UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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# PUBLIC WORKSHOP - ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA) PILOT

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## PLENARY SESSION

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May 22, 2018
9:00 a.m.

FDA White Oak Campus
10903 New Hampshire Avenue
Building 31, Room 1503 (the Great Room)
Silver Spring, MD 20993

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M E E T I N G

(8:11 a.m.)

DR. SHUREN: Welcome to our public workshop on the Accreditation Scheme for Conformity Assessment. I'm Jeff Shuren. I'm the Director of the Center for Devices and Radiological Health. I'd like to welcome everyone.

As you know, ASCA is a commitment under the reauthorization of Medical Device User Fee Act, now MDUFA IV. But more important for us at CDRH is that ASCA could serve a critically important role in helping to further our ability to achieve our vision of patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance, first in the world. That technology needs to benefit patients, but we also want them to have timely access and, hence, first in the world as a metric.

And the reason being, in order to get there, we need to have our programs, and that includes our premarket programs, our postmarket, as efficient, as consistent, and as predictable as optimally possible. And ASCA can play a critical role.

You know, traditionally, we do not have a lot of engagement with the testing lab community. Typically, we will work through sponsors. If there are issues, we go back to the sponsor, and then we sort of leave it to the sponsor for having interactions with testing labs. And, of course, ASCA can help change all of that for the better. There are a lot of benefits to this program. And, you know, we're going to start with a pilot, but if successful, we turn it into a program.

And the benefits include the following: that there's greater assurance that the right tests are being performed because we will have high confidence that the labs in the ASCA program know the right test to conduct even if the sponsor does not; and then, secondly, high confidence that the tests were performed properly and the results meet acceptance criteria in national and international standards that we have recognized and have included

under the program; third, that there's greater predictability for sponsors that we will rely on the results that they provide because we have high confidence in the testing labs who perform them. And then, of course, too, even our review times at CDRH may be reduced. And we even estimated in one case we could be talking about a reduction from about 11 hours down to maybe 15 minutes because we're focused on those test results and have high confidence in them.

But beyond that, too, ASCA ultimately could link up to several of our other efforts in leveraging standards. For example, a few weeks ago, we had put out a proposal for an alternative program under the 510(k) pathway, what we call the Expanded Abbreviated 510(k). And, you know, traditionally under a 510(k), you're taking the target device, you are comparing it to a predicate device, and you're doing a technological comparison.

What's different under the Expanded Abbreviated 510(k) is you have your target device, you will identify appropriate predicates, but now you're comparing yourself to, and essentially demonstrating conformance with, performance criteria that FDA has developed based upon the performance of more modern day predicates. So there is a substantial equivalence determination leveraging predicates, but rather than a technological comparison, we're focused on comparing performance.

And, of course, the value here is for patients and providers, the opportunity for getting better information for making well-informed decisions because this truly goes to the performance of the technology. And we think it can increase confidence in those devices on the marketplace; more streamlined for companies because oftentimes this can be a more direct and more straightforward way of demonstrating substantial equivalence than sometimes the machinations when we're comparing technological characteristics; third, can be more streamlined for the FDA because we're looking at, if you will, objective measures, and we can say have you met them or not. But even further so, may even drive to a

competitive marketplace around safe, more effective devices, because companies now who have a 510(k) device can not only demonstrate that they meet these criteria, they can demonstrate they exceed them and a better way for them comparing technologies.

And ultimately this can help line up with our work on international harmonization because many other countries tend to apply more of this approach than what we do traditionally under substantial equivalence. And that may help achieve creation of what we have proposed as the medical device single review program under the auspices of the International Medical Device Regulators Forum, IMDRF, namely under which the decision by a participating jurisdiction to provide marketing authorization for a product would be relied on in whole or in part by other participating jurisdictions.

And a critical piece there is not only do we apply the same criteria, but we have confidence in those who are providing the evidence to support meeting those criteria. And that's where ASCA comes in, because if now we are leveraging as part of Expanded Abbreviated 510(k) as we have proposed, leveraging standards, national and international standards, to the extent that we can, assuming they are on target and we have appropriate acceptance criteria, and having a program like ASCA gives us high confidence in the testing that was used to demonstrating meeting those standards, and like I said, potentially then meeting criteria under this alternative 510(k) pathway. So, again, can play a critical role.

Also can help advance our work for our third-party review program. We have a commitment as well under MDUFA that we help assure it's a robust program and have a strategy for reducing the need for routine re-reviewal. Much of that depends upon having strong confidence in those entities that are doing the evaluation. Again, if we have strong confidence in the testing that was performed, the right test, and we have confidence in the results, that goes a long way to being able to better leverage a third party who's looking at that as well.

So lots of good work underway. ASCA can play a critical role on achieving all those. And then, finally, hopefully helping to drive more of, if you will, a marketplace for being able to rely on national and international standards, because today one of the challenges we have, even though as the U.S. we typically have recognized more such standards than other national jurisdictions in the medical device space, we can't use them to the extent we would like to, you know? We use them to address, if you will, bits and pieces for our decision making. And that's because in a number of cases, those standards are not what we call regulatory-grade. They don't essentially meet the needs. They are not essentially fit for purpose for supporting regulatory decisions.

And so under the auspices of IMDRF, our standards working group has been engaging with some of those SDOs, have now put out a document laying out some of our expectations and recommendations for SDOs to assure that the standards they develop are regulatory-grade and create better liaisons with some of those groups, such as ISO and IEC, with the goal that we have more standards developed that are fit for purpose for regulatory needs.

And we think between creating more of a marketplace for those here in the U.S., such as through ASCA and the Expanded Abbreviated 510(k) and a collaborative work under the auspices of IMDRF -- and we're getting other countries, not just agencies in the U.S. but other national jurisdictions, to put their weight behind it -- we can sort of drive not a vicious cycle but a friendly cycle of the generation of more standards that are fit for purpose for regulatory needs. And that serves a variety of benefits particularly for us, helping us achieve our vision of patients first in the U.S.

So, with that, I will say thank you for your participation today. I look forward to very active engagement over the next 2 years -- next 2 years -- next 2 days.

(Laughter.)

DR. SHUREN: You're not locked here for 2 years. Wow. That's even nasty on my part.

And let me turn it over to Captain Scott Colburn, who's the Director of CDRH Standards Program.

Scott?

(Applause.)

CAPT COLBURN: All right. So I got you for 2 years. Excellent. All right. Let's see. We have buttons, buttons that work.

All right. Well, I want to thank Dr. Shuren. You heard a lot of what we're hoping to achieve here in just the use of standards in general, enhancing the use of standards, building out different relationships, taking challenges in areas where we know standards may not necessarily be meeting just exactly what we're looking at trying to get from what our past experience is, but building forward into a new era of where we have relationships building in the right areas, pulling people in from different focus groups and different, you know, areas in that product life cycle where standards have key parts, and building something more important.

And so, first of all, I want to thank everyone who's here. I know we have many more people that are planning to come in throughout the day and tomorrow, and I just want to thank everyone who made, you know, the commitment to come here and help build the beginnings of a program that I think will have a great foundation to build for other programs, as you heard Dr. Shuren speaking to, where he sees this really supporting his vision. And that's humbling, I would say, to know that we have an opportunity here to help drive something forward that isn't just relevant even to one regulatory agency or one country but to actually help support, you know, this industry of medical devices, which is truly a global industry. And that's the important part here that we want to keep our focus

on.

So, first and foremost, logistics, right? Exits. Follow the signs that have green letters on them, and that will help you if there's a need to have, you know, have an emergency exit. And there will be people to help direct you through if there's any issues. Restrooms are conveniently located in the farthest point from this stage right here. So if you go all the way -- go out, take a right, and then follow it down towards the right, you'll see some signs for restrooms.

If you had not already, please make sure you take the time before 10:30 to sign up for box lunches, if you're interested in that, at the kiosk, and those will be made available during the lunch break here today and tomorrow.

We have an app here today for those who have had the opportunity and didn't have their phone crash on them last night. You have the opportunity to use an app to, you know, see what's going on, have some access to information. There's even a link to this YouTube video with a big mug shot of some guy on there. But this is an opportunity for us. And I want to thank the conference planning group as well as the members of the ASCA core team for having a little vision to try something a little different and to see where the use of this app might be helpful.

If you have not done so already and you have the app, there's a little survey in there, too, to help indicate what sessions you'd be interested in attending when we break out later on in the day and then again tomorrow, and that will help us make sure that we put the right sessions in the right rooms, and we don't have, you know, 400 people in a room for 20 people and so forth. So please go ahead and do that.

I guess if there's any needs for contacts for anyone from the media, I guess you come see yours truly for that, and I'd be happy to direct you to someone who can answer the question for you. No, I'd be happy to take any questions we can when we discuss on

this.

And then going on, just, you know, you're going to hear a lot of things, a lot of terms being used, a lot of terms being used maybe in the correct context and also maybe some terms being used out of context. We're merging regulatory science and standards and conformity assessment in areas that not everyone has been involved in all of these in the past.

So you'll hear differences of context when we speak on things like risk management or intended use or different parts of the declaration of conformity, such as attestation or what determinations are made and who makes those determinations. Those are all new. I will probably muck that up even in the next hour, and probably so. So what I ask is if you do hear some terms being used and maybe they're a little out of context, have a little conversation with that person. Let's really learn from each other. What is when you, you know -- say when you mean that, and you know, in the 17000 world, this is how the vocabulary is used, but maybe in the regulatory science world, this is how it's used there.

Those are going to be very important for us when we develop our guidances and our scheme eventually because we need to be able to communicate to stakeholders that go beyond just the conformity assessment world, goes beyond just the manufacturers, but also into the regulatory staff that will be eventually seeing all the work. So it's going to be real key for us. And that's one of our major challenges. Excuse me.

So what I'm going to go through today is just kind of an outline for everyone here because I don't know if everyone here knows all the main topics of what -- part of what Jeff was speaking to. The standards program here has a long history. And so I want to talk a little bit about where the standards program has come from, where it currently sits today, what are some of the enhancements that we've seen over the past couple years, and then, eventually, what does ASCA have to tie into that.

Jeff did mention a little bit about the IMDRF, or the International Medical Device Regulators Forum. And I want to talk just a little bit about some of that work that's going on because it is relevant, and there are a number of people here in the audience today both from FDA and from industry and some of the testing houses that help collaborate on a number of the topics, specifically in standards and conformity assessment and building some of the tools that we're hoping to use for some of those platforms. And then, of course, we'll go into the ASCA program before we break today for lunch.

