proposal by FDA to incorporate by reference the international standard for device quality management systems set forth in the 2016 edition of ISO 13485 into the current 21 C.F.R. Part 820 Quality System Regulation.

MITA sees numerous benefits that will be realized across the stakeholder community resulting from this transition. The transition will drive consistency, efficiency, effectiveness for the industry and FDA as the ISO 13485 is very much aligned with provisions in the current Part 820 Quality System Regulation. It will eliminate the need to maintain multiple quality systems, thus reducing the burden of compliance and recordkeeping for device manufacturers who currently implement both the QSR and ISO 13485 frameworks. Overall, this transition will reduce costs related to compliance and delays in patient access to innovative devices. Of course, transition timing will be critical as the longer medical device

manufacturers are required to maintain duplicate quality systems, efficiencies will be lost.

In addition, similar to Part 820, the ISO 13485 standard allows for scalability in application based on the scope of activities conducted by an entity; for example, manufacturing, importing and/or distributing. This will be especially beneficial for small manufacturers and those entities currently registered with FDA for limited activities.

MITA supports global harmonization of regulations and use of international voluntary consensus standards to demonstrate regulatory compliance. Therefore, MITA strongly supports alignment of the U.S. Quality System Regulation to international standards through this transition to ISO 13485.

The ISO 13485 standard is accepted by many global authorities and many international medical device manufacturers already implement the standards framework.

The Medical Device Single Audit Program, an example of a program whose framework is based on the ISO 13485 standard, allows for the conduct of a single regulatory audit of a medical device manufacturer's quality management system to satisfy the requirements of multiple regulatory jurisdictions. Device manufacturers can be audited once for compliance with the standard and regulatory requirements of five markets: Australia, Brazil, Canada, Japan, and the United States.

The program enables appropriate regulatory oversight while promoting efficient use of all stakeholder resources and importantly, mutual acceptance of the results among regulators while respecting the sovereignty of each authority.

We believe FDA's transition to ISO 13485 will support further alignment of regulatory approaches and technical requirements across the global regulator community, as well as future opportunities for harmonization and reliance.

In addition, we believe the adoption and use by FDA of this international consensus standard without modification is an excellent example to the global community. We value

the FDA implementing the standard as is without changing the provisions by adding additional national requirements; rather, choosing to link to a minimal number of existing supporting regulations. We believe this will influence other jurisdictions to adopt the standard as is rather than implementing their own unique requirements.

MITA would like to suggest the following for consideration. Today, many medical device manufacturers hold ISO 13485 certifications that demonstrate the organization has implemented an ISO 13485 quality management system and has successfully met all applicable requirements to that standard. It will be helpful for the Agency to clarify to the medical device industry that certification to ISO 13485 is not required under FDA's revised 21 C.F.R. Part 820 quality management system regulations.

It's important also that FDA specify the transition timeline from the current Part 820 to integration and implementation of the ISO 13485 requirements. Consideration should be given to the anticipated time needed for medical device manufacturers to update their existing quality systems while minimizing the need to maintain parallel and duplicative systems, which will drive inefficiencies in cost.

It is also important for FDA to factor in the dynamic review cycle for all ISO standards, which is typically 5 years. Depending on the significance of a change, this could impact the rollout over a longer time frame.

We understand that FDA has already initiated internal training plans for FDA inspection teams and we encourage this to continue. In addition, development of educational resources for external stakeholders will be important, especially for small and domestic manufacturers who may not have experience with the ISO 13485 standard today.

It will be important for FDA to clarify how the Agency will conduct inspections under the new quality management system regulation, including routine, for-cause, electronic product radiation control, and preapproval inspections. Also, what changes might be

anticipated in how FDA inspects for other regulatory requirements such as medical device reporting, 803, and labeling.

Additionally, MITA is interested in how FDA might leverage a device manufacturer's existing ISO 13485 certification and surveillance audit results for FDA inspection planning purposes.

And finally, MITA is interested in understanding how FDA will update the inspection manual to ensure it remains aligned to routine revisions of the ISO 13485 standard.

In closing, MITA strongly supports the incorporation of and transition to the ISO 13485 standard and offers its assistance with implementation training and overall, as a resource for the FDA for this transition.

Thank you for the opportunity to present today.

DR. DAVID: I thank MITA representative for their presentation and we'll move on with our agenda to the standards presentation by the ISO/TC 210 chair. At this time the representative, Peter Linders, will now give their presentation.

The statement that this is a public meeting and observer, public observer, are required to participate only at the request of the panel chair is still standing.

Mr. Linders will have 30 minutes to present and we appreciate him coming all the way from across the pond in a live session for 30 minutes. You may start your presentation.

MR. LINDERS: Thank you, Dr. David. And it's an honor for me to be allowed to speak to you today. It occurs to me that there is great consensus about the intended updates of the C.F.R. 820 to include ISO 13485 and I'm happy to share a few slides on behalf of the ISO/TC 210. And I hope you can see my screen, my --

DR. DAVID: Yes.

(Cross-talk.)

MR. LINDERS: -- right now. Just to note, it is among ISO roles to develop documents,

to develop standards, deliverables in general, and support the subject policy and therefore, the announcement that was made by the U.S. FDA a few years ago to include by reference ISO 13485:2016 in its Quality System Regulation was met with great excitement and I'm happy that there is good progress visible right today. I'm also proud to have the honor to the chair of the ISO committee that is responsible for developing and maintaining ISO 13485.

Briefly, we'll go over a few elements. This is the agenda that I have compiled for you. What is ISO 13485:2016? What about the handbook? We'll talk about that in a few seconds, very briefly. Alignment about QSR and ISO 13485. You have seen a lot of that already, so we can be very brief. One remark of stability of the standard, ISO 13485, that is considered to be important for adopting it in the FDA's Quality System Regulation. The benefits of the FDA embracing the standard have already been also discussed and mentioned before. I may add one or two elements there. And I have a very simple short conclusion. And I'm really eager to finish my contribution within the 30 minutes.

But first, please, one picture says more than a thousand words and if you have a close look, please find the snow leopard in this picture. And just to give you a clue, it is looking at your face. And I'll give you hint, so here he is. The benefits of the FDA adopting ISO 13485 are much easier to see than this one.

Now, this is just about me, we can quickly skip that. My main role in this venture here is to be the chair of ISO/TC 210 and to be honest, when I became the chair, the work on ISO 13485:2016 had pretty much concluded. So there is no, let's say, substantial contribution from me or substantial thing that I added to the value of ISO 13485 for the QSR development other than the discussions we have had after that, and we'll get to that, perhaps, in a few minutes.

Again, briefly, there is no crash course; there is not because most of you know a lot

more than I do about these elements here, international standard ISO 13485, the 21 C.F.R. 820, and not to forget the handbook, which is not supposed to be called a handbook, but it is a handbook and we'll get to that in a few seconds, as well.

If you do a search on the Internet on C.F.R. 820, you get a zillion pictures, a zillion references, and apart from this one, the heavy duty garden equipment, most of them refer to the FDA regulation and yet many of them also combine C.F.R. 820 and ISO 13485 already, and that's not a surprise if you remember what was discussed just before.

In ISO 13485:2016 we have requirements for a quality management system in a medical device domain. There is a focus on meeting regulatory requirements for medical devices for quality management systems. And also here, there is an international standard, there is no room to include specific national elements such as labeling, language requirements, all those elements that are typically national, let's say organized in local, national original regulations. So that's something that has to be added in a national implementation.

It has in its scope organizations that are involved in one or more stages of the life cycle of medical devices, of a medical device, and also that was emphasized, that quality management system approach is not just for placing products on the market, but for the responsibility for the life cycle of the device.

And legal manufacturers, that's not a term over here in the FDA, but it's for manufacturers, also for external organizations, external parties such as suppliers of goods and services which may be suppliers of raw products, suppliers of components, suppliers of services like software development, perhaps external parties. But in the end, the legal manufacturer or the manufacturer itself has different, typically has different regulatory obligations than the external parties, which are subcontractors or outsource partners of the manufacturer. And this is connected to the responsibility for what you may call the chain of

responsibility. The weakest link has to be as strong as the minimum requirement for the manufacturer.

Now in the end, the manufacturer is the one that will have to face the regulation, the requirements of the FDA in this case, and therefore all the organizations that he or she has to rely upon will have to be at a similar adequate level of performance. There may be different requirements for them, but it is not to say that they can avoid any of the abilities and for them, it may be useful to adopt as much as possible from the ISO 13485 and their quality management system.

So now here, this is the table of contents of the ISO 13485 standard. It is nothing particular, that is to say the first four, five elements are normative elements in the standard. This is prescribed in the ISO/IEC directives, or two in particular, and actually only the elements 4, 5, 6, 7, and 8 are more specific.

So the section 4, Clause 4, is about QMS and the documentation requirements.

Clause 5 is about management responsibilities, management role, how to organize internal audits; for example, how to make sure that all the processes are made and kept compatible and up to date.

Resource management is not just about personnel, but also about the facilities, making them up to date, keeping them up to date, keeping them adequate for a required product.

Then product realization, which is the big boat in the standard. It is, let's say, combining all the elements from product development, product conception, user requirements, up to validation and verification and even service providing and installation activities, if relevant. And that's an important thing. For example, if you are an organization, a manufacturer of software products, you do not need to have a clean room and you do not need to have sterilization services, for example. So those elements can be

tailored to the needs of the product.

And Clause 8 deals with monitoring, post-production, nonconforming product.

And we have a few annexes. The first one is how to connect, how to compare the 2016 edition with the one before from back in 2003, almost 20 years ago. And the Annex B is linking or is comparing the 2016 edition with the most recent ISO 9001 edition.

As you heard before from Melissa, the first edition of ISO 13485 was in ISO 9001 plus additional requirements above and beyond ISO 9001. And with the 2003 edition, it was decided to step away from what then had become the latest version of ISO 9001 because that contained several requirements that were not part of the boat in a proper manner. And after that, ISO 13485 started to live its own life, more or less. We still like to connect and like to monitor what is going on in the ISO 9001 domain. If we can learn from quality management principles over there, that's wonderful, but we pick and choose what we decide to include in the standard.

So it's a voluntary standard, that's what it is called. Now, my question to you: What is voluntary if it's required by the legislation? And well, is it really important? No, I would say not. Let's not focus on that question. It is not that important if it's voluntary. If the standard is voluntary but the regulation is not voluntary, as a manufacturer, if you want to place a product on the market you will have to comply with certain requirements and if they're in the legislation, and the legislation requires you to comply with the standard, then even ISO 13485 might be considered, might be mentioned, a voluntary consensus standard. If its requirements are in the applicable legislation, then you have to meet those requirements. It is not that important, that discussion. And besides, as has been amply made clear, the C.F.R. 820 and ISO 13485 are not that different. They're even labeled -- let me -- sorry, I think both Keisha and Melissa said they are substantively similar. So not a major issue here, although I do not disagree that implementation will be a bit of an activity,

especially for those manufacturers that are not used to ISO 13485.

And just to give a bit of a background on how widespread the use of ISO 13485 is, it is one of the top-selling standards for ISO management system standards. And this is information that I received from ISO and it is, in any case, here. ISO 13485 has -- and this is a statement from 2020 data -- 25,000 valid certificates and number 34,954 sites that have been certified against ISO 13485.

This, however -- and this is the third bullet -- is information from -- oops, go back. This is information from a survey that was held by International Accreditation Forum and it is not complete data. So the number of certificates is substantially bigger than this one, but in any case, that after ISO 9001, 14001, 45001 and 27001, the one for security, this is the number five top-selling documents for ISO.

And also from the survey from the International Accreditation Forum, it was concluded that there were well over 100 countries that have certificates to ISO 13485 issued. So considering that there are some 200-plus countries in the world, that's a lot. It is really an international standard.

And a few words on the handbook. ISO/TC 210 developed a handbook which is called, officially, "A Practical Guide for the Implementation of ISO 13485:2016." This is replacing another guide that was published in conjunction with the previous edition of ISO 13485 and that was a technical report. This one is more elaborate, more wordy, more explicit in its statements, and it's helpful to implement ISO 13485 as a standard as it is. It does not provide information on the national implementations, the national requirements, that needs to be added in developing the quality management system.

This handbook is helpful in that it explains and guides, it supports implementation, and it has an interesting format because it gives the text from the standard and what was intended, as if that may not be clear, but sometimes we use a bit of a formal standard-ese

language to make the statement, make the requirement in the standard and then provide guidance on how to work from that.

And I think I have a picture here. Yeah. Oh, yes, this is one example for Clause 4.1.6 about documentation for procedures and just to highlight, that's a bit of a coincidence, but just to indicate that yes, software is definitely mentioned in the handbook and in the standard. So you see here in the gray text, this is a copy of the text of the standard and the intent this new section makes explicit, etc., and then comes a bigger piece of text that helps to understand what was meant here.

The handbook annals of the standard include what we call improvement areas, software and outsourcing, and the ISO 13485 historically is more focused on producing hard devices or products, tangible products, if you will, not so much on software, and outsourcing has been labeled -- has been called differently in the earlier versions. So this is to clarify what is meant with those elements, software sometimes as a medical device or software that is driving or controlling a device.

And the handbook has been adopted and this phrase is going back to 2019, and right now China is developing a different, a more integral adoption of the handbook. So also this one is seeing a pretty much global uptake in here.

And one of the benefits, and we'll get to that in a few seconds about stability of the standard, additional insights may be provided by an update of the handbook. This is not planned for the moment, this is dependent on experience with the implementation and so far we have received a few questions, a few remarks about additional explications. But perhaps rather than updating, amending the standard, an additional or a new version of the handbook might also be a tool to provide additional clarification and guidance without touching the standard. And if there's anything unclear, there is always a way to approach the leadership at TC 210 if there are questions, if there are comments, suggestions for

change.

We have seen this before, you have, this is a picture that I took from the Internet, one of those zillion pictures when you ask for C.F.R. 820, and again it shows that this is substantively similar from the layout, but also from the content of the ISO 13485. More than enough details have been shown before, so I'm not going into that in any further detail.