So why don't we go ahead and talk a little bit about the standards program. The standards program has gone through an evolution of name changes over the course of 21 years. We used to be the Standards Management Staff, and then we converted over to the CDRH Standards Program. And then Conformity Assessment came along, and I was like, you know, it's an opportunity to do, you know, standards 3.0, and let's come up with a new name. So the CDRH Standards and Conformity Assessment Program. And so someone said SCAP. Okay. So SCAP was the new acronym that came out of that, but we're just going to go with the Standards and Conformity Assessment Program for today and kind of keep that rolling.

But I want to talk a little bit about -- you know, make sure everyone is aware, you know, what we see as the value of federal participation in standards at the national and international standard. How is it that we are currently using standards? Where are we going now over the last year or two with the enhancement from the 21st Century Cures Act, and what does that mean towards what we're trying to drive forward with this accreditation scheme that we're speaking on?

And then, as Jeff mentioned, how does that relate to some of the current programs we are building on our -- internally with the third-party reviewer programs, with everything from UDI to even just, you know, where ASCA will build foundations for other areas where

we look at how conformity assessment, how the different models of conformity assessment can help assist in how we can do some regulatory reduction on our end so we can really focus on the key elements that we want to address to ensure that we have the best devices that support patient safety.

So our vision: I won't try to read every word here, but it does speak a lot to what Jeff has alluded to, that our stakeholders have access to the high-quality, safe, and effective devices of public health importance and that, you know, we are the world's leader; we believe, you know, not just -- and when I say CDRH and the standards community, it's not just the CDRH standards staff but the community that we work with in the SDOs and with the different trade associations, with the different performing assessment worlds. We truly believe that the U.S. standards market is a world's leader. And it's nice to be a part of that, so that CDRH can stand up and say we are part of that world's leader in standards implementation utilization for medical device innovation and manufacturing and radiation-emitting product safety.

What are we really here for is to make sure medical devices and all their stakeholders are able to benefit from the use of standards and for medical devices and you know, to ultimately do what we're here to do: protect the public health. Every stakeholder in this room has that same vision from their company's own area. Most regulatory bodies have those. It's bringing all of them together to make sure we can do this on a single note and build that forward.

So our idea here is to, you know, build a Standards and Conformity Assessment Program that's been around for a long time, as mentioned, 21 years now; we had our 20th year anniversary last year. The program contributes a lot to the Center's missions and has expanded a lot, I would say, in the last 3 to 4 years to really find where we can help streamline and implement and bring in stakeholders that we haven't traditionally worked

with, hence, this workshop. This is really what we're designed for, and making sure that we can use standards to maximize our business processes as well.

So let's kind of take the step way, way back. And so I want to say, you know, why does FDA care so much about standards? And it's not because we're told to, but yes, we are. We're actually asked to really strongly consider using standards in lieu of building our own little creative, government-unique standards.

And we know that the OMB Circular has been around for a number of years to push that message forward. It was updated a couple years ago to really try to drive it forward more and even put a little bit more emphasis on using conformity assessment practices to help, again, streamline your efforts and show how that can open up doors, not just for how you can relate to other agencies at the federal, state, and local level in your own country but how that can also have power for working across borders and making sure that manufacturers who are international can benefit from the use of standards. And so it builds those platforms there.

And so we had a long history of participating in standards -- I'm sorry here -- just moving things along -- that have built from our standards recognition program. A couple years ago we had the 21st Century Cures Act that updated our recognition of standards, where we will recognize standards through the *Federal Register* notice, and then it goes into our recognition database. But now we're building out forward on how we communicate from a federal agency through our participation and experience of working with the stakeholders, what we mean when we are recognizing a standard. If there's an extent of recognition or a limitation, can we communicate to where that standard might not be, as Jeff mentioned, fit for purpose or meet the regulatory need and how and why we could try to build a different area to help fill in those gaps?

It also asks if you see standards that you think would be of benefit to recognize, for

us to take that opportunity and work with us. We do sit on a number of standards committees, but we don't sit on all the committees, and we're not aware of all the standards. And so we would like to hear from our stakeholders. And we're trying to build a program that will collaborate with requests that come in. And we're also increasing the training to staff on a number of different areas, whether it's how to, you know, utilize a declaration of conformity, how to write additional information questions to standard test reports that are coming in, how to look at device-specific standards in an employee's area of review. And so these are things that are just starting to culminate into new training programs that we're going to see coming in over the next couple of years.

We're updating guidance documents. We have guidance that I will jinx by saying it's in its final reviews, and we're hoping that this will come out, the appropriate use for guidance that we've been working on for longer than I want to talk about. But that's one that will platform a lot of the terminology, too, that we're trying to drive that supports this program, and also kind of refreshes, you know, what is a declaration of conformity, what standards are appropriate for a declaration of conformity, and what's the supplemental information using the platform of the ISO/IEC 1750-1 and -2 that can support a manufacturer's declaration to certain standards in their 510(k) programs or where they're working that through. And it's kind of bringing us up a little bit into where we know how standards are being utilized. And I think that will be a really important tool.

The other guidance we're working on is just the recognition of and withdrawal of standards guidance, which explains, you know, what is it that goes into this process? What is it that we're thinking of when we say, you know, what are the limitations? These are the areas that we really focus on that are really statutory-based and are important to us. So these are the focuses that are coming out of this. And then, in addition, of course, we have the ASCA scheme and/or -- which will come out in the form of guidance and other tools that

will be important for us.

All of this does help us consider the international use of standards. It helps us consider, you know, how manufacturers and sponsors are citing standards and to take into account, you know, how are you utilizing those standards to achieve other regulatory schemes, and what can we do to try to leverage our understanding of those and/or participate in identifying the gaps if we feel that certain test reports don't necessarily meet the requirements that we're hoping to achieve and build that into better standards development or, in the case of ASCA, build that into the requirements that we'd like to see for testing houses to consider so that way we can build that across.

The importance of building that in now and building a relationship to the testing houses and the accreditation bodies and the areas that we have not traditionally, working forward, is that now we can build that in a way where they can also then speak to how those tests are being used to serve other markets outside of the United States. And that's something I think will be a key aspect of this program being able to participate in.

So FDA has had a policy on the participation in standards that came out right after the first OMB Circular came out. And I cite that up there just to make sure that, you know -- make it very evident. You know, it's not just a program that was a good idea that was driven only from the medical device sector, but the Agency as a whole has a strong relationship in participating in standards.

In the food safety standards, we've had a longstanding participation. A couple hundred different working groups I think have been involved over the years. Biologics, of course, has had a close tie for a number of different areas on tissue safety and blood safety as well as the medical device areas. And we also share the medical device standards recognition program with CBER. And we also are building a closer relationship in combination products with CDER, the Center for Drugs, who too is also coming out with

different platforms for how standards can be utilized and are even considering different conformity assessment platforms as well.

In addition, there's a number of new areas. Center for Tobacco Products, too, is trying to figure out, you know, when they're building their platforms, what can they benefit from in developing a program that will cite and use standards in a way that will help streamline their regulatory processes. And so this has become really an Agency tool for us to build upon and keep moving forward.

Going back into our program, we have a program that's built into it. We have a number of specialty task groups, as we call them, or STGs, that cover all the horizontal and vertical areas of standards and medical device-focused, you know, clinical areas, processes such as electrical safety and risk management and human factors and essential performance and all those are built into other areas.

We will be talking specifically about one of our largest horizontal STGs, and that's biocompatibility. And so they have a big room behind us where they will get into a lot of discussions. And I think we have an interesting platform to speak on about how does biocompatibility fit into this? The whole biocompatibility specialty task group as well as a number of the other experts have been really key in helping us see what are some new ways that we can think about utilizing standards in this area and working with the testing community, which thankfully is not an enormous -- there aren't hundreds of testing labs in this area. And we can really focus in and have some really great discussion. So I'm looking forward to see what comes out today of this.

We have a number of people, as you can see, involved in standards, well over 300 people involved in standards and over 600 working groups. As you see, we've recognized over 1,200 standards. That fluctuates a lot. It's actually going to go down here in a couple days, couple weeks, when we get the next FR notice out.

And the reason behind that, it's going to go down, is that we have changed our view on what type -- what is a standard that could be appropriate for recognition under a single recognition number. And what I'm speaking to is we recognize a lot of international standards, and we recognize a lot of their national adoptions through the ANSI, American National Standards, platform. But they're identical, and we give them each a separate recognition number.

What we're doing is we're converging on that, where standards have been deemed identical to the international version, and giving them a single recognition number, which will make it a lot easier for manufacturers to cite the standard if they're using the ISO or using the ANS. And we're also putting in our guidance. If you are using an international identical adoption to a standard that is recognized, you can also cite that. So if you have an EN ISO standard that you have purchased, but we recognize the ISO version, you can still utilize that EN ISO version if it has demonstrated that it is in fact identical and doesn't have any regional deviations in that case. So we're trying to open up our doors and be as transparent on the opportunity for manufacturers to cite their standards.

And the reason why we do that is when we did a utilization survey in 2015, we found that almost a third of the standards that were cited in submissions were not in the recognition portal at the time. So that probably causes a number of different unintended consequences in the regulatory review process.

And we found that many of those standards were international identical adoptions, whether it was a DIN EN ISO standard or a BSI ISO standard or something to that effect. Then we thought, well, jeez, we could probably help, you know, reduce a little bit of, you know, manufacturers', you know, question, well, can I submit a declaration to that or can I not? Or from a reviewer's standpoint, what do I do with this EN ISO standard, you know? How do I look at that? It looks the same. So we're going through that process to try to help

make it a little easier for people that want to utilize standards to support the program overall.

And why do we do that? It's because we see at least seven standards in a 510(k) on average. That ranges anywhere from 0 to like 40, but we see a lot of standards being utilized. And when you get 5,000 510(k)s a year, that's a lot of standards being utilized through the course. So what can we do to help improve anything that would be supportive to make sure our mission can be carried forward and reduce burdens in areas that, you know, we don't feel should be the point of focus and should really be the point of moving things forward in a way to support what we're trying to get to.

A little bit about standards involvement. Our big focus is to be involved as early as possible. We try to be engaged at the preliminary work item proposal stage, even before the work items are coming forward. We are in our IMDRF guidance even talking about the importance of regulators being involved at an international level and communicating not just within your own national body but communicating to the international bodies that you're a part of as well to ensure that standards are being prepared in a way that will work for all stakeholders and regulators being included in that.

Traditionally, we've had problems where we'll show up at the committee draft or final stages of a standard as a regulator and say, oh, I don't like this, this, or that, and then you find out that the standard's utility has, you know, not a bright future in front of it. And that's what we're trying to move past and get involved with, understanding the structure of standards.

I have the opportunity to sit on a number of different policy committees and even one with IEC at their marketing strategy board. And I asked them the question, you know, when you guys develop a new standard or a new addition that really kind of changes the platform of how, you know, the whole quality system is looked at or how we're utilizing risk

management, do you ever take into account how the regulatory structure is in certain countries to be able to adopt that type of standard, and if the regulatory structure would need to be tweaked or modified or a different educational platforms or training should be conducted, because, you know, standards don't happen overnight, but definitely regulatory programs don't shift overnight as well.

And so our goal is to try to be involved at those early stages to capture those elements and develop our programs along with this development of standards as well, so that way we don't have to wait 6, 7, 8 years after a standard is published sometimes if it has a large impact to different changes so we can utilize them earlier. That's why we publish standards is to get them into practice. Not every standard should have a 3- to 5-year window for implementation after years that it took for a regulator to use it. You know, we'd like to be prepared early. And I think that benefits all stakeholders because we're developing those changes for a reason.

So kind of going into the next realm here, I want to speak a little bit about, you know, the IMDRF a little bit more. And I bring this up because it really is growing in its impact. We have some members here. Ryan I saw you; you raised your hand. And is Melissa here yet? No. But we do have our members. Jeff also sits on the management council for the IMDRF.

And this is a key group of regions or countries that are working together to establish international medical device regulatory harmonization, if you can put it as simple as that. This work is not new. It actually gave birth out of the old Global Harmonization Task Force that did a lot of interesting work in trying to bring together and converge stakeholders' interests to make national and international standards - and there's Melissa; you heard me call your name -- a little bit more.

We're addressing a lot of common public health regulatory challenges and

convergence on these globalization issues in the IMDRF. And the idea behind it is to accelerate innovation, to giving a lot of clear and practical regulatory expectations up front. One of these areas that we're trying to focus on is optimizing standards and getting that focus of what I spoke about why FDA gets involved at the international level.

Up until maybe a few years ago, it was very rare to sit at an international standards meeting and see a regulator that wasn't from the U.S. I mean, we were happy if we could get the U.S. there, but we would rarely see anyone else from another country. Last week, I was in an international meeting in the Netherlands, and we had 5 different countries of regulators present in that one meeting of only 24 people in attendance, 5 different regulators because that was an impactful meeting.

And we're hoping to drive this across not just to the major horizontal standards but also into some of the device-specific areas as well, because the regulators across the world are interested in standards. But they have different hurdles that they need to jump through to participate in standards, and so this guidance is designed to help speak to those regulators up that chain of command and speak to their government representatives and try to really focus on why being involved in standards is very important.

Promoting development of standards helps shape innovation. It will help make sure regulators that utilize standards, say, in a voluntary manner versus a very restrictive, mandatory manner, will see the benefits of why choosing certain pathways will help allow manufacturers to bring new products into their country, helps develop better trade practices, and I think will help leverage a lot of what we're trying to do here in ASCA to be able to communicate how testing platforms can be built in a way to support not just national schemes but international schemes eventually. And so there's a big, big old picture that someone woke up one day and had a big, bright light bulb go off and said maybe we can do this a little bit better.

The work is, you know, obviously always going to be ongoing. None of these are easy tasks, but we're trying to build a lot of new relationships and partnerships. In fact, one of the things we're trying to do in IMDRF is build a category A liaison-type role with ISO and IEC to work within the technical committees that we feel have the greatest importance for us.

In addition to that, we're trying to create MOUs with ISO and IEC proper at their central secretariat levels to be able to share the experiences from an international level of how standards in general could be fit for purpose to meet regulatory needs and try to share our opportunities to see where do organizations like ISO, IEC, and other international standard organizations -- and there's so many like UL and IEEE and ASTM and a number of those that we like to call on because they're in the U.S., right? But a number of our SDOs, even a lot of our U.S.-accredited SDOs, are international-based.

I call an international standard one that's used in more than one country, not one that's voted on by more than one country. And I think that's important. Many of our standards that we recognize are used in dozens and dozens of countries, whether it's, you know, a specific ANS standard or an ISO or IEC standard. And I'm sure there's some SDOs here that say I know my ANS standard is sold in more countries than the ISO and IEC standard. And that's important to realize when we're talking about international harmonization because, you know, it's what products are necessary, are the best products to use to get to that endpoint of what we're discussing in terms of patient safety.

So the standards working group, which I do have the honor of being able to chair that group and work with one of our colleagues who's not here today, Ms. Gail -- or Dr. Gail Rodriguez, I should say. She is actually in another standards effort working on right now. But the idea is to improve the confidence and the quality of standards and, as Jeff mentioned, trying to make, you know, sure that we have key principles.

One of those key areas, though, that we're writing into this is how can regulators better participate in standards? You know, it's not just what can standards do to be better. It's what can we do as regulators to be better participants in standards. How can we not just leverage the IMDRF to say IMDRF wants to send in comments, but what can we do to work it better within our national committees to make sure that the national committees understand the international regulatory platform as much, as well, and share those relationships back and forth. And it's I think serving itself to be a very important and powerful tool to build the structure going forward.

Some of the things that we noticed, you know, and why we don't see regulators using standards the same way is they do feel that there's a lack of confidence -- they have a lack of confidence in some of the consensus processes. And let's be honest. If you've been involved in standards, you know what goes on. Standards are written between 5 p.m. and 9 a.m. the next morning more so than it is from 9 a.m. to 5 p.m. in the working group. A lot of people say, you know, there's a lot of wine that went into that standard.

(Laughter.)

CAPT COLBURN: Then there's a lot of whining that you hear going on during the standards meeting.

But that's an important aspect that we try to teach our international colleagues in standards development is to make sure they understand, you know, if you are participating even through your national committee, you'll understand a little bit more about the balance.

Going to balance, one of the areas -- and I sit on a lot of, you know, standards development activities in ISO and IEC, so you see the countries that are being represented. But a lot of times when you're reading comments from countries, you don't know what that national committee's makeup was. We know in the U.S., if that committee is also going in

parallel with the U.S. national -- with like a U.S. TAG or through the U.S. national committee, there's requirements for balance to make sure you can do a parallel vote. And you have to have balance from the different stakeholders.

That's not necessarily always true for all the other countries that are submitting comments in. And a lot of times you have no idea who's submitting comments in terms of is there any clinicians, are there any types of scientists, were there any toxicologists that came in through those comments from Belgium or something. You don't know that.

Interesting tidbit that we learned is in ISO/TC 210, a lot of the standards I was sitting on, we got a lot of these clinical comments from Canada. And we're like Canada? But, you know, they were never present at the meeting themselves. And so we actually called the national committee and learned a little bit more about what was going on; 100 percent clinicians. I was like, wow, like, that's a really powerful metric to know as a convener of a working group to know that these comments are coming in to address patient safety issues from a clinical perspective. Wouldn't that be nice to know at the working group level?

And so, see, these are some of the things we're trying to work with, with ISO and IEC, is how can we carve away a lot of the work that's happening behind the scenes in the national committees to benefit from those purposes so that as a regulator who's interested in public health and patient safety, we would understand how certain comments being addressed for that could be supported better from our perspective to help support the overall production of a better standard. So what can we do about that? That's what we're working on in the standards.

Building relationships, right? Work hard now, pays off later. Communicate, communicate, communicate. And that's really what we're trying to establish in the IMDRF. This isn't new principles of standards development. There are a few things that we think could be enhanced by developing different tools to help excite the idea of where these

comments are coming from. But really the idea is to build these better relationships, get public-private partnerships built at the national and international level, and try to enhance how can we do more.

So quick drink, and then let's get into the fun that we're all here for, right? Everyone awake?

Maureen, am I doing okay so far?

Maureen Gallagher is on our standards staff here, and she is, as we call, the boss. She works out everything, and her job is to make sure I do my job. And I always call her out here and embarrass her, but Maureen Gallagher, for those who aren't part of the FDA, is the reason why any of our FDA folks get to be in some standards development or get to attend the IMDRF meetings or get to be a part of this. So having key people involved in all aspects of your program is so important. So I want to just, you know, note Maureen.

Also, while I'm at it, as we're starting into ASCA, the ASCA core team has been a wonderful experience in building and working across all the different relationships from the different offices. And I just ask as just a point of recognition, if you've been involved with the ASCA or on the core team or in one of the subgroups, if you could just go ahead and stand just so people know who to come pick on later. I just ask for those who -- standing if you're a facilitator or a moderator, been involved in developing questions; we have a number of people here and there'll be a number of others coming in, but I just want to thank and point out a number of experts.

And I also want to ask my standards management staff if they could also stand at this point as well. These are the folks that are helping facilitate, you know, who sits on standards, what types of standards should we be recognizing, how do we focus on the prioritization of standards. And so we have a wonderful program of experts of all different areas, nurses, clinicians -- nurses are clinicians -- I should know that; I'm a nurse -- nurses,

scientists, engineers. We even have a lawyer involved in our team, right? Ian, you didn't stand. I didn't see you stand back there.

But it's an important aspect to realize that standards, just like anything else, needs to have the balance. And so the team that we have has a great set of balance. And why are we here today? Because we need to extend that balance out further. The job for you today here is to ask a lot of questions. And we always make the joke that ASCA is all about asking questions. But it's very important for these next 2 days that you aren't here in listening mode; you're here to try to ask questions, to get clarifications, to make sure when Scott misspeaks on a term, that you clarify how does that apply to, you know, what we're doing in developing the scheme? That's the most important aspect of what we're here for.

I think everyone who's involved with conformity assessment knows a lot more about the next 10 slides that I'm going to speak to than I do. And I know that. And that's why I'm happy to see that we had, you know, 200 people register to come here, and we have another 200 or so people registered online listening. We want to hear from you. We want to build a scheme that identifies the best practices in conformity assessment that identifies how we're able to communicate clearly to make sure that when we receive those final determinations and reports in a file, whether it's through the ASCA program or through any means where standards are being used, that we have a greater appreciation and understanding for how that work is being conducted in these spaces.

So I will kind of do a quick overview of the ASCA program, its background, its goals, some of the milestones that we're trying to reach, and get a little bit into the conformity assessment model. And as I do that, I also want to acknowledge another great collaborator that we've had in this space. Under the Department of Commerce, of course, we have the National Institute of Standards and Technology. And they are more than just a bunch of labs. They have a wonderful program in their Standards Coordination Office.

And I want to recognize two individuals that have been just really important to the foundation of this program, and that's Warren Merkel and Amy Phelps. If you could just kind of give a wave or something. They're shy folks, but these are truly experts in the field for conformity assessment. And we have been extremely fortunate to work with our federal colleagues in this space and, you know, building more relationships.