Now, there was a question, and I also saw messages, there are advertisements on the Internet that are going to tell you everything that the FDA will be doing in the next couple of years, of months. I'm not sure how they can already tell, but one of the questions that arise: What means incorporation by reference? Well, it means C.F.R. 820 is not going to disappear. It will be amended by replacing the relevant elements and insofar as possible with the relevant similar elements taken from ISO 13485, but as a dated reference. And this is something that in the standards world is quite -- well, maybe I shouldn't say controversial, but it's one of those big discussions that we have.

From a standards perspective, the organizations always like updated references because then automatically, in their view, automatically if there's a new standard, automatically the new standard would apply. I don't think that that makes good sense when you have regulations that refer to a particular document because then you don't control what you are referencing. So to me it's completely logical that this is a dated reference.

As to stable standards, you have already seen the historical development in Melissa's presentation, the first edition updated in 1996. Then the second edition in 2003, reflecting some of the changes in ISO 9001 and the decision to sort of separate from 9001. And then 13 years later, the third edition. Now, if we take that development cycle, then edition 4 might be 7 plus 13, that would be 19 years at least from 2016. That would be 2035. It may

not be that long, but the standard is pretty stable and that's because -- well, it's not perfect, but it's pretty good and it's fit for a long time. And I'll show you a few notes in a second on when that was put at stake.

The best guarantee for ISO 13485 stability is ISO itself. And I should briefly explain this. ISO has a particular requirement for all management system standards and that is not really compatible with the intended use of ISO 13485. So if we would decide to obey the ISO rules in this part, we would render ISO 13485 useless for its intended purpose to serve public policy. So we're not going to do that, that means until ISO is removing that obligation to adopt this particular structure and terminology and there is no appetite whatsoever to revise ISO 13485. So that's a bit interesting and a bit weird behavior from the ISO side.

And as I mentioned minor modifications, when they are needed, explanations, perhaps guidance, perhaps new developments in understanding, they may also be communicated via an update of the handbook.

Now, these are a few statements, input from stakeholders, that we received a few years ago when we were in a forced early systematic review, 2019. So the publication was 2016 and ISO was not so happy that we did not adopt that mandatory layout or mandatory verbiage and they told us you have to do a systematic review in 2019.

Now, the whole world was in consensus that no, no, don't touch the standard. And in hindsight, I think this is a blessing in disguise because now, in 2020, it was decided that we have to keep -- on the basis of the outcome of the systematic review, we have to keep the standard stable for the next 5 years, which is good. So that means that we'll have no change whatsoever or the beginning of a change until 2025. So this is -- oops, I'm losing my ear. We have that confirmation and this is documented in 1156 from TC 210, if someone wants to look into that. So that means the document will be stable until at least 2025, so at

least 3 more years from now, but I can guarantee you, it will not change any substantially within the next 5 years.

And should we make ISO 13485 harmonized approach for management systems HAMSS compliant? No, no. I don't think that we're going to do that. And I could have Peter entertain you at another occasion for a half an hour on that, but we're not going to do that.

Any link with ISO 9001? Possibly, perhaps in the not-too-near future. But for the time being, not even ISO 9001 is considered to go into revision because of that new harmonized approach for management system standards. So that's an interesting statement from that part.

And small updates/clarifications? Maybe. Maybe via the handbook or via other publication means from ISO.

And now I'm getting close to the end, this is my next-to-last slide about the benefits. Amending C.F.R. 820 to include 13485 is beneficial because of cost saving. In the proposed rule, FDA estimates about half a billion dollars savings for the U.S. market. Now, with the U.S. market being something like a hundred eighty billion U.S. dollars, half a billion may not be that, let's say, impressive. But I still believe 500 million is a lot of money and it's worth the effort.

It will allow U.S.A. manufacturers to export products more easily, and there's a comment coming up in a second.

It will stimulate more countries to do a similar update, if not already done. As I mentioned, some hundred countries, hundred-plus countries have adopted or at least have issued certificates to ISO 13485, but there are still some hundred countries to go, so we do have some work, some missionary work to do.

It emphasizes -- and this is, I think, another item that hasn't been mentioned, but it

emphasizes the importance of standards for global regulatory convergence. So not just for the quality management systems, but also for the bigger ambition to share resources in approving devices for placing on the market in multiple jurisdictions. I think that would be a major next step and I would like to see that happen in the not-too-distant future.

And this is just taken from the convener of ISO 13485 Working Group 1. The proposed amendment of C.F.R. 820 helps industry with a single approach to quality management systems, providing a least burdensome approach to global markets by focusing on a set of aligned requirements. Today, a manufacturer has to manage both 13485 and the QSR and there are some country differences which is to some extent inevitable, that still have to be managed but with foundational elements aligned, if that is focused on product and market needs to serve the patient and users better.

And I think that that's a good conclusion to finalize. Thank you for that and from my part, let's go for it. Thank you.

DR. DAVID: Thank you, Peter Linders, very much for the educational presentation to the Committee about the role of the international standards, specifically the ISO 13485 was very well done, I appreciate that.

We're now scheduled to take a break. After the break we'll have an Open Public Hearing and we will take a 15-minutes break. For the Panel members, we ask you that please do not discuss the meeting topic among yourselves or with anyone attending virtually during the break, and we will resume at 11 o'clock. Thank you all for the presentations so far.

(Off the record at 10:46 a.m.)

(On the record at 11:00 a.m.)

DR. DAVID: It is 11:00 a.m. and I would like to call this meeting back to order.

We had a very informative morning so far with presentation from FDA

representative, industry representative, and convener of the ISO/TC 210, and on behalf of the Panel, I'd like to thank all the presenters thus far.

At this time we will proceed with the Open Public Hearing portion of the meeting. Public attendees are given opportunity to address the Panel to present data, information or view relevant to the meeting agenda. Mr. Collier will now read the Open Public Hearing Disclosure Process Statement.

Jarrod.

MR. COLLIER: Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making. To ensure such transparency at the Open Public Hearing session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an individual's presentation.

For this reason, FDA encourages you, the Open Public Hearing speaker, at the beginning of your written or oral statement, to advise the Committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting. For example, this financial information may include a company's or a group's payment of your travel, lodging or other expenses in connection with your attendance at this meeting. Likewise, FDA encourages you, at the beginning of your statement, to advise the Committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

At this time I will now turn the meeting back over to Dr. David. Thank you.

DR. DAVID: Thank you, Mr. Collier.

The FDA has received two requests to speak prior to the final date published in the *Federal Register*. The first speaker is Amanda Benedict, the Vice President of Standards from the Association for the Advancement of Medical Instrumentation.

Amanda, you may begin.

MS. BENEDICT: Thank you, Dr. David, for the introduction and good day, everyone. Thank you for the opportunity to review and comment on the U.S. Food and Drug Administration's proposed rule to amend the device current good manufacturing practice requirements of the Quality System Regulation. The brief remarks that I'm sharing today are on behalf of the Association for the Advancement of Medical Instrumentation or AAMI.

AAMI is a diverse nonprofit membership organization of more than 10,000 professionals united by one important mission, which is the development, management, and use of safe and effective health technology. As a leading developer of national and international standards for medical devices and related healthcare products, AAMI specializes in standards that address the safety and performance of devices and device systems as they relate to patient safety.

AAMI is accredited by the American National Standards Institute as a standards development organization and we also administer the U.S. technical advisory groups to a number of international technical committees and subcommittees, as well administering the secretary to ISO and IEC technical committees and subcommittees.

AAMI does not advocate and is respected around the world as a neutral honest broker between its diverse stakeholders, which include medical device manufacturers, healthcare technology, management professionals, independent service organizations, regulators, clinicians, researchers, and independent experts.

AAMI does not normally submit formal comments in response to FDA notices. In this case, although we maintain central commitment to our role as a neutral and objective convener, we believe that AAMI's long history of administratively supporting the standards development efforts that led to the creation of ISO 13485 can add valuable perspective to consideration of the proposed rule.

In 1994, AAMI proposed the establishment of an ISO technical committee with a major focus on quality management systems for medical devices because at that time, Europe had developed their own draft quality system. This area of international standard -- standard station was approved by the ISO member bodies and created ISO/TC 210, quality management corresponding general aspects for medical devices which, as you've learned, is the international technical committee that's responsible for the development of ISO 13485. AAMI administers the secretariat to ISO/TC 210, as well as the U.S. technical advisory group to ISO/TC 210. And that's the group that's responsible for the U.S. national adoption of the ISO standard.

Consensus-based uniform and systematic approaches to quality management across the world can improve the safety and performance of medical devices globally, which benefits patients and also encourages innovation within industry and facilitates expedited and less-costly introduction of products into new markets. And from its inception, the intent in charge of ISO/TC 210 has been development of global requirements for medical device quality management systems that can serve as the basis for national and regional regulations.

In our specific and continuous efforts to coordinate ISO/TC 210's work program activity and the development of national and regional regulatory requirements including, through a collaboration of organizations that have goals and objectives that are related to those of ISO/TC 210, such as the International Medical Device Regulators Forum or IMDRF, the 2016 edition of ISO 13485 provides foundational support to the advancement of global harmonization of quality system requirements for medical devices and has been incorporated into IMDRF's Medical Device Single Audit Program (MDSAP), which has been implemented in a number of jurisdictions around the world.

AAMI has long believed that ISO 13485 should become the global quality system

standard for medical devices worldwide and we support efforts towards regulatory convergence. We have adoption of the new rule by the FDA, but essentially make this a reality leading to improved safety, effectiveness, and availability of medical technology for all.

So thank you again for your time today. We hope that our comments provided deeper understanding of the context of this proposed rule and underscore AAMI's support for the rule.

MR. VEIZIS: Sorry, you need to unmute.

DR. DAVID: Amanda Benedict, thank you for bringing AAMI position about the subject of our meeting today and we will move to the second speaker. This is a prerecorded presentation from Mark Swanson from QRx Partners. You may begin the presentation.

MR. SWANSON: Thank you to the FDA and the Committee for allowing me to make these prerecorded comments and my questions. As an active member of industry, I particularly work with small and start-up companies in the medical device industry to develop and manufacture finished devices, to provide help in meeting quality system and other regulatory requirements including acting as a U.S. agent. In general, this work is very much appreciated to bring consistency across the industry, the quality management system requirements for regulatory purposes. As I go into this, I have a couple of clarifications and questions, hopefully, that the FDA and the panel can address.

Here's a listing of my bullet points on the clarifications and specifically, I think, the industry question has to be will certification to 13485 be a requirement? While it's not a requirement in the draft rule as proposed, it is unclear whether or not the certification of 13485 will provide satisfaction to the industry, as well as if this will be a requirement at some point in order to place product on the market in the U.S.

The second item I have is the quality manual versus quality planning. As currently

outlined in the QS regulation and the emphasis on quality planning, development planning, ISO 13485 specifically has a requirement for a quality manual and the interrelated processes of the quality management system. This needs to be clarified so that industry can understand what the true requirements are.

The third item is the process approach that's outlined in ISO 13485 versus the normal compliance approach that comes through the regulation. Understanding and working with FDA and MBIC on the case of quality, that quality beyond compliance is a goal to be achieved, to be stretched for, we're worried that this improvement may cause some compliance issues. In other words, as items are noted, how that enforcement action will be taken for voluntary action or official action, if necessary.

The fourth item here is inspections versus audits. Again, going back to the certification question, whether or not that certification would provide any benefits as the current MDSAP, the Medical Device Single Audit Program and MDDAP, the Medical Device Discovery Appraisal Program, do for organizations that currently go through the FDA routine inspections.

The fifth item here is postmarket surveillance and the use of real-world evidence versus reporting. I think there's a concern in following 13485, that gathering and then providing that information as it's currently being done in Europe, could become a requirement as we implement these changes.

And then the final item that will require clarification is the current regulation outlines some exceptions for recordkeeping, in particular, talking about internal audits, buyer audits, management review or records that are not normally reviewed during a routine inspection by the FDA and whether or not those would now become subject to the audit or review during new inspections under the new rule.

Moving on to my next piece, again, I want to thank the FDA for their involvement in

many of these organizations. In particular, I want to tap on AAMI, the Association for the Advancement of Medical Instrumentation and the quality management group, in the creation of TIR102, which did the comparison between the current quality system regulation and ISO 13485.

Also want to acknowledge and call out the Combination Products Committee because this draft rule is intended to also affect 21 C.F.R. Part 4, which is the combination products requirements, that their involvement will be necessary in continued clarification in how this rule is to be implemented.

Also, MDIC, I had mentioned already the case for quality, understanding how this is going to affect the industry in that regulatory environment.

And the final two organizations, American Society for Quality, the biomedical division, and the Regulatory Affairs Professional Society, all need to be involved in providing additional inputs.

Looking forward to the commenting period and seeing how this draft rule is continued to move forward as industry moves to that harmonization across the world in our quality management system requirements. And thank you for being able to ask these questions and present, and I look forward to seeing the information, hopefully in some sort of a method similar to the FDA's current preamble so that these questions can be answered and be public. Thank you.

DR. DAVID: Thank you, Mark Swanson, for your initiative in bringing those questions to the attention of the Advisory Committee.

I now pronounce the Open Public Hearing to be officially closed. We will now proceed with the next topic of our agenda and that is the panel deliberations. The panel deliberation is open to public observers; however, public attendee may not participate except at the specific request of the panel chair. Additionally, we would like to remind you

that we request all person who are asked to speak to identify themselves each time. This will help the transcriptionist identify the speaker.

With that, I would like to look at my Committee members and see if you have any comments or questions to the topic we discussed this morning.

(Pause.)

DR. DAVID: You have the raise hand button on the bottom of the screen, if you will. If not, you can just wave. I can see Robert has his hands up. If you can unmute yourself and I recognize you for your comment, please.

MR. PHILLIPS: Thank you. This is Robert Phillips. I really appreciate the presentations today, both from the FDA and from industry, on this really important topic. I think that moving the U.S. regulatory framework towards a more international framework is really important for many manufacturers, not just those that are only domestic, but certainly those that are international.