We do work with NIST in a lot of areas in the labs and build that up, but we've also, because we have a long history in standards development, have had a great opportunity to work with the Standards Coordination Office and all of the participants and, you know, benefitting from that. So you will get to hear from Warren a little bit later, but also Amy is here for the -- been working with us. I pick on her. I said we need to make sure she had such easy access to here that I gave her an FDA badge just to make sure she doesn't have to go through the security every day. It's important to make sure that your resources can get to you and help you achieve your goals. And so we're very, very happy to have them here.

So the ASCA goal: We've been seeing these slides rotate throughout the morning before we started. But, yeah, we're here to improve the medical device premarket review in areas where conformity assessment activities are met with inconsistent testing practices, conformance declarations, and regulatory review, right? Big old dirty laundry basket right there. It's not to say that there are bad practices, but we see some inconsistent practices.

Conformance declarations, we see them all over the map. I have seen one-page declarations of conformity to a risk management standard with no risk management process or anything to follow it to a beautiful outline, very succinct summary test report that was very appropriate and made us understand exactly the approach that was being used.

So we're trying to hone in on what is it that FDA would like to see for a test report and standards that would be fit for purpose for our regulatory needs so we can get through

and streamline our review practices because we will know what to predict when we see certain standards being cited. And hopefully through the ASCA program, you'll have a little bit more predictability on what our responses would be to reviewing that information. Increasing consistency and predictability, that's really what we're about here today, and that's what the design of this whole program is about.

We want to make sure we understand a lot more of how to judge conformance to standards in product review. We want to reduce needs for consultations to a lot of the "me too" type products where we're seeing the same types of testing, the same types of essential performance requirements or testing requirements being done over and over and over. A lot of times, we will send consults to experts for all of those types of products, and that really bogs down our experts in areas where they could be focusing on the new technologies, the new risks, the new areas where we could focus on and collaborate with the experts here in the room.

And so the idea is to build these schemes in an area where we can have confidence in knowing how their practices will meet the needs from our standpoint and have confidence in it. And from the same point, you too, especially those in the testing laboratory and accreditation body world, will have the perspective of what was it that FDA was thinking about when, you know, they recognized the standard.

These are the areas that we don't believe have the relationship today as -- when I was a reviewer for 7 years, I don't remember once ever calling up the testing lab and asking them, when you applied the standard, how did you do this method? We're not supposed to. We're supposed to call the sponsor number identified in the submission. And that's the practice. Sometimes that sponsor is someone in the U.S., and then they have to call the company in France who submits back the information after it get translated, and then comes back and then what we see is something very different. We want to build a better

relationship, and that's what we're trying to get through on this whole practice here.

So this is kind of what we're -- sometimes we'll say where we're at. We have a perceived standards assessment model, where sometimes it's really clear, but it might take a little bit of time and action to unravel the knots that come through our practices, and so we can get to a device decision by making something a little bit clearer. Our goal is to make sure what comes in looks just like what's on the right side of that picture as when it's coming out. I'm not saying it's not always there. In a lot of cases, we see a lot of great test reports. But in some cases, we see test reports that just weren't necessarily designed even for FDA.

We'll pick on one standard with 60601-1. Sometimes we get a nice test report and it's certified from a NRTL lab, and it says it fits exactly what's needed for OSHA's requirements for workers' safety. But it doesn't necessarily meet the requirements of what we're looking for, for the device performance or safety aspects of it for the patient. And so these are the areas that we think if we communicate into the accreditation environment and speak to this is what we're hoping to see when you test to a particular standard that's in this program, it will make sure that a manufacturer when they go into contract with a testing lab can talk about these are the tests that we believe we need to do. And the lab will have a bit of knowledge, too, of saying, you know, if this is going to FDA, you know, this is the platform that we've been accredited to in ASCA so we can help make sure you have a better opportunity of first-chance success. That would always be a nice goal.

One time I actually got a 510(k), and it was the first one I did. And I went through it, and I read it like two or three times, and it was amazing. I couldn't find any questions I had to ask. That was a wonderful feeling. And I want -- you know, that's a vision, you know, that Jeff has and that we have, is that, you know, the information comes in, it's really clear. And that was really nice because all the standards were cookie-cutter, and it was a simple

type of like needle submission for a hypodermic needle.

But, you know, it shouldn't be hard to interpret what are the regulatory requirements if they're not baked into a standard. We should find a better way. And this is where we came about in learning what could ASCA do for us. What is it that we can build from this?

So this is a pilot, right? This is a pilot program. It has a shelf life on it that could go away, but it has a renewable date if it works well. And that's the important aspect of this. But you're going to hear this over and over, and I really want to stress it. This is a pilot program. This is a program that's not going to take in 1,200 standards and put them into third-party conformity assessment. We have selected a small subset of standards and, you know, from that, we've actually been very encouraged.

And there are certain areas that are trying to make sure there's the opportunity for potential organic growth. But we, you know, specified the use of certain standards because we felt they had the greatest impact to those manufacturers who really are already working in this environment. We didn't want to pick standards that are being done at the bench level of a manufacturer's lab that may not even be accredited. That wouldn't make sense.

Rather, making sure we want it focused in the areas where standards have a long history of working in accredited testing labs to ISO/IEC 17025 and/or even have regulatory schemes that are utilizing those standards but aren't always being seen with the same level of predictability and not giving us that same level of confidence for us to be able to know that those determinations from the labs and the declarations of conformity could be looked at with a high level of confidence, because sometimes we see some inconsistencies coming through.

And, you know, as we keep diving into this program, we see that a lot of it just really depends on so many different variables: What accreditation body was used? How did that

accreditation body assess the testing lab? There are multiple accreditation bodies that assess laboratories to the same standards. And that's great, but we don't have a relationship with any of them right now. So what can we do to help improve the predictability and consistency of how testing is being determined to be competent from the access by working with an accreditation body to see what experts do you have when you're going through and doing your audits? Do you have access to the right type of experts?

Should we leverage ourselves to help assist in areas where maybe we could help promote and have the right type of assessment, even if it's not from a technical expertise but maybe even from a regulatory science aspect? That would just help bring that right perspective in so a laboratory understands the audience of -- the different customers in the platform, but what they're -- where these tests are going and how they can help communicate to the manufacturer what is necessary for them, then, to submit to the Agency when they make their declarations of conformity.

So a lot of the different breakout groups later today will try to take a deeper dive into these discussions of what is necessary for a laboratory to not only just demonstrate that they're competent -- and you know we believe that testing laboratories are competent -- but what can we do to make sure they understand how to make a determination of what tests need to be selected, potentially, based upon the essential performance of a medical device or the risk profile that the device has been presented to them, that some of that makes sense, that they can then, you know, work with a laboratory in a way that helps get to a closer -- you know, gets us closer to making the selection of what tests should be conducted the first time without putting that responsibility, obviously, to the testing lab because it's not their responsibility to say these are the tests you have to do for FDA.

We know that's the responsibility of the manufacturer. But can we collaborate and

build a relationship for you in a way that you have confidence under the accreditation scheme this is a little bit -- you have a really good understanding of what it is we are looking for that the manufacturers that are coming to you with in the requests for what tests would be necessary.

So we're capitalizing obviously on the increasing relevance of standards and device development and regulatory review. You heard Jeff earlier today speak to, you know, how he sees ASCA playing into so many different platforms even here at FDA, and also having a potential platform through the IMDRF. To be honest with you, when we were talking about this 2 years ago or so, that really wasn't the topic of our discussion. That really wasn't the driver behind this. But then when we started talking to the management in CDRH and to the different areas in the stakeholder community, they're like, jeez, what about this, or this could be a nice platform for that.

So really think about the big picture, right? Think outside the box in these next 2 days, too, of how can we leverage working with a regulatory body who has not traditionally operated and communicated a relationship into the accreditation world in a way that will help benefit and streamline what we're trying to do. And that's bring, you know, product in to get to our patients that are safe and can get there with the least amount of regulatory burden for all parties, you know? We like regulatory reduction as well. We don't want, you know, an increased burden from the ASCA program.

Standards, as we know, have the power to enhance innovation, to streamline submissions, to promote public health. The logical next step in this is to do an accreditation program with the long-standing history that we have. So conformity assessment is, you know, a key element in successful expansion of the standards. I think we saw this as the natural next step, you know? We've done a lot with participating standards.

Now let's try to get involved in putting standards to work better, an important

vehicle to bring the accreditation bodies, testing labs, manufacturers, and FDA together. Again, I'm going to keep repeating this: building a relationship of what we're trying to do.

The major milestones: And this isn't meant to just be an eye squinter, but the major milestones that we're trying to do here is, you know, we have our workshop. We met that one. The workshop was supposed to be done before the end of this fiscal year. We got this one in advance.

The other dates that you see up here are what's kind of communicated in the commitment letter. I'll be right up front with you. We're not striving for those dates. We're really wanting to try to see what can we do to get ahead of some of that. But, you know, because the important thing is trying to get the metrics of success to build this to encourage all the other programs, too, that could potentially benefit from this both inside the FDA and externally through tools like IMDRF. But these are the big ones that we're shooting for.

So that pilot launch date, yeah, that's what the commitment letter says. Can we change that date and move it over to the right -- or left? Yes. That is always the goal. But we want to make sure, too, that we're not doing something that isn't ready. We want to make sure we do have the right level of communication, that we've conducted the right level of training both internally and with the stakeholders that are going to be involved in ASCA and that we have a platform for success that can expand organically and at a pace that should be represented of the area that we're already involved in with these types of standards.

And for those with the cameras, don't worry. Eventually, these slides will be available.

Relationships: This goes back to relationships. Here, you'll see the relationships where the accreditation body accredits testing labs; the testing labs operate under ISO/IEC

17025 plus the FDA-specific requirements. That's what we're working on for the next 2 days in our breakout sessions. When we look at some of the standards that we're discussing, how is it that from a regulatory viewpoint do we see additional requirements?

But we're also interested in knowing, especially from the labs and accreditation bodies that are here today, if you're a accredited to, say, the alarms standard, which is a breakout session we're discussing, when we look at 17025 and from a laboratory's perspective, how are you accredited today? I mean, that's the base accreditation standard for everything. Obviously, it's tailored to each lab for their scope of accreditation. So what does that look like today? Could you share some of that information that would help drive us write a regulatory scheme that doesn't look so different from what you're currently doing in a way that would then extend that pilot launch data?

We don't want to change the world in a way that it doesn't need to be changed, but we want to enhance the opportunity of how you're being assessed for competencies, meets the regulatory requirements that we're trying to use standards for. So we're not trying to change the world, but we're trying to see if there's a spoke or two that needs to be added to the wheel or see if the wheel is turning just fine and we just need to work more closely through a relationship and allow testing labs to call the regulator if they have a question on a particular type of technology. Or maybe they see that their testing methods aren't quite fitting for this type of device and they might need to tweak it a little bit. Will that work in ASCA? Let's find out. Can we call FDA and get a determination or -- and work in those significant interpretation-type conversations that we want to have.

In the end, you know, we're trying to work to make sure the medical device product characteristics are specified a little bit further, we have a little bit better understanding of some of the standards that we're going to focus on. But throughout this whole relationship, we want FDA to be involved.

So you saw that earlier, you know, spool kind of mess. What we're trying to do is unravel that by opening up doors, by getting better relationships, by having CDRH as the scheme owner work with accreditation bodies that are accrediting testing laboratories to the standards that we're looking at doing. I'm not here today to tell you what accreditation body or bodies or the types of accreditation body or bodies that we're focusing on. That's not really the driver of today's discussion. It's more of, you know, building the relationship of how an accreditation body is determining competencies through the additional requirements FDA feels are important for ASCA under the ISO/IEC 17025 and then building that through.

But what you'll see with this model is that, you know, test laboratories in this idea of ASCA will have the opportunity after they've been accredited to the ASCA scheme to come and apply for recognition. And that's an important element that FDA felt they wanted to have, is the ability to have an official relationship on those laboratories that went into the ASCA accreditation environment and communicate to FDA as such so that way we can work with them on improving education platforms or have the opportunity to ask questions, you know, in both directions on how things are going, to have a close relationship with the testing laboratory community.

Manufacturers, then, will have the opportunity, if they choose to, to select an FDA-recognized testing lab that's in the environment for the standards that are included in the pilot. And then from there, a lot of it starts looking the same, you know? You're getting your testing done. You're getting your test reports back to the manufacturer. The manufacturer will determine, then, based upon how testing was conducted, does that meet the qualification of a standard that you can submit a declaration of conformity to?

And what I say to that is was testing conducted per how the standard was recognized by FDA; you didn't have to do big deviations and such because then you're kind of moving

away from, you know, how the standard was recognized, and a declaration of conformity is not necessarily appropriate anymore. But if it's done under the scope of accreditation and the testing platforms that are built into ASCA, this platform will allow the manufacturer to submit a declaration of conformity.

And the discussion that we'll have over the next day is, and then what? What else may need to be added to a declaration of conformity versus today, where we might have to see very large test reports or full test reports, you know, depending on how the standard is developed, to what do we need to see to make sure that we have confidence that testing was conducted, that we can see that the results of tests are appropriate to support the declaration of conformity that will help fill in the pieces of a puzzle that support the safe and effective use of the medical device for the users and patients.

That's really it in a nutshell, in many cases. Kind of going back to the relationships. This is kind of how I see us operating today. And Jeff spoke to this in his introductory remarks. FDA works with the manufacturers. Manufacturers work with the testing labs. Do manufacturers call up the accreditation bodies? Probably not. I don't know. Do you? I've never heard that in a conversation. Does FDA call the accreditation bodies when there's a question? No. We don't call the testing labs either.

What we're trying to do is build relationships and build out those perspectives, as appropriate, so we can have that opportunity to enhance these. So what we want to build out coming from this workshop is what is it that our scheme would look like? What are those technical requirements? What are those administrative requirements that we're hoping to see that an accreditation body would be working for? And we'll work with the accreditation bodies that would want to participate in the ASCA program, as appropriate, build that relationship, create the foundation for what types of education platforms are necessary on both ends, and then from that, that will allow them to, once it's ready, go out

and start updating the accreditation to laboratories that would want to apply for the ASCA program.

From there, now we can build relationships through the ASCA scheme that they've been accredited to right directly from the testing labs. And that's the key element here that we feel we have not had the opportunity to do. I mean, to be honest with you, we sit on lots of standards meetings, but not all the testing labs are involved in the testing meetings as well. So we don't have those same relationships as we do with some of the sponsors and other areas of the standards development.

But there's an entire world we found out that goes on beyond standards development. And I mean, I'll be honest with you, before I joined the standards program, even just 5 years ago, I didn't know what the IECEE was. What the heck was that? And then I'm finding that's where the test report forms are and the CB schemes and all this world. I mean, I'm not afraid to, you know, to play, you know, dumb on that one. The culture here is because we work solely through the sponsors, we don't realize there's this whole world behind putting standards to work.

And in many cases, when we see a regulatory scheme built into that, there's an enhancement on how that operates, and there's a lot more consistency and predictability because it's meeting the needs of that regulatory requirement. Well, why don't we get to play in that, too, right? That's really what this is about. Build those relationships in so we can have those really good communications. We can work with the testing houses on the scheme directly and in a consistent way.

We'll be able to focus in on metrics, too, with how standards are coming in and how -- of the approach of where they're meeting the requirements for us, where can then we go back and communicate to the SDOs that are developing these standards on how we can maybe see the next edition or an amendment, help clarify and help produce better

testing requirements, make it easier for the testing labs to understand how to approach this and through their accreditation. So I think there's a lot of great opportunities for the entire ecosystem of what we're trying to do.

So I'm getting close to the end. I'm getting pretty good with my time, too, eh, Maureen? All right. I didn't even get the cut-throat that she was going to give me.

So the standards that we put up under consideration, we didn't kind of pull this out of a rabbit's hat. This wasn't something that we were like, oh, what can we do here? We have been working with a number of different stakeholders, both at the SDO level with a couple of the trade associations; we have communicated with a lot of the different testing house groups as well to try to hear, you know, what are the main standards that are being utilized in this space, not just, you know, what are some really good standards that we can do accreditation to and build a program around, but what are the ones that would make the most sense, and what are the ones that would have the greatest utility by the sponsors who are utilizing these standards in their submissions?

And we kind of broke it up into two main areas. One is dealing with the basic safety and essential performance in the IEC 60601 paradigm. And we know there is a number of standards. And we said why not pick the easy ones, right? Let's go right to 60601-1 because that one is so easy, and you know, we have recognized it the first day it came out of the publication. We knew this was going to be a challenge. We knew that there's a difference of terminology that's used in how, you know, essential performance is going and, you know, in how basic safety is addressed and how that fits into the quality management system.

But we also know that this standard is primarily utilized by an accredited lab. So how can we learn more about what is going into that? We really want to hear from our labs that are working in the 60601 space, how are you accredited to this? What does this mean

when an FDA regulator now wants to come in and talk about accreditation, recognition of an accredited testing laboratory to 60601? How do we build our confidence to that?

We're going to share some of our thoughts about what we feel are important when we deal with basic safety and essential performance. We're going to speak to what we feel is essential performance and how standards may do a good job or may not always do a great job of identifying the essential performance. And what is it that, based upon how we regulate on a risk-based platform, can help communicate to the testing laboratories to help them work on ensuring that the test reports are reflective in the profiles that go to manufacturers, so that way, when we get those attestations of conformance from the declarations, that it makes sense to us, that it did follow what we were hoping to see go through this.

So there will be a lot of discussions on this. We've included EMC as well as alarms, so we're going to have a lot of magnet throwing and alarm beeping going on, I'm sure. It should be fun.

But we're also interested, too, how does this all apply into the device areas? Are we going to focus in on device-specific standards that do, you know, bring out these horizontal standards, the collaterals a little bit more, or do we think we can open it up even more so. And so we want to hear from how stakeholders are applying certain types of medical devices that may not have a -2 standard in the IEC world. That's of interest to us as much as it is to know how does the ventilator standard that we know is in IEC also work itself into the collateral standards.

And you'll notice, too, that not all the collaterals are up there. Does that mean that they can't be a part of ASCA? Yes -- no. No. But we also -- we were trying to build something that isn't such a huge mountain to begin with. We wanted to hit with something that we think we can build from. Could it grow out organically? Yes. Are there ones that

really should be on there to really help make sure that these standards could be put to work more easily? Let's have that discussion if you do feel so, and that's why we're breaking out later into smaller rooms so we can hear, you know, how can we do this in the most appropriate way that makes sense as well. But I want to really -- a lot of good effort went into this approach.

On the other side, we have biocompatibility. And the biocompatibility group has done an amazing job to really sift through the 90-some standards that are in that profile of recognition to really find out which are the ones that could give the greatest impact, that can be utilized by the greatest number of stakeholders, and give us a nice opportunity to see the benefit of a really high-quality program that we have confidence in, reduce our requirements.

Jeff mentioned some of the review times that go in. That 11-hour to 17-hour metric was actually on biocompatibility review, not a submission review. And to be able to bring that down into a smaller platform where we don't need to spend as much time -- because we understand how the methods were done, we understand how the approach was taken through the ASCA program -- provides great benefit to us as well as the predictability of how those tests are going to be assessed from the manufacturer.

And, again, biocompatibility, from my understanding, is primarily done in the accredited world today. So we're not going into an area where the labs aren't accredited. They already are, but we want to build in a little bit more of that perspective.

So next steps. I've mentioned it a few times. I'm going to say it again. We really need to hear your input. This is a pilot program. We're going to build it. There's going to be a few areas that it won't be perfect. What we are going to present to you over the next day for this afternoon and tomorrow will be an imperfect presentation of what we're looking at of how we've assessed 17025. But our experts have done a really nice job of

trying to learn that standard to try to see where we feel some additional requirements may be.

Certain areas in some breakout rooms have gone a little bit deeper into the standard. Other areas have not yet really gone into the technical requirements so much, and we're wanting to hear from the laboratories that are in this space of how do you assess yourself, what are the additional requirements you place upon yourself to be a competent and high-quality lab. Let us hear that.

We're going to be taking lots of notes. We want to hear questions and dialogue going on to that effect to really build this out because the goal from this is to collect all the information on what we're doing and develop our scheme, which may come out in a guidance, it may come out in a couple different things, but developing the scheme, the program of what we're trying to do here. That's a term that we didn't know as well, too. When we first said scheme, someone went scheme, that sounds negative.

(Laughter.)

CAPT COLBURN: Terminology. Make sure when we're talking in our breakout groups, that if we hear a term, you see someone do, you know, like a little shudder, let's make sure we're on the right terminology, too, and we're speaking the language that everyone understands. Pull out that sheet of paper if we have to. Those are going to be very important.

But our goals are to get the scheme identified in a way that we can help move forward over the course of this summer, build the relationships with all the stakeholders, the sponsors, the testing labs, the accreditation bodies, other regulatory agencies. I believe OSHA is here, are they not? OSHA? Oh, there. I'm sorry. I looked at you 10 times, too.