I think the presentations today certainly did highlight a number of topics that continue or need to be discussed continually as this sort of moves forward. I think topics around whether certification is required or even expected from an inspection point of view is something that needs to be clarified moving forward.

I think the transition period is also something that needs to be thought through perhaps a little bit more. When we look at how the industry would adopt new regulation, we actually need to understand what that new regulation looks like in all aspects, right? So as the Agency considers moving forward with the adoption, parts of 13485, certainly the industry needs to see what that looks like in written form, but the industry also needs to see how that affects other parts of the regulation, so 803, 806, C.F.R. 1000, potentially. Also needs to look at how it may affect existing guidance documents as well as how it may affect the quality system inspection manual. And all of those documents in that entire

landscape really needs to be available to the industry as they work through the transition. So I think we would want to understand at what point would the FDA have all of their updates available, publicly available, so that the industry can start the transition and then move in that direction.

So I think a 1-year transition after the final rule may be a little aggressive for industry. I think what was proposed by AdvaMed is a 2-year transition or potentially even a 3-year transition based on how the FDA plans on finalizing all of the associated documents is something for further consideration.

I think another topic that we may want to know more about relates to the 13485 standard itself and whether the Annex A/Annex B come into play in FDA's adoption of certain requirements in 13485. But I think the other consideration is whether it makes sense to hardcode 13485:2016 directly within the QSR language.

A number of years ago there was another regulator in another country that adopted a specific version of a standard. When they didn't move very quickly to update the regulation to the new version of the standard, it required the industry to actually maintain compliance to a down-road version of the standard and the current version of the standard.

And so I think there may be a way for us to consider writing language that would say we recognize the current version of 13485 in the QSR and then as 13485 gets updated, then the FDA will consider whether those updates through the ISO 13485 transition period required an additional update to the QSR to maintain conformance. But I think hard-coding 2016 in the regulation potentially creates conflict down the road, not only with potential revisions to 13485 but also where 13485 is recognized elsewhere, such as the MDSAP program.

That's my top-line comments for now, but I'm open to other discussions.

DR. DAVID: I appreciate that. Excellent comments, Robert.

And I would like to move around the table, if you will, and see other Committee members comment and I'll jump to Gordon Gillerman.

MR. GILLERMAN: Thank you, Chair. And I, as well, appreciate the FDA's, as well as the industry and the trade association presentations today, it was very informative and helpful on the subject matter and helpful for me, as a panelist. I want to first start off by applauding the FDA's desire to move forward with the incorporation by reference to an international standard.

As was already mentioned, it is in conformance with the National Technology Transfer and Advancement Act and the Office of Management and Budget Circular A-119, which are the implementing instructions and guidance for the federal agencies on the standards provisions of the NTTAA. I know a lot about that because I'm the chair of the interagency committee on standards policy and the implementation of that act, and on the A-119 across the government is part of my core duties as designated to me by the director of the National Institute of Standards and Technology. So I think this is an excellent move.

It sounds like, from the presentations, that there are many in favor of moving toward a more voluntary consensus international standards-based approach to the Quality System Regulation for regulated medical devices. And I also appreciate the FDA's diligence in the detail of looking at those aspects of the current regulation which may need to be clarified or may need to be added. It is federal agencies' prerogative to adopt standards like this or incorporate them by reference in whole or in part and with amendments if they need to, and the FDA has a long history of recognizing voluntary consensus, international standards, in their programs for the application of medical devices and others.

Just as a response to the last panelist's comment, it is challenging for regulators to adopt undated references to standards as they incorporate them by reference and regulations. There may be some paths to ease the process of moving from one addition to

the standard in the regulatory context and those are certain areas that I think need a great deal of discussion because, as the last panelist said, it's very challenging when the regulatory system lags far behind the current version of standards that are well used around the world. Thank you.

DR. DAVID: Thank you for bringing the NIST experience to the table and I appreciate your comments.

Scott Sardeson.

MR. SARDESON: Hello, this is Scott Sardeson. I just would like to say very well done, the information this morning was very good. Being a convener for the standard, I do know the amount of work and the effort it has taken to get to this place and I'm very appreciative of this direction that the Agency has taken.

I don't have too much to add, I think Robert Phillips did an excellent job on the voice of industry. I would like to reiterate the transition. You know, you hear in the presentations small companies are going to have maybe some trouble, U.S. companies might not know ISO 13485, I think that that really needs to be considered as part of the transition. But large companies have just as much trouble. We have many, many sites all over the world with much that would have to be updated.

So the 1-year transition is quite aggressive and I do think that the suggestion by AdvaMed of 2 years is more adequate when you consider the amount of training and also a change in culture you may have to face, whether you're a small company or a large company.

I also think there's some elements in this new approach that are going to be hard for some 21 C.F.R. 820 companies to acknowledge, and I saw that in the risk management discussion. The standard brings a new state of the art to risk management with ISO 14971 and although the FDA always expected that same approach, it's in the preamble and many

smaller companies that are 21 C.F.R. 820 read the QSR but aren't always in touch with that preamble and the depth of what risk management applies to. And that's a very big shift in mindset, so that also, I think, warrants a 2-year transition and not just one as, technically, companies will have to think a little differently in that area and many of us maybe are already there. But if you're a U.S.-only market, you may not have that same understanding and that is a pretty big shift.

I also would like the FDA to really consider their guidance and how they're going to approach the areas of, like management review and internal audits. I think there's a lot of concern in the industry on how that enforcement discussion will be looked at in the elements of 13485 in our audit practices, and Robert picked up on that, too, in his comments.

Lastly, I would also say with Robert and Gordon's suggestion, really hard-coding 2016, I lived that same experience that Robert talked about. If there would be a way to use more of a consensus standard approach, recognizing the current standard, and the FDA addressing what they agree with or don't agree with, I think would be good. I don't envision that we will try to change 13485 drastically, we are trying to keep it as stable as possible, but we know that there are improvements in how things could be done.

The mitigation to that is I am very thankful and I hope that the FDA will continue to be as active in the standards development. My hope would be if it has to be hardcoded, that by being involved in the revision that we do if we need to do a revision, there will be an early indicator by the Agency of where the standard is going so that when a change would be made that the FDA would already be working on how that might impact the regulation and the approach. And I think that as long as the FDA stays active in this ISO/TC 210 work we will be okay there, but I do prefer if there was a way not to hardcode the version and the year because of that problematic issue. Thank you, Chair.

DR. DAVID: Thank you, Mr. Sardeson.

And I see that Jeri has a hand up, we'll go to Jeri Culbertson.

DR. CULBERTSON: This is Jeri Culbertson, thank you for all the presentations, it was greatly helpful and I appreciate the people that have commented already.

I am representing more of the end user and agree with moving to standardization with that. Even as we receive devices from different manufacturers and countries, there's still variations within how we receive them, how we reprocess them, if we're able to reprocess them, making sure that they are safe for patient use. So really respect the FDA's decision and hopefully moving forward with this standardization with that.

Little bit concerned that there are still some clarifications between having the standard document versus having a little bit of our own tidbits that we need clarification on, so I would really like to see that further honed in on to just adapt it as is rather than modifying it to make means met. Thank you.

DR. DAVID: Thank you, Culbertson, for bringing the end-user angle to the discussion. I think that as we hear you, we realize that the concept of life cycle has been now added to the regulatory that was not there before and suggestion that in addition to the manufacturers, there might be an outsourcing third-party independent service organization and perhaps biomedical engineers at the hospital participating in receiving and installing and integrating component of a system from a single or multiple manufacturers at the point of care and that is a requirement that was not there before on those outsourcing personnel and biomedical engineer working in the field. So we need to make sure that we can address and clarify the relationship to the requirements of regulation and for those particular portion of the impacted community.

I see, Robert Phillips, your hand is up again and I recognize you and looking forward to hear you.

MR. PHILLIPS: Thank you, Chair. I guess as a follow-up to what the panelists have already said, I think it is important maybe for this Panel at some point to actually see a redline of the C.F.R. so we can actually see how things will move between 13485 and the actual C.F.R., so we can see the devil in the detail, if you will, about the language being used, the definitions, and actually look at how the industry would be expected to implement the new regulation.

And I think, Chair, to your comments, what we may want additional clarification on is we're talking about manufacturers, but there are a number of registrant types that the FDA oversees activities on, so importers, distributors, manufacturers, remanufacturers, processors, servicing organizations, and understanding how those organizations are in scope or out of scope of what we're talking about today. My assumption is they're all in scope, but we really have only been focusing on the term "manufacturers."

And related to that is the fact that some other entity, such as importers and distributors and perhaps even complaint file establishments, may have chosen to go with ISO 9001 for their quality management system because they were non-manufacturing entities. And so as part of the transition, as part of the education, I think there needs to be some consideration for companies, not only just domestic but maybe even global companies that are not educated in 13485, to show them how they map from 9001 to 13485 in addition to the new QSR. So that's my thoughts, as well. Thank you.

DR. DAVID: Thank you, Robert. I believe that you captured well some of the comments you heard and I do look myself for an idea of redlining a process more clear of what's in and what's out of scope, especially to then, what I would call non-manufacturing members of the community that now is included.

With that, I'll go back to recognize Gillerman.

MR. GILLERMAN: Thank you, Mr. Chair, this is Gordon Gillerman from NIST.

So in addition to the comments about the standard and the technical requirements in the language of the regulation, we've heard a lot of comments that relates to how certifications to ISO 13485 would be looked at in a regulatory sense by the FDA.

So I'll just bring the FDA and the community's attention to a NIST special publication called "Conformity Assessment Considerations for Federal Agencies." This document was published several years ago with public review as well as a significant interagency review which definitely included the FDA. This document helps guide federal agencies on the things that they should be thinking about as they implement conformity assessment systems both for regulatory purposes and others. I know the FDA knows this document well because in the current rollout of their ASCA program for accredited laboratory testing used in device applications, that's just a recent pilot program, they use the tenets of this document very, very well.

One of the most important things in this document is to have public and stakeholder engagement throughout the process and I think that will be very important and certainly, this meeting itself is a part of it. But I also think the kind of engagement we see from the FDA, engaging the industry and the industry stakeholders in a way that helps them understand the expectations of the FDA if they choose to move forward with the incorporation by reference of 13485, how conformity assessment as it's currently conducted by other countries and by private organizations may or may not play a role in the FDA's acceptance of manufacturers and other regulated entities complying to 13485 and how they should address that, I think that would be very helpful for all the stakeholders involved, including the industry and the stakeholders. Thanks.

DR. DAVID: I appreciate your comment and I wonder if it is acceptable for you to note in the checkbox the document you reference so people who are not familiar with that might be able to be better educated.

MR. GILLERMAN: Certainly. There's actually a document called "The ABCs of Conformity Assessment" that we published, as well, these are kind of companion documents. The first one is for people to have a broader understanding of conformity assessment and associated terminology, the second one is specific considerations for federal agencies. I will put a link to the checkbox for both of those publicly available documents. Thank you.

DR. DAVID: I appreciate that.

Any other comments? Any member of the Advisory Committee that has not been heard from before?

Lisa, I see you waving there.

MS. DIMMICK: Yes. Thank you, everyone, for excellent presentations this morning and great information.

So I wanted just to comment that with my career, I first was a -- worked for a facility that used medical devices, I worked in hospitals, and then from there I went on to industry and I worked in regulatory affairs and quality management for a medical device manufacturer. And then in my last stage of my career, I'm now a regulator, I'm at the Nuclear Regulatory Commission, so I have a pretty good perspective of all aspects of medical devices in that regard. So I really do appreciate and respect the tremendous effort on the part of the regulator, that being FDA here, to incorporate by reference this standard.

I'm familiar with the standard back in 2003, so in those early days of the 13485 standard, so I think moving in this direction provides clarity. Obviously, it makes it more efficient and effective and that so everyone, from an international perspective, is kind of speaking the same language and has the same understanding of the requirements.

So I just wanted to make a couple of comments that with regard to the FDA's specific requirements provisions that have been included, I can appreciate the legal requirements

that FDA has to make those additions to the regulation, in part, because these terms and other aspects are in other parts of FDA's jurisdiction with drugs and biologics and other type of devices, so I can understand and appreciate that FDA has to make certain specific provisions in this particular regulation. I just wanted to make that note.

The other thing that I note, though, with the language is that while the standard is written fairly broadly with some level of specificity but it's really -- the language is more broad, whereas FDA, in adding the specific provisions, they're actually a little bit more specific and proscriptive in that regard. And I just point that out that for going forward for compliance and inspection of those areas of how you can apply kind of an equal inspection technique to those specific items as opposed to and in addition to the more broad criteria of the standard. Just something to think about going forward as we develop the inspection protocol for the new regulation.

And the implementation, I really do believe that industry will need a longer time to implement given the significant changes that are going to occur with regard to guidance that will be needed as well as the inspection program. Thank you.

DR. DAVID: Thank you, Lisa. I do have a background noise, I apologize because in my high rise they are cleaning the windows outside and on their platform there is music played in addition to waving on the glass behind me every now and then. So it's not that I'm trying to entertain you with extracurricular activity here.

Alisha Loy, please.

MS. LOY: Yeah, this is Alisha Loy. So the thoughts that I have related to the user sector of this is what we cannot afford is to have a backslide in where we currently are. We still experience difficulties where there is a significant amount of responsibility and ownership that is placed in health care as it relates to device defects. And so right now what that does is it forces us not only to develop partnerships I completely support, but it

also places the onus for safe patient care solely to many healthcare instances. If we backslide and we don't maintain the levels of labeling and the requirements for our IFUs and things like that that we function with, we're going to put additional responsibility on healthcare organizations that transfers that, in my opinion, to where it does not belong. We need to make sure that as we continue to move forward with the quality standards that we are meeting these requirements for risk management. That is a level that I'm very excited to hear will be increasing. And then I think this also supports the dynamic where the FDA is coming forward and making the comment that we need to have additional regulations that will not allow for backslide within the labeling areas and others that they identify.