OSHA is here. Why? OSHA has an interest in this as much as we have an interest in their program. They take care of workers' safety. Medical devices are used by workers. A

lot of our 510(k)s and sponsors have to go through OSHA for workers' safety issues as well as FDA, sometimes being tested on the same standards platform. Would it be a shame in the United States if we had two completely different schemes for certain safety elements? That would be, right? Has it happened? It does sometimes.

Our goal in working with groups like the ICSP group with NIST is to build those relationships and build a platform where can make sure, too, that what we are developing in our scheme does work for OSHA, and vice versa, too, to have an understanding of what does OSHA's scheme do that covers, you know, what part of the FDA's requirements, so that way we can use that information to build into ASCA and then carry that up a level into the international level and then, if lucky, maybe carry it down a level into the state level as well sometimes, where those standards are being assessed again at the state level. And we know that can always be an interesting venture.

So this is hard work, right? Opportunity is missed by most people because it comes dressed in overalls looking like hard work. So I put my fancy duds on today, but I almost wanted to put on my low-crawl blueberry uniform instead, which we go deploying in. But this is really going to be hard work. I don't expect everyone to be happy, you know, but try not to kick sand in the face when we're having discussions. Let's try to build the sandcastle.

I really want to tip my hat to everyone who's here as well as those who are online and calling. We have people calling in, I think, from Asia, from Europe for this meeting. So there are over 200 people that are also online listening, watching, so you can wave to them in the cameras. They're hidden somewhere. And they will also have opportunities to participate through the chatrooms.

I do want to note, and we'll try to give housekeeping items as we go through, we'll be breaking here very shortly, but then we'll come back to listen to a presentation. Then we'll go into some public comments that have -- we had a few registered speakers that I felt

would -- if you notice, the agenda switched, where public presentations were at the end of the second day. But we had a couple presenters that I thought, you know, it might be good to bring that up into the first day. And so they will talk before we break for lunch.

As always, there will be opportunities for question and answer periods as well. And then tomorrow we'll have a long -- we'll have an opportunity for those who are here today, if you feel you would want to present, you know, go ahead and sign up at the registration desk, and we can have short presentations tomorrow.

So, with that, I want to thank you in all the international ways possible. And I do believe we have a few minutes for questions before 10:45, right?

Any questions? We have one coming.

Yeah, and when you do a question, because we are doing transposition [sic] and everything, if you could just introduce yourself and then go ahead and ask your question.

MR. FREEDMAN: Good morning. My name is Fred Freedman. I am with the Dental Trade Alliance, representing a number of dental manufacturers and distributors and laboratories, basically the dental industry.

First of all, I want to say, Scott, thank you very much, you and your staff. Obviously, this is a very long, well thought out ASCA program that you're developing. I'm sure for the rest of you in the room, like me, it asks a lot of questions as well as answers a lot of questions. And I would probably assert that everybody in this room agrees that it's always patient and practitioner safety first. So, you know, we applaud all of this and trying to check all those boxes.

The one thing that -- concern that comes up, and I address this, Scott, not only to you but your team, when you were talking about the laboratory testing and accreditation, not every manufacturer is a big, multifaceted manufacturer making millions of dollars. Have you given some consideration to what costs are involved and how this may impact

small manufacturers and ultimately raise the cost of healthcare here in the United States?

CAPT COLBURN: So that's always a hard question to answer, but the idea behind this -- and this kind of even goes into what standards we selected and why -- was to look at what's currently going on in this space in terms of accreditation, which standards are typically tested in the accreditation space, and which standards are we sometimes asking additional information questions on to get clarifications based upon the information that was provided to us mainly because certain parts of the test report weren't thought of being necessary or maybe certain parts of the test were not conducted.

But in any case, any time there's a delay because there was a question asked, even a couple days in a delay of a review has a massive cost impact to the sponsor. You know, we know sponsors do a ton of effort to try to predict that magic date of when they get their clearance or approval. And there's millions of millions of dollars that go into that date being shifted a week off one way or the other.

And so when we looked at building a program and started saying why don't we focus first at where is testing being done in an environment where accreditation is already taking place, take a look at that and see what are any of the additional requirements FDA would need to see, if any. And, you know, we went through ISO/IEC 17025 and from our perspective wrote in what we thought would be the additional requirements. But we actually don't know what a lab is truly being assessed to. We know they're 17025, but in many cases, based upon the scope of accreditation, there's additional requirements that are written into that. And that's what we don't know yet.

So we built what we thought should be appropriate, and now we're hoping to hear what you are being measured against right now and see where hopefully that has a very, very close mapping to what people are doing today. Maybe a few tweaks, maybe a few areas where communication has to go. But the idea is not to try to make it more difficult to

be accredited to the standards that are already being tested to, but to provide the key elements to us and open up the doors for laboratories to communicate to us and us back to them, and work through the accreditation bodies in a way that we feel that will enhance and make it easier for businesses, especially small manufacturers who are trying to weigh do we go to a laboratory that's accredited or one that maybe isn't?

You know, sometimes there's cost factors in there, but to provide, you know, the appropriate incentive without hopefully -- you know, we don't have a control on cost; the program is not going to address cost -- but hopefully not have a negative impact on that question.

So our goal is to try to make it easier. But sometimes, you know, and I think manufacturer would attest to this, sometimes spending a little bit extra for great confidence and predictability, too, has its positives. So, you know, we'll see where this kind of goes out, but the idea is to learn and build ourselves into the existing wheel and hopefully not make it -- you know, we don't need to, you know, put crown molding on it and paint it gold and things like that, right?

MR. FREEDMAN: Thank you. Yeah, just a quick follow-up, I would just say that as you go through all this in the next 2 days, and this is for really even everybody in the room --

CAPT COLBURN: Yeah.

MR. FREEDMAN: -- you know, keep in mind sometimes when you're building these great programs, there's additional costs, and especially for small and medium-sized manufacturers, it can actually push somebody out of the space because of cost. And it's very important. Something like a 60601 third edition, the testing for small companies is astronomical and actually prohibits some companies from actually putting new devices into the space because of cost. And I would just ask everybody as you participate in the next 2

days to think about that.

CAPT COLBURN: Thank you.

MR. FREEDMAN: Thank you.

MS. TELLES: Thanks, Scott.

CAPT COLBURN: Thank you.

MS. TELLES: My name is Roberta Telles. I'm with IFIA, the International Federation of Inspection Agencies. We represent the global testing, inspection, certification industry, so a lot of my members are here today and also online. And our members are all very active in the medical devices space across the globe, in Europe and other markets. So we're very happy to see FDA moving forward with this program. So congratulations, again, for this initiative.

My question is what is your expectation on how much the ASCA pilot program is going to actually reduce the review time so it gives enough incentives for the manufacturer to join such program?

CAPT COLBURN: Well, the manufacturers don't join the program. The labs do.

MS. TELLES: The labs join, exactly --

CAPT COLBURN: Well, of course, what's the incentive for a manufacturer --

MS. TELLES: Manufacturers to contract --

CAPT COLBURN: -- to go to a lab under ASCA?

MS. TELLES: Yes.

CAPT COLBURN: Crystal balls in that area are still being built, I guess. That's a hard question to answer, but I think what the goals are, you know, and Jeff spoke to this, this morning as well, the goals are for us to have confidence in knowing what is actually being tested and how it's being tested and how the competence was determined through this accreditation program. So that way what we do see is a lot of the questions that maybe

sometimes a reviewer would have in the back of their head have now been addressed. And so they can look at the evidence, you know, that's coming out to support a declaration and be able to move past that.

Even the metric that we presented, where 15 hours down -- or 11 hours down to 15 minutes, that doesn't equate to 3 days less review time obviously, but it allows us to work more closely and put our resources in areas that we are most concerned about with patient safety. And a lot of that, if you look at the new platform for how the Center is being developed, we are looking at postmarket data to help use in the premarket areas as well. And so that now opens up doors for us to use those resources.

I can't make promises on how many days, you know, because I don't know how many standards are going to be a part of our particular 510(k) or if that sponsor chose to use accreditation program, but I do think in working with the experts that you'll hear over the next 2 days, the design of this is to make their workload a little bit easier and put our experts that we feel really understand the "if only" question that we always ask, if only they would have thought of this or if only they understood what we were looking to do. It would really reduce our burden and our concerns and have the ability for us to then, from what we do in standards development, improving standards and making sure we're communicating those needs and then working into the other environment where test reports are being done. I think we would see a natural lowering of some of the regulatory burden.

But, again, I wish I could make a promise. That is a metric that we will be looking at, though. You know, obviously, I don't know if there will be a way to correlate it to something actual, but one of the areas we desperately will be looking at is how our standards in the ASCA program versus those same standards that are not going through those labs are being assessed and where are we seeing inconsistencies still, and you know,

you'll see the correlations to those. And I'm hoping that there will be an obvious advantage to seeing how working in this program will at least help understand for some of the -- especially in some of the areas -- we'll talk about some of the devices that are complex that we need to have those discussions on and maybe have a communication with the lab.

From my understanding in some of these -- you know, because devices -- Jeff mentioned, you know, technology is moving so fast. You know, a lot of times the testing labs are looking at this, looking at their scope of accreditation, and they're saying, you know, maybe we have to tweak this a little bit. Depending on how that gets tweaked and then who's the end assessment of that conformity assessment platform could -- you know, that's where the predictability goes out the window.

If they have the opportunity to call us and have a discussion, or we can see something that's coming in and say, you know what? We've seen three or four test reports on this new technology come in. Maybe we need to have a course on this. And get all the labs that are in the program to call in and let's have a course on this so it benefits everyone. That's the idea. Build the relationship. I would hope that everything else that you're speaking to will play out and hopefully a crystal ball will come out later.

MS. TELLES: Thank you. Yeah, I think the whole idea there of having this more closer collaboration is great and important for the program -- feedback mechanisms and training of the labs and ensuring that this is flowing well.

CAPT COLBURN: But I mean are there those in the house here who have worked with premarket submissions, developed 510(k)s, PMAs, and stuff, that aren't FDA, of course? I'm sorry. Good. I would like to hear -- you know, when you're in those breakout rooms, do you think if you had confidence to some of the declarations or statements of conformity that you're making to the standards knowing that there is a greater understanding, do you think there would be a benefit on that? Do you think it would be a

lot easier for you to have a communication with the reviewer about the standards that you used in that program? And that's what we want to get out of that.

I see a lot of little heads going up and down. I think our own reviewers would like to know, too, a little bit more about how can this benefit their understanding of how standards are being used. Our review staff have to be knowledgeable on 1,200 different standards sometimes, you know, right? That's a really hard thing to do, and that's why we have so many consults going out to so many different divisions. And, you know, what can we do through this is build a platform and an opportunity for our experts to speak to experts in the community and build understanding, and I think that will do something. That's the dream.

MS. TELLES: Thank you.

CAPT COLBURN: Ms. Elisabeth George?

MS. GEORGE: Elisabeth George with Philips. I wanted to kind of respond a little bit to that question that was asked. I think as a manufacturer, one of the things we're looking forward to is the consistency, then, because if the reviewers do feel the confidence coming from those test labs, that that will prohibit or inhibit them from having to ask all those extra questions. Because today, for example, we may have one item that we're submitting with three different 510(k)s, three different reviewers. One goes through like that because that reviewer does either have comfort with us or familiarity with that standard, and the other reviewer may not have that. But if they can feel that level of confidence through this ASCA program, that will be an ultimate gain that we're hoping to see. So --

CAPT COLBURN: Absolutely. And those are some of the metrics we're trying to figure out, too, is how to appropriately implement this internally. What types of platforms do we need to build inside? What type of IT systems, education platforms can we do to help communicate what's coming out of ASCA and bringing that into -- right in front of the

reviewer, too, so they see that. I mean, it's -- there's so many different programs and platforms reviewers have to know and understand and leverage that it's a huge challenge.

And I think we're seeing better outputs now with the smart templates and the e-submissions and stuff. This should be one other added value into this because that's the idea is to be able to then understand, you know, what comes from the test report, what gets generated, what's necessary for us to have that determination.

Yes, Anthony?

DR. RAGHEB: Tony Ragheb from Cook. Thank you for putting on the workshop.

Toward this topic about reducing the review burden, some of that reviewer-to-reviewer variability, I think, perhaps depends on how personally responsible a reviewer feels, how compelled they feel that they need to look through the details of a submission or a test. What type of support will the program offer for a reviewer to maybe help ease that feeling? Won't a reviewer still feel -- they're the reviewer. They have the responsibility to look through the data, look through the test report in detail.

CAPT COLBURN: So, you know, that's an interesting platform. That kind of builds upon some of the enhancements on the use of standards that came out of 21st Century Cures and what we're trying to do. So ASCA is another building block to what we're going to try to achieve in this in helping the review staff understand how to utilize standards, how to utilize standards as a confidence tool of assessment as well. But building that, we also have to update our guidance documents.

And I just spoke a little bit about some of the guidances that will speak to what is a declaration of conformity, what are the contents of a declaration of conformity that goes beyond the, hi, I use this test lab to these standards, signed Joe Smith of such-and-such company. But what are the types of -- what's the level of information that's necessary based upon the type of standard that was built? Is it a process standard that has multiple

methods that you use a risk management tool to open up what door that brings you then into a bunch of test methods that don't have acceptance criteria? What level of evidence is necessary to support that type of declaration versus another standard that has very, you know, walks you right through and gives you the endpoints built into the standard? Then how do we translate that into regulatory review practices?

So our guidance, you know, tries to take that first step into it. Our program also is trying to extend in working with the premarket and postmarket offices on the types of training platforms that are necessary to help improve the consistency of how we approach the use of standards.

I agree. As a clinician and working with my colleague that I share an office with who was an engineer, we had different perspectives on what is risk and what's a risk -- how far down, you know, do you go where you have achieved an appropriate level of risk? We understand that internally as well, and so we are trying to build programs that share, you know, the strategies that both types of specialties work with in a way that we can be consistent as well. And that's what you're trying to get at is how can -- and I think Elisabeth, too -- how can we approach things in a consistent way from a standards utilization. And that's really what we're trying to do here.

What is necessary to review, I think, is another, you know, element that you brought in your question. And that's part of what the outputs of the ASCA scheme is going to be working towards is what's the level of evidence that would be necessary to support a declaration of conformity in the ASCA program versus someone who's declaring conformance to a same -- similar standard outside of the ASCA program. They're all voluntary programs. Even submitting a declaration of conformity is voluntary.

But, you know, how do we leverage this in a way where ASCA helps us understand specifically how testing was conducted, and how was those who were conducting the tests

already determined to be appropriate and competent to do this in the scheme, and be able to share that information as a benefit to help the regulatory review staff to understanding? You know, these are, you know, areas that we should have high confidence in. We should really just focus on the results of tests and those endpoints to make sure that that supports the intended use of the product, so that way you can make a determination, you know, in your regulatory review process.

You know, we understand that many of the standards, you know, and even the test reports aren't going to say passed, right? That's not what they're there to say. They're there to give you the level of evidence for the manufacturer to determine does this support my intended use so I can make my claims to the Agency. But what can we do to try to, you know, streamline some of those actions and understandings is the goal.

All right. I have a few more minutes. Is there any more questions, or does everyone have to run to the bathroom?

Mr. Grant?

So before Grant talks, I just have to say I always love coming -- giving talks in the standards atmosphere because I think I recognize almost 85% of you or maybe even more. It's humbling because if I had to do this in a room where I didn't know anyone or the drug department, sometimes talk at PDA, oh, man, start knee-knocking behind a lot more. So it's always comforting to see a lot of colleagues in our space. And, again, thank you for coming.

Grant?

MR. RAMALEY: Yeah, thank you very much for allowing me the opportunity. I'm with Fred. I'm a member of the Dental Trade Alliance. I actually apply 60601, so I know exactly what he's talking about cost-wise. And I'm really appreciative of OSHA being here and the fact that they recognize the older version, which is 17000 versus like 150 if you get them with usability and all the other risk management evaluation that goes into the third

edition version.

But I also work with the International Accreditation Forum. I'm familiar with ILAC and NVLAP and what they do and the 17025 standard a little bit. I usually work in the 17021 because I'm with the IAF. But one of the biggest problems I've seen with the -1 standard, the third edition standard, is it's kind of a hybrid. It's not something you can just measure. It has components for risk management that are built into it, which is actually the biggest cost for the whole program.

At one point, A2LA decided that when they were accrediting a lab for 60601, they would only be accrediting them for the part where they're actually doing the testing of the product. They would not be accrediting the activities where they're certifying the risk management portions because it's out of scope for technicians who are testing product to be doing assessments of risk management processes.

In the same way, the IECEE CB scheme is now requiring that everyone who goes into a test has to do a 62366 evaluation to usability. Again, a lot of soft skills there, a whole lot of checkboxes, and assessing the usability of a device is really something that the manufacturer is checkboxing a lot of stuff in a usability standard, sending it to them, and they're seeing that they just say that they did that. There's not really a good assessment.

So I can see a great value in what you're trying to do here with this scheme and the ASCA because it opens up the opportunity to really have a discussion about what do we do with these hybrid standards. But I really do -- like Fred said, I wish -- you know, you mention all the stakeholders in here. I didn't see any accountants, you know? From my end, I've got a CFO who comes in here. He's looking at my budget for the year. And he's looking at this giant spikes, and he's going what the heck, you know? And I go, well, yeah, we had to send a product to testing, and that was, you know, $100,000, and you know, which is like two employees for a year.

So it's tough. So I mean I'm happy OSHA is here so I can thank them for keeping the old standard. And when I approached the FDA about the cost of these things on that end of it, usually what I get is, well, they're voluntary; you don't have to use them. But then I get calls from members of the DTA saying, hey, you know, the reviewer is saying I have to do this, so what do I do? And I'm like, well, you can use the old standard because OSHA still recognizes it. And you can kind of do a little bit of a gap analysis, and we can try and push it through that way. But they just don't have the technical competencies to even do the gap analysis.

So the complexity of the new standard has really created a lot of problems for small companies, but I think it -- I hope that the ASCA program will certainly help resolve some of those more challenging issues with the soft skills that are built into the newer standard.

CAPT COLBURN: Yes. Thank you. You know, we've walked through, and Grant and I have had a couple discussions as well over the years and with OSHA. And, you know, again, I think we'll see, you know, what is FDA looking at when we're talking about 601 in general and then applying it -- you know, when we go into the breakout sessions, we can have some of those discussions. You know, I don't like hiding behind the "it's a voluntary thing," but I mean it is a true thing as well. I mean, even the use of the second edition is not prohibited because it's not recognized, but it's also determined, you know, not to be what we're hoping to see that would support the declaration of conformity on the use of standards under Section 514(c). So we moved into the third edition a couple years back.

But it was a hard move even for us because it took a long time for us to figure out how to manage, you know, understand risk. And we're still working on that. I think we've done a lot of work in risk management over the years.

But I think, to your point, Grant, and it's not even just even to the small manufacturers and working between OSHA and FDA, but you also alluded to where test

reports even in the third edition don't work in other countries, and you're having to retest even again. And that really knocks the small business manufacturers out, if even when they take the commitment and use the -- get testing to the third edition and it works in one country, and then they get told they have to go test again in another country because -- and where does that work?

And, you know, that's why some of our international regulatory folks are here, to help hear those discussions as well and see what we can do to improve that. And where could ASCA maybe help leverage confidence to other regulatory bodies that, you know, here we have a scheme that was developed with a regulatory body that has some experience in working in this space, and can that help enhance confidence of other regulators in the world to help accept those types of tests in the future?

There's opportunities to this as well, so it'll be a great discussion. I know you'll be involved in a lot of it. So thanks for the commitment.

All right. I think we hit right on the mark of 10:45. So why don't we go ahead, we'll take a 15-minute break, and we'll come back to another plenary session giving an overview of ISO/IEC 17025 being presented by Warren Merkel and some of the activities going on there. And then we're going to have a public session for a few people that have come forward with some topics. And so thank you very much. And we'll see you in about 15 minutes.

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

(On the record at 11:01 a.m.)

CAPT COLBURN: Okay. Thank you very much. Just a few other housekeeping items. So I hope everyone has had an opportunity to -- if you wanted a box lunch, to go ahead and preorder one. I think you can also order one during lunch as well. It's just that there may not be -- the prediction -- predictability, right, may not be -- you know, we might run out if

there's a bunch of people that haven't registered.

The other one, there were some questions about wifi, and we do have wifi here. It's under the wifi public access account. The password is publicaccess, all lowercase, I think, with no spaces, if I'm not mistaken. So for those who are trying to get on the wifi, you can do that.

Okay. So I want to go ahead, and it's my pleasure to introduce Warren Merkel from the Standards Coordination Office at NIST. Warren has been a strong supporter of helping us build this program and through a lot of the resources of working through SCO and with Amy Phelps, who has been working with us directly. But we've also been working -- we've stolen a good chunk of their staff for a while there. Also, Lisa Carnahan has worked with us on our UDI project, unique device identifier, and other areas.

But I want to welcome Warren. And I asked Warren, you know, to kind of just give -- you know, one of Warren's roles he will talk about is he's the co-chair of the working group that deals and builds ISO 17025, ISO/IEC 17025. And I thought, well, you know, it'd be a great shame if we're going to talk about 17025 for 2 days to not hear from a co-chair of someone who's helping us in this program. And so I wanted to have Warren come with us and introduce him.