So I think there's going to be continued opportunity for multidisciplinary collaboration for us to be able to come together and work towards unified practices that help support the manufacturing of devices as well as the users within this.

And I support all of the aspects that I saw today, including the additional opportunity for transition time periods to make sure that all of those, especially those that may not be as familiar with the scope of the document moving forward, and I question where some of the aspects of this will land within the healthcare sector.

So I'm excited to receive additional clarity in those pieces and just want to offer the support and thanks for all of the incredible effort that's already been done in this and just request that as we continue to move forward that those considerations of how that responsibility lands to us, as healthcare providers and professionals, is considered within all of the scope of the work that's being completed. Thank you for your time.

DR. DAVID: I appreciate the voice of the healthcare consumer being brought, Alisha, and I think you're making several interesting point. In a way, I had more of a question than a statement, but the role and responsibility that might be increased on healthcare provider,

I understand is an issue that you would like to see more clarity about and I welcome that. Thank you.

Benson Kuo. Dr. Kuo, please.

(Pause.)

DR. DAVID: You are on mute.

DR. KUO: Thank you, Chair. And I concur with all the comments from other panelists. The other areas need to be further devised or reviewed, but I'd like to draw our attention to a small subset of the device developers, which is the research institutes and the recipients of the small business research grants, SBIR or STTR. They are considered the seed for the technology developers. They don't have huge funding to advance their technology. However, they're still under the regulation and supervision from the FDA. So the quality system requirement has been a concern, especially if we transition to 14971, the risk management part may impose an extra burden for these small "developers." So I'd like to bring a voice for them and bring this small group to our attention. Thank you.

DR. DAVID: Dr. Kuo, thank you very much. You added another stakeholder in the form of research institution manufacturing processes that we would like to receive clarification about. There were some questions that were raised initially as clarification by the FDA relating to adoption of specific definition and amending or retaining existing definition from the QSR 820 as contrasted with the ISO 13485 and that probably will help some of the research institutes to better understand how much they are involved in the process of the new regulation that we're discussing.

Let me recognize Alisha Loy.

MS. LOY: I just wanted to thank you, Dr. Kuo. If I mispronounced your name, I apologize. But I think it leverages a really great question and within the university platform, as an academic medical center, what we look at is the dynamic of clinical care pathways and

some of the aspects of research actually could potentially fall to aspects of the IRB process. And so I do think that this lends itself to a very significant question that needs to be addressed and that is where does the standard of care fit, which is really what we're talking about here, versus where are those additional avenues for innovation and creativity, which could be created through research and development or could also be created through additional other clinical care pathways through physician innovation and things like that.

So I appreciate your question and I think it's a very valid one that does need to be addressed because I believe there are different associations and standards and regulations that could potentially be called out depending upon how we would want to associate those clinical care pathways.

DR. DAVID: I can see that the life cycle development might be a jump into the design phase where the IRB board might be considering incorporation of technology not yet on the commerce market yet, but is in the process of the life-cycle development, and that need to be clarified.

Scott, I recognize you.

MR. SARDESON: Thank you, Chair. This is Scott Sardeson. Yeah, those are some really good concepts and I think it's something that maybe wasn't resonating as well in the information this morning. One of the improvements to the 2016 version of the standard was to embrace that there are other regulations and there are other requirements. So throughout the standard, it's trying to remind users of the standard that this is a starting point, but they have an obligation to look at other things like the preclinical work, IRBs or even nationally specific differences like the FDA is proposing. So I think that we did our best to bring in that this is an all-encompassing standard and that the users have to be educated and I think that those are things we should also look at when we consider what kind of training tools are going to be needed, what kind of links are we going to have to make in the

documentation that we provide industry and users and even the customer side of this as the FDA goes forward. But that was an intentional improvement brought forward into the standard so that it could be used more globally for regulatory purposes. And it also then matches well that the FDA can have some of these national prescriptive "I need this in the U.S. because of legal jurisdictions."

So I actually think we succeeded there and I think that the approach the FDA is taking is again, very much like other jurisdictions have already done where it's a foundational starting point with some prescriptive national needs in their countries or in their jurisdictions, as well as reminding the users of the standard that there are other places and other things that they are expected to be aware of and to comply with and I think that that's been shown in the MDSAP audit program that it doesn't stop with the standard, that there's many other things that they're checking as part of inspection. So I really like that conversation because I think that there's a lot of people in the life cycle of the product that are involved where the standard could help, but also the standard has other linkages like you have brought up, so thank you, panelists.

DR. DAVID: Thank you, Scott. The preclinical stage of product development and manufacturing is an interesting point you are magnifying and highlighting, and I appreciate the comments.

Let me recognize Robert Phillips.

MR. PHILLIPS: Thank you, Chair. I just wanted to follow up on something that you said and Scott said, as well, as when we look at the education campaign around rolling out new regulations or changes to regulations, it's really important to understand who all the stakeholders are and certainly we know from those entities that are actually registered with the FDA, we have contact names, we have U.S. agent names, there's a way to get this information out certainly through webcasts and others to make sure that those entities are

informed of what's going on with the regulation change. But, Chair, as you mentioned, there's the third-party service providers which are actually not registered entities with the FDA and so there may be that population as well as other populations, healthcare providers and such, that are unknown to the FDA and so the education plan should consider how to roll out these new requirements to entities that are unknown to the FDA to make sure that the entire ecosystem understands what the regulation is and the requirements to move forward.

DR. DAVID: Your comments are helpful for clarification of the scope of the issue and I appreciate that and would like to see if there are any other comments, questions, from the panel.

(No response.)

DR. DAVID: There is something that was mentioned and I'm not clear about it and maybe Gordon, maybe it's more relating to your area, but the mention of regulation including non-dated voluntary standards as time plays on and do you have an example of something that has been done or it's a question that needs to be addressed?

MR. GILLERMAN: So thank you, Mr. Chair. Gordon Gillerman from NIST responding.

So generally, when regulatory agencies incorporate a standard by reference, there's a set of rules and procedures, actually the Office of the Federal Register and NARA, one of the agencies of the federal government, has requirements and one of the requirements is that it's a dated record, but it calls to a specific edition of the standard, I think conceptually, otherwise the regulatory agency is seating its regulatory authority to the body that develops the voluntary consensus standards. So generally speaking, when it's done through a regulatory action with an incorporation by reference, it's done to a specific dated reference. There is one different approach and the different approach is through an act of Congress. So the Consumer Product Safety Improvement Act actually specified a different

process for adopting toy safety standards and children's product safety standards after the spate of recalls in 2007 that were related to excessive lead in toys and other hazardous issues with toys and there Congress spelled out to the Consumer Product Safety Commission a very, very specific timeline for evaluating new editions of these toy safety standards and making the regulatory decision to use them or not use them, I believe that time period was a hundred and twenty days after their publication, but that was done through an act of Congress, not through a regulatory agency. I hope that's helpful.

DR. DAVID: Very helpful. I have a better understanding of the process, thank you.

Anyone else?

(No response.)

DR. DAVID: If it's the lunch reason, that's okay, but just want to visit one more time. Is there any comments or questions that you would like to propose?

(No response.)

DR. DAVID: There is none. I think that I will close this panel deliberation session and we'll move on to the next item on our agenda, which is the lunch. So if it's okay with you, we will break -- Jarrod, is it 1 hour lunch we have? And remind the panel not to discuss the topic among yourself or with other member virtually or in person until we get back. We will now break for lunch and we'll resume at 1:00 p.m.

(Whereupon, at 11:52 p.m. a lunch recess was taken.)

AFTERNOON SESSION

(1:01 p.m.)

DR. DAVID: It is now 1:00 p.m. and I would like to call this meeting back to order.

Before we're going to start with the next subject of the Food and Drug Administration questions to the Panel, I would like to introduce additional member that just recently joined us, Lisa Owen, if you please, tell us how to pronounce your name, your affiliation, and the -- please.

MS. OWEN: Of course. Thank you, Chair.

My name is Elise Owen, I work for the U.S. Environmental Protection Agency as the Standards Executive. That means I oversee and coordinate our agency's pursuit of private sector standards like ISO, as well as our staff's participation in those activities. As it happens, I also, in a past life, worked for the medical device industry so I'm excited to be here and hope to contribute to this important work. Back to you, Chair.

DR. DAVID: Thank you. We're looking forward for your input.

At this time, we will turn to the discussion of the FDA questions to the Panel. The copy of the questions have been sent to you electronically just recently and posted online for public review. I would like to remind you that as you make your comment during this part of the agenda, please identify yourselves so the transcription can be accurately reflected our comments. I will turn to Captain Kimberly Lewandowski-Walker to either post or read the question to the Panel.

CAPT LEWANDOWSKI-WALKER: Okay, thank you. If maybe the presentation could be shared with the questions, that would be great. Thank you. So again, I am Captain Kimberly Lewandowski-Walker and I will be reading the FDA questions to our Panel.

Under 520(f), before promulgating any regulation related to GMPs, an advisory

committee will be assembled to submit recommendations and hold an oral hearing, ensuring such regulation conforms to the extent practicable with international recognized standards defining quality systems or parts of the standards, for medical devices. Given this charge, FDA has the following questions for the Panel to consider regarding the proposed amendments to 21 C.F.R. 820, which primarily incorporate ISO 13485 as the foundational requirements for its medical device quality management system regulations.

The first question: Does the Panel agree with the benefits that FDA has described that would accrue as a result of the proposed amendments to 21 C.F.R. 820, and does the Panel anticipate any additional benefits to the proposed amendments that FDA has not described?

MR. VEIZIS: Let me see. Do you want us to go the next slide, go through all the slides now?

CAPT LEWANDOWSKI-WALKER: There are several questions, we can do one question at a time or I can read all the slides.

DR. DAVID: Let's do one question at a time, if we can.

CAPT LEWANDOWSKI-WALKER: Okay.

DR. DAVID: Thank you.

We have the first question posted and read, and I see some hands. I would love to engage the Panel in providing us feedback and opinion. So let's start with recognizing Robert Phillips.

MR. PHILLIPS: Thank you, Chair.

I think the first part of that question is does the industry likely agree with the proposed change and the accrual of the benefit over time, and I think the answer is generally yes, I mean, I think the industry is very supportive of any opportunity that we have to harmonize the regulatory landscape. I think that when we look at the cost of

change, any change to regulation that the industry has to find new ways to comply with, revisions, processes, documentations, upgrade of tools, training, resources, there is significant cost. And so I think that the accrual of that cost or the potential benefit is likely to be realized very far downstream because there will be a very large effort up front and a cost up front to move to the new regulatory landscape, although I think in the long run, the closer we get to a harmonized global regulatory footprint, the better it is for industry.

DR. DAVID: Thank you.

Any additional comments?

(No response.)

DR. DAVID: So far it seemed to me that what I hear is that the Panel agree with the FDA assessment that the benefits it proposed from adoption of portion of the 13485 are positive. There is concern expressed -- and I see more heads. I'll recognize Gordon Gillerman.

MR. GILLERMAN: Thank you, Chair. This is Gordon Gillerman from NIST.

So I do agree with the benefits that have been discussed today. In addition to that, one of our experiences as the technical requirements that underpin regulations, particularly for manufacturers who sell into multiple markets that use the same basis of regulations, as well as the "prove-it" process, the demonstration of conformity with those requirements becomes more unified, the sector of manufacturing generally can use more of its resources for things that benefit the public, like new research and development and additional areas of public health.

So I think there are some additional benefits as we streamline the technical requirements for quality systems for medical devices and the process for demonstrating conformity with those, we'll see, particularly for manufacturers that sell in multiple markets, a set of resources available that they may be able to utilize to provide additional

access and new technologies.

DR. DAVID: Thank you.

Elise Owen.

MS. OWEN: Thank you, Chair.

I also agree with the statement, and building on what Gordon said, it's been our anecdotal experience that when we use international standards or use standards that are already used broadly in the world, that can also increase compliance and decrease compliance cost to the regulator because the good actors in the market globally are already doing this. So I didn't see that in the benefit from FDA, but I think that is one worth noting potential benefit, as well.

DR. DAVID: Thank you.

Robert.

MR. PHILLIPS: I just wanted to add on to what Gordon had said. You know, I think conformance is a really important part of any regulation and I realize that when you look at what 13485 is scoped to do with safety and performance, whereas the mandate within the U.S. with FDA is safety and efficacy, there are some nuances there that have to be bridged.

One opportunity that I do see for additional benefit is really taking a critical eye of what's required under the preamble with the FDA's mandate and looking beyond sort of just the gap analysis that's being proposed of, here's 13485, here's the QSR, here's where we need some additional language to bridge the gap, looking at that gap analysis, saying are these conditions, these national requirements that we're talking about that would be 13485-plus, like AdvaMed said, do they really drive the industry to ensuring safety and efficacy, or are they just there as remnants of a gap analysis? And so I think we really would want to take a critical eye in saying 13485-plus and is the "plus" really relevant to ensuring safety and efficacy for the U.S. public.

DR. DAVID: And to your point, do you think that in the FDA presentation earlier this morning that referred to a pilot study with the Canadian that was done, I believe 2016 if I'm not wrong, do you believe there are any outcome that can demonstrate to your point if this gap analysis has been identified and contained or are those two different issues?

MR. PHILLIPS: I'd have to go back and look at the results from that pilot program, they're not at the top of mind right now, but I think that would make sense to go look at those and then see if there are some learnings from that activity that now come into this opportunity, right, and provide additional benefit for this activity.

DR. DAVID: So if I need to provide a response to Captain Kimberly about concern, how would you abbreviate your comment?

MR. PHILLIPS: I think the opportunity is to look at the gaps and identify whether the additional requirements that are being proposed by the FDA on top of 13485 drive the industry and the healthcare organizations for providing safe and effective devices for the U.S. population and not just sort of a kneejerk response to "okay, here's a gap, now we just need to put into the regulation because it's not addressed in 13485."

DR. DAVID: Okay.

And Captain Kimberly, your question actually raised the search for additional benefit, so would you suggest that we keep this comment to a later question?

CAPT LEWANDOWSKI-WALKER: No, we can address it now if anyone has something to say on the second part of the question about any potential additional benefits.

DR. DAVID: Okay.

Okay, any other comments?

Alisha.

MS. LOY: I believe we had two speakers today that addressed an additional benefit which was related to the dynamic of use for consensus standards within regulation and how

this was setting a precedence that may have a potential global impact for other countries to consider a similar model. So I'm not sure that that had been formally outlined but it was brought up, I believe, by our AAMI representative ,as well as by Peter, was it Peter Linder (sic)? I think both of them also spoke to this, which I think is an important benefit.

DR. DAVID: Right. The issue was raised that additional international convergence, I think the words that were used, will be impacted by FDA adoption. Thank you.

Anybody else?

(No response.)

DR. DAVID: So with regard to Question 1, Captain Kimberly, it seems like the Panel reached a conclusion that the overall benefit were adequately summarized by FDA presentation. There's some expression of concern that we will adapt or move to a different question and the additional benefit that were not mentioned relating to specifically manufacturers who deals with multi-market endeavors might be helped by that, and the overall convergence internationally towards single documented compliance path would be encouraged by that.

I believe there's one more benefit that was not mentioned, but we raised the issue that the overall community of stakeholders is wider than what was mentioned this morning because we have -- in addition to patient and consumer, we also have the outsource activity and independent service organization, as well as research institution that might be also benefiting from having a clear map or a path to how to comply better with rules and regulation. Captain Kimberly, does that address your question?

CAPT LEWANDOWSKI-WALKER: Yes. I believe there were two other panelists that had hands up, Jeri and Scott had hands up for this question. I don't know if we wanted to let them speak before we move on to the second one.

DR. DAVID: Absolutely. I overlooked it, apparently. Let's go to Jeri.

DR. CULBERTSON: I was just going to add that another benefit is going to be with less maybe regulatory burden from manufacturers' standpoint and just getting devices to the patient in a more timely fashion and safely, still. Thank you.

DR. DAVID: Excellent point, thank you.

And Scott.

MR. SARDESON: Yeah, you did not miss me, Chair. This is Scott Sardeson.

When you were talking, I thought of another one and that is that if the Agency does this correctly, it's going to allow them to adapt to best practices faster in a QMS. If you think about it today, we are very old in our concepts of the QMS in our existing regulation, and the standard has evolved to better practices and more robust ways to look at things. So if done properly and the future state is thought about, this should allow the Agency to actually adopt best practices faster than they could traditionally by putting it in the Code of Federal Regulations in a proscriptive manner.

DR. DAVID: I like this point. Thank you very much for the comment.

Anybody else realize something that they haven't told us yet relating to Question 1?

(No response.)

DR. DAVID: Then I will go back to --

MS. DIMMICK: So I have one.

DR. DAVID: Yeah, yeah.

MS. DIMMICK: This is Lisa Dimmick.

DR. DAVID: Please.

MS. DIMMICK: So I think just simply, I think this adds a level of regulatory clarity that maybe we haven't seen before by incorporating the standard, and there will be regulatory clarity of the requirements for industry and all users of the regulation.

DR. DAVID: Thank you.

With this, I will go back to you, Captain Kimberly, and see if we have addressed your question.

CAPT LEWANDOWSKI-WALKER: Yes, thank you very much.

So maybe we could put the presentation back up and go to Question Number 2.

So the question is: Does the Panel envision challenges with implementing 21 C.F.R. Part 820 as proposed?

DR. DAVID: So the question to the Panel is based on the FDA presentation this morning. The question is implementing 21 C.F.R. 820 with adoption, partial adoption withdrawn and retention section that were described, does the Panel envision challenges?

Let me go to you, Scott.

MR. SARDESON: Yeah, this is Scott Sardeson.

I think most of the challenges have been identified and presented. My only concern is a little bit about the amount of work it will take, I think it goes back to the transition period, about the need for some real clear guidance and really looking at some of the new thoughts and the way things are. So I don't think there are unrecognized challenges, in my opinion, I think we just need to be careful that we don't underestimate what some of it's going to take and, as we always say, the devil is in the details as you start to implement this. So I think that that's something that the Agency really has to consider and work really closely with stakeholders on because that's where the challenges will appear early, as well as if not thought through, that's where I think we'll have bigger problems with the transition.

DR. DAVID: Thank you.

I'll recognize Alisha.

MS. LOY: I would echo what Scott said, but I think in addition to that is the dynamic that we discussed earlier as far as really ensuring that we have a finalization of scope, of

what is in/what is out. We had talked a little bit about those clinical care pathways and ensuring that we really are identifying what is within the requirements discussed versus where do those other standards and regulatory sections come into play, I think that clarity will be critical in this, and then the aspect of truly identifying all identified stakeholders and providing education at a multi level. So this is an impact to healthcare organizations such as what Jeri and I represent, all the way in to our manufacturing partners. So overlooking anyone within the dynamic of education and the recognition of the impact of this could have negative downstream effects, so we just want to make sure we're covering all of those pieces.

DR. DAVID: Thank you, Alisha.

And recognizing Robert Phillips.

MR. PHILLIPS: Thank you, Chair.

Yeah, I certainly would like to echo what Alisha and Scott have said. We talked earlier about it's not only the QSR that's going to change as it aligns with 13485 by reference, but there's a discussion around what are the guidance documents changes and other regulations may have a touch point or an update associated with this. And so it's making sure all of those activities are identified, they're all gated so that they line up with the final rule so that industry understands all of the touch points that they need to address through this change.

And then tied into what Alisha had said, it's the education campaign that goes with that, right? So here's everything that's changing and then how does the FDA communicate this to those entities that it knows through the registration activity and the entities that it doesn't know because they're registered, right, and so making sure that the entire ecosystem, if you will, is aware of the changes, understands the changes, knows how to comply with the changes, and then has adequate time then to make those changes and

show objective evidence within their own internal documentation and records, that they now can comply. So things have to sort of add up and I think that's going to be one of the challenges with any type of significant change like this, is making sure that things are moving forward in a very structured manner.

DR. DAVID: And Robert, were you the suggested individual that a redline document would be helpful in this process of clarification?

MR. PHILLIPS: Absolutely. I would hope that the Panel could reconvene at some point in the future and actually review not only a redline of the QSR in the references that it's making to 13485, as well as the additional changes that the FDA proposed today, but then maybe even look at a set of other documents that are affected by this change, whether they be guidance documents or otherwise, so we can get a sense of the totality that this change is going to effect within the regulatory landscape. So I would love to see the Panel reconvene and look at that and provide feedback on that activity.

DR. DAVID: So in addition to the 803, 806, 810, you 're saying put also on the list the guiding documents?

MR. PHILLIPS: Everything that's going to be affected by this change, I think it would be relevant for the Panel to see, and also for industry to have an open document and other stakeholders to have an open document on which to comment on all of the changes that are affected by this seemingly quick transition from QSR to 13485.

DR. DAVID: Okay.

Dr. Kuo.

DR. KUO: I could share. This is Benson Kuo.

I'd like to address the most stricter risk requirement might occur from this condition because in the current QSR we address many diverse wide range of devices, but in transition to 13485 it might require the lower cost device companies to develop a most

robust risk management scheme that might add in more cost or at some point, noncompliance issue is based --

(Audio feedback.)

DR. KUO: The stakeholders, as we mentioned earlier, involve a wide spectrum of stakeholders, including the industry research groups. So this higher-risk requirement may cost them more resources and manpower to comply, not to mention that FDA has identified CAPA as the number one noncompliance issue in risk management, so it might increase the incidence of noncompliance. And this leads to a downstream event, which is inspection, and then the inspectors need to enhance their risk management capability to identify these risk management issues. Related to inspection and MDSAP, I don't -- and the pilot study in 2006 is still engaged to regulatory agencies, but I'm not sure if the FDA is open to notified body inspection at this point.

DR. DAVID: Let me understand, when you're saying notified bodies, I take it you refer to the European?

DR. KUO: Europe, yes.

DR. DAVID: Okay, okay. Thank you.

Gordon Gillerman.

MR. GILLERMAN: Thank you, Mr. Chair. It's Gordon Gillerman from NIST.

So I think I agree with all of the panelists who have made comments about the need for an organized approach to education. I'll suggest that it's not just the FDA, but also the Small Business Administration and the NIST Manufacturing Extension Partnership program that reaches out to small manufacturers across the United States that could be leveraged to help these manufacturers understand what would be required of them in their role in the medical device supply chain as we transition from 21 C.F.R. 820 in its current state to 21 C.F.R. 820 that primarily references the ISO 13485 standard.

I think the other dimension of this is particularly involved for electrical medical products. So 13485 and the entire suite of IEC 60601 series are connected by 14791, really, and it's intended that these standards, the product standards from the 601 perspective, the management system standards from 13485, and the underlying risk management there, are meant to be a unit of standardization used by the medical device community to achieve a goal of design through end-of-life safety and effectiveness for medical devices. And I think it would be helpful for the FDA to help the community understand, for those IEC 601 series that they've already recognized on their recognized list from CDRH, how the interaction between these standards and 14791 would be expected to be handled by the manufacturing community and their supply chains. Thank you.

DR. DAVID: So my understanding is the point you're making, Gordon, is that we have established, within the regulatory compliance record, the document known as IEC 60601 family of dashes and addressing electro-medical class of medical devices, and then the risk management that 14791 is bringing to the table, and now that all relate and reflect on the 13485.

MR. GILLERMAN: And then I'll just go on a little bit. And in the FDA system, those IEC 601 standards and sub-standards are not required, they're recommended standards in the FDA's process of recommending standards, they have a different status than 13485 would have if the FDA continues down this path and incorporates 13485 via reference. So manufacturers will have the option to use those series of standards or go through a substantial equivalence or a PMA or another process that the FDA already has in place for medical device product approval.

But I think it's important for those manufacturers who would choose to use the 601 standards, and many of them do, how the interplay between the underlying quality management system, the risk management system standard that's referenced by both

13485 and the 601 series would have to be handled, not just in the device application approval system but also in the quality management system as it applies to the design, manufacture, and through to the end of product life.

DR. DAVID: Through the end of the product life, good. Life cycle coming back to us. Thank you. It is more clear now.

Other comments?

(No response.)

DR. DAVID: So Captain Kimberly, you heard the Panel expressing a list of concerns from identifying the complete stakeholder community to estimation of what will it cost small manufacturers to adopt something in low-risk class level, to the issue of how the CAPA is related in 13485, specifically the issue of inspection/inspector training was raised as a concern and how we relate to the notifying bodies in Europe from manufacturers coming from over there and finally, the family of recommended standard listed in the FDA documents, but not required, and the relationship between them. I think that's a good list to look into and would like to ask you if that satisfies your question?

CAPT LEWANDOWSKI-WALKER: Yes, thank you. All excellent points.

DR. DAVID: Let's move to Question 3.

CAPT LEWANDOWSKI-WALKER: Okay, we can show Question 3. The proposed rule includes FDA-specific requirements and provisions which clarify certain concepts used in the standard. These requirements and provisions are intended to ensure that incorporating ISO 13485 by reference does not create inconsistencies with other applicable FDA requirements. As it relates to the FDA-specific requirements outlined in the proposed rule:

a. Does the Panel believe FDA has identified all areas that may require further requirements?

b. Does the Panel believe FDA should consider other specific requirements?

DR. DAVID: Thank you. We'll ask the Panel to consider this Question 3 and provide their comment and remember, Captain Kimberly, from the first question we have a carryover of concern that was expressed and probably more fitting to this question better.

Let's see, Scott Sardeson.

MR. SARDESON: Hi. I thought maybe I can set us off on this, this is Scott Sardeson.

I was actually involved in a lot of the analysis as part of the AAMI working group, so I feel pretty comfortable that we've identified the right things with a lot of work, so I'm really actually curious if the Panel has picked up on some other things. What I would like to put in this response, though, is I think there's a valid point as we progress, to go back to what Robert Phillips said, is do we need these things in the future. You know, part of standardization is aligning and as we see countries adopt 13485, the plus, 13485-plus requirements, it's good that industry can focus on the differences, but can we do better on that? So I think we found them all, but I would love to see that there's some work towards are they really critical to patient safety, are they really critical to the best practices, or are they a legacy, as Robert Phillips had recommended earlier.

DR. DAVID: I think you just raised an extremely important point, Scott, and that is outcomes, what is the relationship between the existing or modification of the regulatory guide and requirement as far as patient safety, product efficacy, or for that extent, the volume of defect and failure identified. That would be extremely applicable if we can identify sources that have information relating to that question. Thank you.

I will recognize Alsiha.

MS. LOY: Chair, I'd like to hear what Gordon has to say, he had his hand up first, so I'd be happy to have him go before me, if possible.

DR. DAVID: Thank you for being so kind, Alisha.

We'll recognize Gordon.

MR. GILLERMAN: I thank you, as well, Alisha, although I would have been happy to hear your comments first.

I actually just want to lend my support to this. So I was involved in the process of the initial adoption of the IEC 601 standards into the U.S. and when we developed that set of national differences or national deviations, as they were called in the voluntary consensus standard that was originally published by Underwriters Laboratories and now continues to be published through AAMI.

One of the questions was are we just looking at the old standard and plugging in what's not in the new standard or are we really looking at what's necessary to fulfill our legitimate objective here? And I think it's a really important eye that we have toward those legacy requirements from 21 C.F.R. 820 that we don't continue those requirements by adding them as plus requirements or national differences or deviations just because they existed in the regulation before, but we make sure that they actually provide a contribution that's worthwhile to patient safety and device effectiveness. And so I think an evaluation of the gap analysis, it's the first place to start, you have to do that. But the next analysis is are those differences that are outlined still necessary as we move toward a standardized basis for a quality system for medical devices. Thanks.

DR. DAVID: So with your knowledge, is there a gap analysis that was produced?

MR. GILLERMAN: So I'm referring to the gap analysis that I participated in when IEC 601 was originally adopted as UL 2601, so I participated directly in that technical process. It sounds like we have some of the panelists who participated in the process during this adoption of looking at the gap analysis between the existing 21 C.F.R. 820 and 13485. And again, the next step is to look at those identified gaps, the things that aren't covered by 13485 that are in the legacy regulatory requirements and not just plug the hole, but ask them do we need those things to be in the new regulation. Thank you.

DR. DAVID: Again, thanks for the clarification, good contribution. Thank you, Gordon.

Can we recognize Alisha now?

MS. LOY: Thank you, Chair. So this is Alisha.

So this is one of the things that I was speaking of earlier and I think it does include the dynamic of the gap analysis, but I think what I might be requesting is that it be broader than the documents. So as a healthcare organization, this is where I was speaking to the dynamic of responsibility when we have manufacturer defects and how that impact and hit is managed and taken on by healthcare organizations. Part of that speaks to clarity around real-world application and gaps within the existing system that really don't broaden the testing aspects that are required for devices to be able to be safely produced, cleaned, sterilized, and returned within the healthcare environment that they're used every day. So if we're going to go down the pathway of assessing documents, then I think we also need to challenge ourselves to say where is this onus of responsibility falling and are we really in a place where we're partnering effectively enough that we can truly bring ourselves to a place where we have real-world application of devices that is ensuring that dynamic of patient safety outside of a research or outside of a validated environment that is not working every day to produce those devices for use.

DR. DAVID: And you present that as a generic, not necessarily for contracted cleaning or sterilization sources?

MS. LOY: I think it's broad enough because of the barriers that we see within the healthcare industry as a whole, but it is sufficient for all clinical pathways of care, so that would include clinical standard of care, that would include research, that would include clinician or physician based innovation. I think it's significantly broader than what the industry as a whole has been able to acknowledge and I think part of that is because of the

nature of multidisciplinary collaboration that that type of effort would require. But if we're going to get ourselves to a place where we really are going to raise the bar and truly look at the dynamic of risk management, I don't see how we do that in isolation. I think we have to be able to come together and partner in order to ensure that those are met.

DR. DAVID: Thank you. The community of stakeholders needs to be included.

Any other comments on this question?

(Pause.)

MR. COLLIER: Dr. David, we have Robert Phillips with his hand raised.

DR. DAVID: I just want to remind myself that the question has two subcategories, so we address them.

Please, Robert Phillips.

MR. PHILLIPS: Yeah, thank you, Chair.

Yeah, I certainly want to echo what everybody has said here and I certainly appreciate and am thankful that Scott was part of the AAMI working group that looked at the gap analysis between the standard and the regulation.

I think, from my perspective, not being part of that working group and sitting in the industry, I think that redline copy that we spoke about earlier would be really helpful to understand how the identified requirements and opportunities that the FDA identified today in their proposal, that need to be in a 13485-plus environment and how do they actually map into the QSR, seeing that on paper in a redline version is going to be really helpful for the industry to provide very pointed and specific feedback to whether we see everything's being addressed or not being addressed.

And then in addition to that, it's understanding the other guidance documents that also need to be redlined so we can see, again, the totality of the change and be able to comment very specifically and very pointedly and very definitively on whether we think

everything has been included, satisfactorily addressed, documented, explained, right, and then feeding into that education campaign that we spoke about. So I think, in a general sense, I understand the direction that the FDA would like to go. I think we just need more specifics so we can provide very definitive feedback. Thank you.

DR. DAVID: Thank you.

Recognizing Scott Sardeson.

MR. SARDESON: Hi, this is Scott Sardeson again.

I guess I would just like everyone to know that the AAMI document TIR102 was the outcome of that work and so if people aren't familiar with that, that was the mapping of 13485 line by line to the QSR and vice versa, QSR to 13485. Now, maybe some ideas have changed since that work, and I think it's something we should look at again, but there was an actual document published by AAMI and it's called TIR102 and it was that analysis where we looked line by line on how these line up and it can be very helpful to stakeholders to be aware of that document, as well as in the ISO 13485 handbook that Peter Linders talked about, the voice of the FDA was quite strong in our guidance in that document.

So that also gives a nice indicator of how the FDA expects requirements to be met in the framework of what they're looking for. So there are some good starting points out there and I'm not saying that they're exactly what we need for a future state, but there's some really good work done and I think revisiting that is an important part of this question.

DR. DAVID: And Scott, the TIR102, just for clarification, is referring to 13485 version 2016.

MR. SARDESON: Yes, it was a mapping of 2016 13485 to 21 C.F.R. 820 and then the other way, 21 C.F.R. 820 to 13485. So it's very helpful to see kind of how things line up, as a user.

DR. DAVID: And that is publicly available, you mentioned.

MR. SARDESON: Yes, it can be purchased through AAMI. I don't believe -- yeah, I think you have to purchase it, it's a technical report, but it is available through AAMI.

DR. DAVID: Thank you.

So we are highlighting the approach, the need for better understanding of gap analysis that would lead to substantiation of need, not just dragging legacy to cover gaps that might not be contributing to patient outcome and eliminating more risk.

Any other comments from the Panel?

(No response.)

DR. DAVID: Captain Kimberly, are you satisfied with the Panel comments?

CAPT LEWANDOWSKI-WALKER: Yes, I am. Thank you.

DR. DAVID: Let's go to the next question.

CAPT LEWANDOWSKI-WALKER: And the slide presentation.

Question 4: FDA has considered and addressed the impact of the proposed rule on the following groups of stakeholders. Does the Panel believe that FDA should consider any additional impacts not addressed in the proposed rule on:

a. domestic-only medical device firms;

b. foreign firms and firms that have foreign manufacturing sites;

c. medical and healthcare providers; and

d. patients and end users?

DR. DAVID: Thank you.

I think that I heard today several additional members of stakeholder mentioned and I would like to ask the Panel for specific comment, if you will. Any hands?

Scott.

MR. SARDESON: Yeah, this is Scott Sardeson again.

I think when you look at the earlier discussions, Robert Phillips had brought up the

various kinds of manufacturers, service providers, I think this list should include them. This list is much more about the user and the traditional manufacturer, but you have contract sterilization, you have service providers that support the industry, so I think really looking at what are the different players in the supply chain of a medical device is important than to just stick with the (a)-(b)-(c)-(d).

DR. DAVID: Thank you, I agree with your comment and let's see, there was another hand.

Yeah, Gordon.

MR. GILLERMAN: So thank you, Chair. This is Gordon Gillerman form NIST.

So I agree that it's important that we make sure that we consider the supply chain for manufacturers of devices. Often in 13485 and associated 14971 requirements, the information that's needed to inform that risk management process and the quality management process draws information from the suppliers of medical device manufacturers and so there will be a press for new kinds of information down the medical device supply chain to complement in subassembly suppliers that may have to be delivered in a new way or brand new information. So it would be important, especially in these days of fragile supply chains and a focus on having a sustainable supply chain, that we make sure that we prepare the supply chain tiers for participation in this, as well. Thank you.

DR. DAVID: Thank you, Gordon.

Professor Kuo, please.

DR. KUO: Thank you, Chair. This is Benson again.

I would like to add, too, research organization, research group, and also NIH grant for these, for the small business grant receivers, recipients.

DR. DAVID: And Alisha, we cover your community? Go ahead, please.

MS. LOY: Thank you, Chair, for calling me out. I raised my hand just to make it

official.

No, I think that covers it all. I appreciate the shout-out there, but I think what we were talking about with the dynamic of collaboration was really again brought forward with identifying all of those different stakeholders and ensuring that they're a part of those discussions and education.

DR. DAVID: Yeah, absolutely. Clinical pathway might include IRBs and etc., so they are mentioned and included.

Anyone else?

(No response.)

DR. DAVID: Very good.

Captain Kimberly, we added a few additional categories or members to your list and did we answer your question?

CAPT LEWANDOWSKI-WALKER: Yes, and thank you for the additional input and suggestions.

DR. DAVID: Are we ready to move to the next question?

CAPT LEWANDOWSKI-WALKER: I believe so. Slide presentation.

Question 5: FDA intends to provide additional information and educational opportunities, including guidance and/or compliance guides, for manufacturers that are not as familiar with ISO 13485. Does the Panel have further recommendations of resources FDA might consider to support manufacturers in preparing to meet the requirements outlined in the proposed rule?

DR. DAVID: The question posted and read and the Panel is invited for comment.

Scott.

MR. SARDESON: This is Scott Sardeson again.

I think it's good that maybe I start since I already mentioned the two. So you know,

we have the AAMI TIR that is the mapping of 13485 to 21 C.F.R. and vice versa. Then I also mentioned the ISO handbook, 13485 handbook or practical guide that Dr. Peter Linders talked about. I think another tool that I find very, very helpful and I think could support the FDA in the transition is the MDSAP module. That document really explains to manufacturers and individuals what is going to be looked for at a national level and uses 13485 as the backbone. And I think that if there are some new ideas or concepts that this work is bringing forward as a change in the Agency's approach, that MDSAP manual and how the auditors are looking for things, along with -- somebody earlier mentioned the FDA inspection manual, those are things, I think, that are going to be very important as industry looks to try to see how they have to adapt to the way that the new requirements will be -- well, I should say the difference in approach to the requirements will be looked at.

I'm sorry, I thought of one other thing. I also heard this morning, both AAMI and AdvaMed and even to a point, ISO, I think, TC 210 is willing to help with some training and also some collaboration and I think really relying on those groups -- MITA was the other one -- to help with some of the training and help be our own explainers of things would be very beneficial. So I look forward to more collaboration and I think that the Agency really should lean on organizations like that, who have probably already done some of this in multi-sector environments, like myself. So I think that that's another thing they should really consider.

DR. DAVID: Professor Kuo.

DR. KUO: Thank you, Chair. This is Benson Kuo.

Throughout the year, FDA has developed guidances for specific devices like AI-assisted devices or software as medical devices or as tissue-specific therapies. We rely on those specific guidances very much, so if we can -- FDA can develop some device types specific sections and literature to help us develop the quality system, that will be very helpful.

DR. DAVID: So if I understand you right, you are suggesting to take the classification and be more specific at education towards the low-risk versus high-risk devices.

DR. KUO: And specifically, more importantly for some innovative devices.

DR. DAVID: Innovative, okay. Thank you.

DR. KUO: Thank you.

DR. DAVID: Recognizing Robert Phillips.

MR. PHILLIPS: Thank you, Chair. It's Robert Phillips.

I think when we look at some of this education opportunity, there's directionally a couple ways to look at this. One is that you've got the domestic manufacturers, who are probably very familiar with the QSR, that need to be trained in 13485 and then certainly, the merged opportunity we're talking about here today. There may be companies that have much more of a global footprint that are already using 13485 and the QSR that just need to understand the merger. And then you may find certain companies that are also global but are using 9001 and perhaps the QSR.

So you need to figure out a way to crosswalk them from ISO 9001 to 13485 and then to the merged solution here. So I think that there are, potentially, directionally a lot of different ways to look at how you want to educate and, in addition to what Scott and others have mentioned, you could look at 13485 Annex B, which talks about the crosswalk between 9001 and 13485. But I think the entire training activity, education activity, needs to look at people coming from different directions, entities coming in in different ways.

DR. DAVID: Thank you, Robert. And although the question specifically asks about manufacturers, I take it that your comment will be extended by saying manufacturers with 13485 experience, manufacturer with a 9001 experience. I would add all the other stakeholder of ISO service provider, contract sterilization, supply chain there that has none of the above.

MR. PHILLIPS: Absolutely, including all stakeholders, but sort of the shortcut of using manufacturers to really refer to the entire ecosystem, right, everybody who's part of the supply chain, service providers and others.

DR. DAVID: Yeah, I do think that on this first reading we need to just keep bringing it up so it's not becoming --

MR. PHILLIPS: Yeah.

DR. DAVID: -- a legacy term. We used manufacturer before.

MR. PHILLIPS: Absolutely.

DR. DAVID: Thank you.

MR. PHILLIPS: Good point.

DR. DAVID: Thank you, Robert.

Recognizing Alisha.

MS. LOY: Thank you, Chair. This is Alisha Loy.

So I agree with exactly where you just went and I think the other thing, everyone's done a great job of summarizing the need here, but I think the other thing to consider is the relate-ability of the training model and how it is approached by leveraging the stakeholders to help guide, lead, and support. That includes our community-based partners, our governance, our standards organizations that are in existence now, and then those well-respected organizations that exist within those models, they can help support these. But the better opportunity we have to partner and bring in representation of those like stakeholders, the more opportunity we have to ensure that that education is really going to cover the needs, concerns, bases for clarity, based on those individual groups.

DR. DAVID: Thank you.

If I would expand on the question to the Panel and ask you if we are looking beyond the word "education" on other activity relating to explaining the transition, what else, what

kind of activities come to your mind?

Scott.

MR. SARDESON: So one of the challenges we had with 13485:2016 is because it wasn't an FDA requirement, the U.S. industry was kind of silent. And I think what we tried to do then was do kind of almost road shows, get out in front of conferences, do panels, trying to get the U.S. industry to understand that 13485 will affect them. This is a big change for the U.S. industry and I think it's not just an education or training thing we should be talking about, but there's actually some PR work, there's some -- again, getting in front of a collective communication about it.

So I think that it shouldn't just be about can we create nice training modules on YouTube or on the FDA page, but really promoting what the Agency's doing here and again, using all the stakeholders. There's a lot of venues for this and I think that that's going to be really, really important because there will be a lot of questions and I think showing what the effort is as well as what we're talking about today is going to be really important.

DR. DAVID: Thank you, that's essentially what I was looking for, is those additional activities of get in front, and you call it road shows, and that's one example, but that's exactly what I wanted to hear.

Let me recognize Elise Owen.

MS. OWEN: Thank you, Chair.

I completely agree with everything that's been said and I think one additional point that maybe doesn't go without saying is continued FDA participation in the development of the ISO standard. I believe the FDA has been involved in that ISO work for a long time, but I just want to stress how important continued participation is, both in terms of hearing feedback on what's going right and what might not be going so right, and also that's an important place to address or to understand different views or different on-the-ground

experiences both in the U.S. and internationally. So I assume that's the plan from FDA, but I think it's important to be said.

DR. DAVID: And important for us to support, that expression of support is appreciated, Elise.

Recognizing Gordon Gillerman.

MR. GILLERMAN: So thank you, Chair. This is Gordon Gillerman from NIST.

So I'll go beyond a little bit what Elise just brought up. So this brings to the precipice not just the importance of the regulators' participation in the development of this standard and the ancillary documents, but actually the entire community of stakeholders' vigorous engagement and influence in these international standards, including 14971 and the allied product standards that are going to become part of the regulatory fabric of the medical device community.

The United States has a long history of participation and leadership in the development of voluntary consensus international standards. This is an area where we've done well. It's also an opportunity to find new and innovative ways to bring the small manufacturing community, those who typically have not had the resources to be directly engaged and influential in the standards development process, into the process by bringing their views to the table during the international standards development process. Thank you.

DR. DAVID: You're bringing a very delicate point because when you mentioned small manufacturers, that maybe does not make the top 10 funded items on their agenda and it's a real dilemma how can we continue to change to move it up the list, get support, because I talk to the engineers and they tell me that they would love to know more about standard development, get involved, learning the process, bring the lessons back to the company, but do not get funded. So we need to help bring it up.

MR. GILLERMAN: So we at NIST actually are thinking about this with much of the other parts of the U.S. government because U.S. engagement in international standards and critical and innovative technologies is a cornerstone of our technology leadership and it's really important that we find a way to let the voices of those small innovators come into the standards development process. And I agree with you, we've talked to small companies, they don't have the people power to send to sit on standards committees. I think we have to afford new and innovative ways of bringing their influence into the standards development process even if it doesn't mean their in-person attendance at traditional standards meetings. So this is something that we at NIST would love to work on with the standards community.

DR. DAVID: Hopefully, next time we'll talk, we'll say we made the top 10 list. Thank you for the comment.

Dr. Kuo.

DR. KUO: Thank you, Chair. This is Benson Kuo.

I'd like to switch gear and talk about -- but thank you, Chair, for this question. I think this is important, but I think the impact for global companies is not as huge because most of the global companies, they implemented 14971 in the company already. But I think the public would like to see how the Agency, the FDA, can adapt to this new standard. So I think it will be also helpful for FDA to make that extra step and show the public how hard effort and how the Agency going to adapt to this new regulation. Thank you.

DR. DAVID: Thank you.

Any other panelist comment, questions, addition?

Lisa. You're on mute.

MS. DIMMICK: I thought I was prepared. List Dimmick.

So just based on some of the conversation on this particular question, so

testimonials might be a way to help share the information, you can post those on your FDA website or send them out through other means, so perhaps people who have experienced implementing what will be the new regulation or the standard in and of itself, maybe testimonials to share their experiences and maybe how it helps them. And that might help to get buy-in and excitement about -- for companies that need to implement this rule when it might seem very daunting to take it on, to take on the task. So just another way to maybe outreach with education.

DR. DAVID: And especially for the young innovators that are using their mobile devices, looking at the --

MS. DIMMICK: Yeah.

DR. DAVID: -- right information like that would be stimulating. Good, good. Thank you.

Any more comments?

(No response.)

DR. DAVID: With that, I'll address Captain Kimberly and you heard the Panel, did we answer the question satisfactorily?

CAPT LEWANDOWSKI-WALKER: Yes, and thank you for the input. We'll go to the next question.

FDA has explained its thinking about current risk management expectations in the QS regulation and outlined its proposed expectations for risk management activities in the proposed rule. Does the Panel agree with the description of the risk management expectations in the proposed rule? And does the Panel agree that the more explicitly integrated risk management expectations are essentially equivalent to the current regulation?

DR. DAVID: Thank you, Captain Kimberly.

And please note that Question 6 has actually two subcategories. Do you agree that the description of risk management expectation in the proposed rule is clear and is it equivalent to current regulation level?

I'll recognize Alisha Loy.

MS. LOY: So I'm very excited about the dynamic of the risk management and I think I've expressed that multiple times here throughout today, so I won't dwell on that. However, what I will say is, based on what I'm hearing from other panelists is that it seems as though the spirit in the existing language is present for this to be equivalent; however, I don't believe, based on the feedback we're hearing today, that it is in practice, at least not in all organizations.

And so where I think there may be a disconnect here is that the FDA is working under the premise that this is not that significant of a change because of the spirit that was attempted to be captured in the preamble, whereas our partners in manufacturing that have spoken up today are stating this is a significant change, it is a lot different than what many domestic organizations have already in place. So I think we need to make sure that we're overcoming that or accommodating that as we consider the dynamic of transition and then the supports that would be put in place in order to implement that at the level that we're asking them for.

But overall, as a user within the healthcare setting and again, looking at that dynamic of onus of responsibility and the levels of which risk management should be partnered, it should be proactive, I am very excited about the direction of where we're headed here.

DR. DAVID: Thank you, Alisha.

And I will recognize Scott.

MR. SARDESON: This is Scott Sardeson.

Alsiha said exactly kind of what I was going to say, so I concur with her comments. The only thing I would add to that is that where this will be a problem, I think, is a U.S.-focused company for U.S. market. Any global type of market, Canadian, Australian, Europe, we're already being pushed and have been pushed to 14971, as Gordon has talked about, and it's part of the inherent way you have to get your 13485 assessed. But I do think that you do need the focus or the FDA needs to understand that there are some players that this will not be understood as always been there and I think that Alisha said it very well.

DR. DAVID: Very, very clear comment. I appreciate that, Scott.

Others? Professor Kuo, from innovators and research institute, this is going to be new practice or you think it's going to be lumped as a small change in present practice?

DR. KUO: No, for small -- for research institute, for those who have not been exposed to quality system requirement, this is new for both, but for some is used in projects. In my sense, there are differences. But most importantly is there's some hidden agenda in 13485, which everybody has highest standard of risk management where there will be more stringent auditing activities, which they don't -- they're not aware of. So when they apply for grants, they didn't include those funding and resources to address these needs. So that would be, as the other panelists said, they need to be educated and to get prepared. But thank you for the comments.

DR. DAVID: I appreciate that addition you made and that's the main reason I called on you is to hear that, that's very appropriate.

Let me recognize Robert Phillips.

MR. PHILLIPS: Thank you, Chair.

I agree with everything that's been said so far and in fact, wanted to sort of add on to Scott's statement about U.S.-only manufacturers with U.S.-only markets. I think this will be a significant change and I think that the conversation may need to include not only

what's expected under this merged QSR/13485, but what are the other resources that these companies can utilize, right, so 14971, which is identified as a consensus standard, the 60601 standards for medical/electrical equipment, which are consensus standards. So maybe the education opportunity for those specific manufacturers with only a U.S. footprint in the U.S. market is explaining to them the rest of the landscape so that they don't feel that they don't know where to go for additional guidance on how to implement risk management throughout the entire life cycle. That would be my only suggestion.

DR. DAVID: And it's a good one, so thank you, Robert.

Elise.

MS. OWEN: Thank you, Chair.

It's interesting, the topic of U.S. manufacturers for the U.S. market. I'm curious about other panelists' views, but it seems that with this transition, that would lower barriers for U.S. companies to export internationally and may also open up doors for them. So I'd be interested in others' perspective on that, whether that might be the case and if so, it might be worthwhile in outreach, also helping to link smaller U.S. manufacturers up to the commerce department that has the promotion programs to help small manufacturers entering markets. So I'll stop there and see if others think that's worthwhile to explore.

DR. DAVID: And your comment is extremely important in light of the 2 years of pandemic that created a sudden increase in local production of medical product in corner of the worlds that we did not believe they're able to produce. So that's all new to them in those corners, as well, and you made a good point.

Others? Gordon.

MR. GILLERMAN: I'll just comment since NIST is part of the Department of Commerce and we work with a lot of those export programs from the Department of Commerce headquarters. And again, one of the avenues here is the NIST Manufacturing

Extension Partnership program has worked exclusively with small manufacturers across the country during the pandemic to help them get information about standards and regulatory requirements as some of them have transitioned from making other kinds of products into the world of regulated medical devices. It's interesting that a lot of these are not the devices that you see kind of in the high end, they're not multi-parameter patient monitors, they're things more like gowns, right, things that were really needed in tremendous supply in the United States and that were needed all over the world and so shipments around the world became very, very difficult to come by.

You also saw manufacturers who were making other kinds of products who were actually capable of transforming their production into the production of these kinds of products but really didn't understand because they were coming from significantly less regulated or unregulated sectors of the economy. So Elise's comments are right on.

DR. DAVID: If I may, I'll share with the Panel a small example to what was just stated. And I serve on the World Health Organization innovation assessment panel and we're looking at the submission to World Health Organization for production of medical technology in low-resource setting. All started with the pandemic with the other application of medical equipment there.

What was interesting in relation to the comment that I'm hearing is that there is a lot of new transitioning from energy market, from clothing and other market in the commerce into medical applications, specifically in garments, face mask, helmets, from bicycle racing and so on, into health care. They're all familiar with European CE process. They are not aware of FDA substantial equivalent 510(k) or any of this discussion we have here on risk management. So you are right that there's another area out there that should be exposed if they are bringing the device over here.

I recognize Scott.

MR. SARDESON: Hi, this is Scott Sardeson again.

Yeah, I represent a large manufacturer now, 3M, but my first company was 30 people and eight people and 62 people. So I think that the advantage of this is if the companies are small in our thinking of where we're going, they will be ready for that global market and that is the advantage. I think the other positive thing about this risk management discussion, and you heard it a little bit today, is while low-risk devices need this, I manufacture a lot of devices today and lot of my devices are low risk, gowns, face masks. Well, after the pandemic, are they truly low risk? There are things about those that have to be done right and the patient and the user have to be understood.

So I think that this doesn't necessarily change any philosophy, but it's going to make the market more open to U.S. manufacturers if they can understand the way that this is to be viewed, and I think it's going to be better for the clinicians and the users of the medical devices. So I think that it's a complicated topic, but the more we can align and the more that we can have these good discussions around the expectations on risk management, it's going to be better for every stakeholder.

DR. DAVID: Thank you, and I think we all support what you just stated, we agree with that.

Looking at the Panel of any additional comments to Question 6 that was read and posted?

(No response.)

DR. DAVID: And will that satisfy, Captain Kimberly, the information you were seeking for Question 6?

CAPT LEWANDOWSKI-WALKER: Yes, thank you, very good points.

DR. DAVID: We are ready to move to the last question.

CAPT LEWANDOWSKI-WALKER: Okay, this is our final question.

As mentioned in the proposed rule, FDA would need to create a new inspection model, if a regulation based on this proposal is finalized. We are interested in the Panel's thoughts on the following:

a. What are specific regulatory considerations the Panel thinks FDA should consider in the development of a new inspection model?

b. What are the Panel's thoughts on the current inspection model, the Quality System Inspection Technique:

i. In other words, what are the things that work well in the model?

ii. What doesn't work well, or where would you want to see change?

DR. DAVID: Question 7 was posted, read, sent to you earlier, and we are ready for the Panel comments. And I see hands raised and I recognize Scott Sardeson.

MR. SARDESON: Thank you, this is Scott Sardeson.

On the first question, I think it was already brought up earlier today, maybe by the Mark Swanson presentation on the new inspection model needs to help adjust the different kinds of inspection. My opinion of the program and where we're looking at going, I think surveillance inspections, I envision them to be very much like a MDSAP inspection with the FDA view of it and the FDA doing it, because that's 13485 with national requirements. However, I think, as an industry, we know there are many other kinds of FDA inspections and I don't know how that really would be -- how that would look and how I would prepare my company for that. So I think really thinking about the different various ways the FDA uses inspection is going to be important.

DR. DAVID: Just personally, I struggled with what you said at the end, so if you can clarify for me, when you say FDA used different ways. So let's say Inspection A can be used in different ways.

MR. SARDESON: Yeah. So for example, I think it was Mark Swanson's slide, he

talked about you've got pre-inspection for high-risk devices, you have a surveillance inspection, which is your typical every 2 to 3 years you might have a for-cause. So the FDA uses the 21 C.F.R. for all kinds of inspections and it's very clear to me how this will work with the surveillance inspections because that's very well aligned with the three programs the FDA told us about. What's not so clear is how would that inspection for a pre-inspection audit, how would this apply? Would they look at things differently? So I think some clarity to industry on how 21 C.F.R. changes what we're proposing will affect the various kinds of inspections -- I think I said it was in Mark's slide -- is going to be an important concept that the industry's going to want to understand.

DR. DAVID: Thank you for clarifying.

I will recognize Robert Phillips, please.

MR. PHILLIPS: Thank you, Chair.

I agree with what Scott said, I think we certainly need to identify how this change affects the different inspection categories. But under the QSIT, one of the great things is, is there's a lot of transparency, right, the QSIT manual is out there for the public, it's out there for the industry to understand how the FDA plans on conducting inspections, and that's really helpful so the industry can prepare in advance for those types of inspections.

I think the other thing that's really beneficial about the current inspection program is the Agency recognizes that there are certain document types that the industry really benefits from not having inspected, such as management review minutes, some audit reports, that type of thing, so the industry can sort of set up a process by where it self-polices itself without essentially airing its dirty laundry to a regulator, which really is not what we want to do, we want the opportunity to self-police, we want the opportunity to have very effective corrective and preventive action processes that prevent these types of things from actually impacting commercial products. And so I would hope that the new

inspection process built around this merged QSR/13485 activity retains some of those things, the transparency, the exclusion of certain records so the industry can police itself and actually innovate and evolve and deal with its nonconformities in a way that makes sense. I think the other opportunity that the Agency may have is, as the move to a new inspection model, is really looking at what's being done under the MDSAP and how does that inspection model look, and since we are really leveraging 13485, not reinventing the wheel but looking at the MDSAP audit process, how that is logistically performed and adopting much more of that, merging in a little bit of where it's necessary, the 13485-plus content based on the national requirements.

And so I think there are really good things in QSIT and I think there are opportunities to improve upon that as we move towards adding the 13485 content that also leverages the harmonized activity where 13485 is audited elsewhere in the globe.

DR. DAVID: Thank you, Robert.

And Alisha.

MS. LOY: Thank you, this is Alisha Loy.

I was heading in a similar direction, so for me it's the dynamic of contract management. So we've already identified that there are multiple additional aspects of scope and so where does the oversight fall for especially subcontracted services to those who manage or oversee those contracts versus where does the requirement step in and have a certain amount of audit and surveillance and postmarket surveillance that then would hit from the regulatory organization, in this case, the FDA.

So as it stands, at least in the healthcare world, if we subcontract a service, we have a certain level of responsibility to ensure that they are meeting the contract requirements for safe patient care, whether that is a product or a service that is being provided, and to partner in the aspects of corrective action and action limits and things like that. So I think

one of the things we need to consider here is, as this is revised, where do those lines fall and what and who is the most appropriate for those levels of responsibility and oversight for each of those different areas or stakeholder groups as we've been talking about.

DR. DAVID: So if we identified those stakeholders as part of the community, you're asking where the lines are drawn?

MS. LOY: Yes, and maybe it's a blended model, I'm not sure. I can speak to the dynamic of many of those services, as I oversee many of those contracts, but with what we're talking about here, we're talking about a little bit of a different approach to this, so is it all or nothing? Is it a blended -- you know, I think we have an opportunity to really ensure that this is going to allow us to have that right level of oversight and that right level of visualization for those needs.

DR. DAVID: Thank you, Alisha.

Gordon, you're patient there, I recognize you.

MR. GILLERMAN: Thank you, Chair. This is Gordon Gillerman from NIST.

So as we look at harmonizing with the technical requirements of international standards and those used by other regulatory regimes in developed countries, we're going to accrue part of the benefits. We also should be looking at the conformity assessment methodologies that we look for regulatory confidence in the manufacturer distribution and end of life, the complete life cycle of medical devices, because we would accrue additional benefits by harmonizing there, too. The regulator's first job is to assure that medical devices, as they're used in practice, are safe and effective and we shouldn't let that slide.

And we should really use our participation in forums, like the International Medical Device Regulatory Forum, to shape the way conformity assessment is done locally -- I'm sorry, globally, to make sure that it's comprehensive and that with one integrated regulatory system and one integrated conformity assessment system and one integrated

demonstration of conformity by medical device manufacturers and other folks in the systems who are regulated, as we've talked about here, that that demonstration of conformity can be used globally, make it effective and make it accepted by the whole world. That really should be what our eye on the prize is. So we shouldn't just think about stopping at the technical standard and adapting the way we do inspection. We should really tilt our arm toward having an effective conformity assessment system for regulatory purposes and influencing the rest of the world to jump on board and do that and then all do the same or very similar things. Thank you.

DR. DAVID: Thank you, Gordon.

Jeri.

DR. CULBERTSON: Thank you, Chairman. This is Jeri Culbertson and I have a few different topics I'd actually like to pull from as I've been listening to this.

One of them is Gordon talked about the life cycle of devices. What happens at the end of that life cycle? Who owns that device, is it the patient, does it go back to the patient? Is it something that needs to be returned to the manufacturer? Is it something that needs to be discarded? There's a lot of gray area when it comes to that, in regards to what do we do with an explanted hip, you know, something like that that we can only do so much with it, but the patient owns it, so there's a risk with that, in giving it back to the patient. So it kind of even goes beyond the life cycle of that device.

Another thing that I wanted to touch on is looking at regulatory real-world validation. When we talk about manufacturers' instructions for use, we see they've validated their sterility parameters by just putting stuff in a basket and sterilizing it, but then when it gets to the end user some of the practices they're seeing is that they'll keep it inside of the basket and send it through versus that's not how it was validated. So what does real world look like versus how is it validated and what's the gray area with that, that

could come with it?

And then finally, just talking about surveillance, anywhere from PPE to endoscope reprocessing. You know, just recently a couple of studies came out in regards to PPE being used and also what's required is fluid resistance. So when it's actually being used, though, in the correct manner, fluid resistance doesn't meet that standard in that the user is actually getting compromised. It's not even the patient at this point, potentially. So looking at something that might be low risk, there are still implications that go beyond what is just baseline okay.

And then like with endoscopes, we're finding multiple problems with those in reprocessing and how that can potentially impact hundreds, thousands of patients with one endoscope that might have compromised multiple people and what does the surveillance look like on that to make sure it's being properly done and when it is properly done, is it still appropriate in the real-world experience to do it that way and still make it patient safe and patient ready? Thank you.

MS. LOY: Real-life examples, thank you, Jeri.

James. Are you on mute, James? James Swink?

(No response.)

DR. DAVID: I don't know, maybe a mistake, somebody push a button there.

Any other comments?

(No response.)

DR. DAVID: So --

MR. SARDESON: Chair, I have one comment I'd like to make.

DR. DAVID: Is that James?

MR. SARDESON: No, it's Scott. Sorry, I raised my hand, but I was worried you were going to move on.

DR. DAVID: Go ahead, please.

MR. SARDESON: Hi, this is Scott Sardeson again.

On the last question on QSIT, what could be improved, I'm not -- I don't think the QSIT program is what I wanted to bring up, but I do know that when QSIT was first launched, I think there was, again, maybe not a full understanding of what it takes to change auditors and how they look at things and I think that we found the same thing when 13485:2016 came along and that the concepts in 2016 were to a new way and a new paradigm and the auditors took about 2 to 3 years to get there. And MDSAP was the same way.

So back to, I guess, an earlier comment on don't underestimate the need to do that front-end change management. Because auditors are the inspectors and they will be the voice in front of the users of the standard, it's really important that they are knowledgeable and understand what the objectives are for the new era and not go back to what they're comfortable with.

DR. DAVID: Thank you very much.

So I'm looking around to see if we have any more comments on the last question and I think it looks like the Panel exhausted the ideas we contributed today and happily, I will approach Captain Kimberly now and ask her did we answer Question 7?

CAPT LEWANDOWSKI-WALKER: Yes. I wanted to give one more chance for part (b) of this question. As you know, to Scott's point, it is very important that our investigators and auditors are well versed in whatever our new current inspection model will be and if anyone -- one more chance, are there things that currently work well in QSIT that you'd like to bring up and what does not currently work well in QSIT? For any of those of you who have some experience with being inspected against QSIT. I just wanted to give one more chance because this is important feedback for us.

DR. DAVID: So before I call on Scott, let me reflect from the consumer end. When I'm asked to advise having a new investor in stock of company who's making catheters and I suggested we'll visit to see what the competitors' experience under this type of auditing visit and field service auditing as published by QSIT on the public domain and it was very difficult for newcomers to the field to understand the results of the field service visits and the field report, the deductions that are consistent there, the type of comments are not straightforward for -- again, for newcomer to the field.

So if we're talking about the change and something new, I wanted to share that experience with you, that the model need improvement as far as public utilization of information shared so they can learn from that. Right now it is documented, it's not very useful for this purpose.

I will now recognize Scott.

MR. SARDESON: Hi, this is Scott Sardeson.

I probably have more positives than negatives on QSIT. I think Robert Phillips already mentioned transparency, that's huge. It's really, really important for us, as users of the standard, to know the expectations. I think both the MDSAP program and QSIT with the focus on the areas where you know there could be direct impact of product or patient safety, not trying to do it all, you will get to all if you need to, but really focusing on where is the biggest risk in the quality management system.

What I enjoy about QSIT is such a nice strength on management's responsibility and I think that that's a strength in the QSIT program that sometimes gets lost in the MDSAP program. But I think that modular approach, really using your resources to what could have the biggest impact on the market with a product, with the patient, is really, really important. And I think that what -- you know, I was kind of negative about the start of QSIT, that was many years ago. I think the knowledge of the auditors, over time -- and in the QSIT

audits I've always been impressed with how good the FDA inspectors are and how much they really do know. I just think there was a really long learning curve there and that was kind of challenging, but the recent QSIT inspections that I've been in, I walked away kind of in awe at how good they are at seeing the foundational linkages and audit trails. And I think that's a very, very powerful strength in the Agency and I think that a program that continues, that's going to be very important.

DR. DAVID: Thank you, Scott.

Any other comments for Captain Kimberly?

(No response.)

DR. DAVID: Thank you very much. We are at the end of the question to the Panel by the FDA session and I hope, Kimberly, we met your need for information and --

CAPT LEWANDOWSKI-WALKER: Yes, thank you. It was very, very insightful and important feedback for us as we move forward, so I appreciate all the panelists' participation in this session greatly.

DR. DAVID: Thank you. And we'll move to the last item on the agenda before adjourns and that is the FDA summary. At this time the Panel will hear summation comments or clarification from the FDA and we put 15 minutes on the agenda for that. And who is going to do the summary?

MS. THOMAS: I think it's me, Dr. David.

DR. DAVID: Oh, Keisha.

MS. THOMAS: Right. Hi, everybody. I just want to first thank everyone for very thoughtful, insightful dialogue today. I think we've got a plethora of experience and a wide spread of experience with the panelists today. I think what you've seen is that dialogue converged together and can provide us various perspectives across the sector and stakeholder group that's going to be impacted by this rule. I think what you also saw and

heard, at least I did, was a plethora of experience and understanding regarding the FDA requirements as well as, in a very short period of time, your review and assessment of the proposed rule. So I want to first thank you all for that. I think listening to the dialogue today, you've given the Agency a lot of things to discuss and consider, which was the intent here. Some of the things that were brought up we had already thought of. As you saw, based off of the panel deliberations earlier in the day versus the FDA questions that came forward, there was a lot of overlap there. So that was nice in a way that we're at least channeling in some ways the things that we think are going to impact and things that we need to consider as we move forward down this path. I think --- and I want to thank you all -- in addition to some of the other perspectives that we hadn't thought about and considered, that were well thought out and laid out and give us an opportunity to kind of take this information back and consider what the next steps are.

In addition to thanking the panelists, I also want to thank those who submitted comments and presentations on their own. Just so that we could get the perspective beyond just what FDA thinks, it's always important to hear perspectives that are outside of those of our own. I'm sure all of you can understand, when you've been so close to something for so long and there have been comments for everything, this has been taking a long time to get here, there have been kind of extenuating circumstances over the last couple of years that have kind of sidestepped our ability to get here today.

So because of that, we have been living, breathing, looking at this for the totality of 4 years at this time and so it's nice for us to be able to kind of take a step back and listen, because we have been looking at it so long and so closely and sometimes things get lost, so you just kind of feel like what you expected to convey or what you interpreted came across and so this was a great opportunity to hear those areas where maybe there was something left for consideration or wasn't clear. And so I learned a lot, I am really glad we had this

opportunity to hear back from industry. We hear the areas that everyone is calling and some in repeat, which is radio -- you know, we're radioing in on those. The next steps is the comment period before the proposed rule is out, I think, until the end of May or near the end of May. Feel free, despite those who have commented today, to still, please, go and comment on the proposed rule. We're looking forward to those comments, we will be taking our time going through them, evaluating those, again, with what we heard today. And I'd just like to thank you for your thoughtful feedback today.

Dr. David, I think you did a great job today.

I also want to recognize the fact that this panel turnaround time was quick compared to when the proposed rule actually published. So again, thank you for taking the time in a very quick manner to come prepared to discuss the proposed rule today.

And so I think with that, Jarrod, is there anything else that I need to do besides thanking everyone? And again, this was a great panel. I think we've got a lot of people listening across the Agency and across the public and across the stakeholder groups. I'm sure -- good, Melissa, I saw you just pop up. I just can't express how helpful I think this session was today and I think it will be helpful in us going forward with next steps and considerations.

So I see the FDA panelists popping up now, it's good to see your shining, smiling faces. If any of you want to share any of your thoughts, feedbacks about today, please feel free. Otherwise, I will hand it off for adjournment.

DR. DAVID: Thank you, Keisha. I don't know if you want to take a picture of the panel while it has everybody popping up their cameras. But I want to reflect, as a chairman, that I really enjoyed meeting the Panel and the FDA, the public, industry, and presenters who were coming and going. But most of all, you, the Panel, show me how varied and wide-scoped we are and how smart FDA is in getting us together and got feedback from

such different areas of the implementation of this regulation. It's not just manufacturing, not just supply chain, not just health care, not just consumers, not just patients, and it's all inclusive and that came across nicely as you all shared your expertise resource.

I will go around and thank you personally because you were so kind to me. Lisa. Chiaoyun, I learned your name even though you have Benson, that is easier. Jeri, Alisha, Robert, Scott, Gordon, and where is -- there she is, Elise. Thank you very much to all and to the FDA members.

And finally, I would say thank you to Jim, who is behind one of those posters that is hanging there, and taught me how to count from five backwards so we can start on time. Thank you, Jim, for all your help and making sure we are in communication.

Jarrod, I don't know if you have any other comments before we adjourn.

MR. COLLIER: No, I have no other comments other than you being a wonderful chair for this discussion and I'll just mention something to Keisha, I really appreciated her FDA summary, it was beautiful. So thank you all for your participation in terms of this meeting and that's all I have.

MR. GILLERMAN: Thank you, Dr. David, you made this an enjoyable and interesting experience.

MR. COLLIER: Absolutely, absolutely.

UNIDENTIFIED SPEAKER: Yeah, very nice job.

DR. DAVID: This bring our meeting, our panel meeting, to adjourn and have a great rest of the week. Thank you.

(Whereupon, at 2:48 p.m., the meeting was adjourned.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

DEVICE GOOD MANUFACTURING PRACTICE ADVISORY COMMITTEE

March 2, 2022

Via Microsoft Teams Videoconference

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health, Medical Devices Advisory Committee.

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TOM BOWMAN

Official Reporter