So, Warren, take it away. This is yours.

MR. MERKEL: Well, thanks, Scott, for the introduction and the opportunity to speak. Wow, it sounds a lot louder up here. Can everybody hear me in the back?

UNIDENTIFIED SPEAKER: Yes.

MR. MERKEL: Better?

I was a teacher for like 6 years, so I have a teacher's voice, so if it gets too loud in the back, just like give me one of these.

As Scott said, we are supporting this effort for a lot of reasons, not the least of which

is our role under the National Technology Transfer and Advancement Act, to help coordinate standards and conformity assessment activities across the government. So I'll wrap with some of that. But I wanted to give you a little overview of the changes and the revision of 17025 and the impact of those changes.

To help me gear the talk, though, just by a show of hands, how many of you have read any version of ISO/IEC 17025? Giddy-up. All right.

(Laughter.)

MR. MERKEL: How many of you have read the revised version, the 2017 version? Okay. Good. That means I can't lie.

(Laughter.)

MR. MERKEL: Usually that's not the case, but it's been out long enough that people have seen it.

Clearly, in the 30 minutes that I have, I can't go through the whole thing, but there are a couple of changes that use terms that maybe could use some explanation of the context within 17025 versus the context that may be more familiar to all of you in this area. I'll talk to you a little bit about the transition to this standard at least globally, and then at the end, I'll talk about again our role at NIST and how we support this function and the fact that we're in the process of generating some documents that help with the use of conformity assessment by federal agencies. And I'm going to do all that in 20 minutes or less.

So I'll start with why we changed it. And in the process of the normal review of ISO and IEC standards, there's a 5-year reconsideration. And we actually went a year early with 17025 because people had some things that they felt needed to be changed. One was to align the structure and content with some other ISO standards, mainly the CASCO toolbox. CASCO is the ISO committee on conformity assessment, and they have a series of 17000

series standards. And so with those standards, there's been a change in the structure and the content. So 17025 is now aligned with some of those.

In the process of reviewing, ISO 9001 changed and was published. And there's been a historical connection between 17025 and the content of 9001 for laboratories. And so we had the opportunity through the revision process to incorporate those changes as well.

One of the major changes that we tried to take on is to focus on outcomes and ways laboratories can demonstrate their competence rather than being prescriptive about how they demonstrate that competence, performance-based requirements rather than prescriptive requirements. And it's been decades since the standard really was completely revised, and so the way that laboratories work, their environments, themselves, and their customers has changed radically due to technology changes and other changes. So we wanted to update the language to reflect that current practice.

The last one: And we tried our best, we really did, to not fix anything that wasn't broken. The standard had been around for a long time, and people were pretty used to it. And so when we had come to a point where we couldn't come up with a change or we didn't feel a change was appropriate, you'll notice that the language may be in a different place, but the same words ended up being used.

What did that result in, in terms of the differences? Obviously, the structure is different. And I'll go through that briefly. We incorporated risk-based thinking. That's a very specific choice of words because it has a context in this standard that needs some explanation. And I'll get to that in a bit. But that helped us focus on those outcomes, because if a laboratories is thinking about how it undertakes certain activities based on at least considering a risk associated with nonconformity in that area, then we could really do more to focus on the outcomes. So there's less variety in the way we describe how a laboratory documents its processes.

Along the way, this one really hit people hard, but we got rid of some of the favorite terms like quality manager, quality manual, subcontracting. Now, if you really have read the standard, you'll realize that other than taking those terms away, these same requirements are still there, and the old standard said a quality manual or some collection of documents. It said a quality manager or somebody with some other title. Why not just cut right to the requirements and let the laboratories and the accreditation bodies, if they use the standard for that, really determine what requirements are met? That results in more flexibility in implementation for laboratories, particularly laboratories that are using the standard maybe outside of an accreditation context but also within the accreditation context.

And on that last bit about updating the language, you'll notice that some of the old terminology around drawing lines through things and the way that documents are generated and retained is different.

So here's the old structure. I'm sorry. Yeah, the old structure of 17025 had basically two sets of -- two clauses that had normative requirements, clauses 4 and 5. The revised standard has more than that, has more words, but the new structure just has clauses 4 through 8. We also have two informative annexes, but they deal with different topics.

Now, just thinking about going from the previous to the revised version, you start connecting lines from one to the other; it gets really messy really quickly. So that's one of the things that we have to come to grips with as we move forward with implementing this standard.

So what's this mean to all of you that are using it? Again, the flexibility is going to translate into the development of scheme requirements. In this case, if we're looking to put more technical requirements around the implementation of 17025, then some of those areas where the flexibility exists in the standard may need to be clarified or tightened up to

ensure consistent operation. The key to that is input from all of you, the implementers of that scheme. That's going to be critical.

The mess here of doing a redline version made it impossible. It looks like a bowl of noodles. But just like a really good bowl of noodles, all your favorite, the good bits, are still sort of sitting right there on top. You can eat a little noodles. You can eat a little bit of the good stuff. At the end, it all really comes back together to make a good standard.

One of the other 17000 series standards was raised before, and they're in this world of medical devices. A lot of these standards get used for conformity assessment, so that's another benefit of the current revision of 17025 because it allows for some alignment of how those requirements are structured.

This is me speaking as a reformed ex-accreditation body manager. My previous position at NIST was the Chief of the National Voluntary Laboratory Accreditation Program. Most of my career was in laboratory accreditation. A whole lot of the previous version of the standard involved you shall have a policy, a procedure, and instructions, and that makes for really good checkboxes on a checklist. Did they have a policy? Yup. Did they have a procedure? Yup. Did they have instructions? Yup, yup, yup.

We've moved away from that level of prescriptive requirements hopefully. So the detail of the documentation is still important, but the way the assessment process works, ideally, and this was the discussion in the working group, should be focused on the competence of the laboratory. And then you look at the documentation at how it supports the consistent operation of the laboratory, one of the objectives in the scope of the standard.

Another challenge that we had was the use of the standard in different areas related to laboratories. So we have a new term that's used throughout the standard, "laboratory activities." And that's wrapped up in how we defined the scope of the standard with

respect to what a laboratory is.

So I'm taking right from the standard. This is the definition that we included for a laboratory, and it's "a body that performs one or more of the following activities: testing, calibration, or sampling associated with subsequent testing or calibration." Now, the reason I bring it up here is twofold. One is that it made it a lot easier through the course of the standard -- if you are familiar with the old version, it said a lot of times "for testing or calibration." And in some places, it said "testing only," some places it said "calibration only," and then there was this weird clause on sampling and the sprinkling of sampling throughout the document.

What this has allowed us to do is use the term "laboratory activities" for any requirements that would apply regardless of the activities being performed. If you think about it, personnel have to be competent whether they're doing any of those three things. The records that you keep may be different, but the way that you manage that process would be the same regardless of the activity. So this is just a little insight into the use of that term "laboratory activities" throughout the standard.

So, again, what this means, ideally, if sampling is involved in what the laboratory does, it's easier for that laboratory to recognize any time it says laboratory activities and we choose to include sampling in our scope, I have to meet that requirement for the sampling.

This is anecdotal, but I'm guessing this will be the case. The whole impetus behind this change to the standard, or a big part of it, was that the previous version of the standard had already been used by some accreditation bodies to accredit organizations that just do sampling. The term that gets thrown around is "standalone sampling." With that already happening, we felt it was important to clarify how that's done. It facilitates that process, then, of recognizing organizations for accrediting organizations for their competence in performing sampling.

I'm going to jump right into the hard stuff now. Risks and opportunities: As I mentioned before, the term that we use is "risk-based thinking." I should have done this, too. Any ISO 9000 readers/users, 9001, I should say? That's fascinating to me. For those of you in the front, like hardly anybody raised their hands. Okay. Wow. That means I can almost lie about that one, I guess.

But we brought the language from the revision of 9001 into 17025, and it is specifically risk-based thinking with respect to the laboratory itself. We are not, the standard does not incorporate a requirement for the laboratories themselves to implement a risk management system process. And one of the examples we use is ISO 31000. Obviously, there are other documents that mean more to some of you in this industry, but the key here is that the intent is to require the laboratories to plan and implement actions to address risks and opportunities associated with the laboratory activities -- just had the definition -- when they're testing something, when they are calibrating something, or when they're sampling something, when the laboratory does that stuff. It has nothing to do with looking at the risks associated with the devices the laboratory is testing.

With that being said, the standard is pretty open in that it's left to the laboratory to decide which risks and opportunities need to be addressed. There's always a "but." There are some exceptions. There are a couple of clauses in the standard where there's less flexibility. There are areas where the standard, in order to be consistent with some other standards, requires the laboratory to look at risks particularly with respect to impartiality and with respect to statements of conformity. And I'm going to get to those in a minute.

So what's this mean? In all of the talk around the revision to the standard, this is one of the big ones that people are worried about. This is a big change. But if you think about it, laboratories have always had to deal with risk. There are risks associated with the operation and the functioning of a laboratory at many levels. The previous version of the

standard had requirements that implicitly helped the laboratory mitigate those risks. The laboratory has always had to have a system in place to determine how frequently devices in its lab get calibrated. That's dealing with the risk associated with their equipment falling out of calibration. That's not new. And if a laboratory meets those relevant requirements in the revised standard, again, I'm not an accreditor anymore, but I would think that that's a very good way of demonstrating that they have addressed that particular risk.

So from my perspective, there should be little change in the practice in the laboratories. So that's sort of a "let's all take a breath and relax" kind of message that for the laboratories, anyway, they've been doing this all along.

And I'll underscore this again. There was no intent in the drafting of the standard that any consideration of risk in the context of 17025 went beyond the laboratory's own internal risk-based thinking. The competency associated with looking at someone else's risk management or how they assessed risk for a given device, totally out of scope. So just to be clear in terms of the perspective of what's in the standard. Now, how you build a scheme around dealing with medical devices, where that is a critical element of the process, that's why we're all here, right, to figure that out. But 17025, when it talks about risk, totally inward for the laboratory.

The other change to the standard, which, again, wasn't much of a change other than terminology, has to do with the concept of statements of conformity. The previous version of the standard always had requirements in the clause on test reports and calibration certificates where it allowed laboratories to make a statement of pass/fail or in or out of specification. What we've done in the revision of the standard is expand how the laboratory deals with that.

So we made up another term that's used in other ISO and other documents. The term is decision rule, which describes how measurement uncertainty is accounted for when

stating conformity with a specified requirement. Now, the experts in the room on the previous version of the standard, there are some of those words you've always looked at. In the previous version, if a laboratory were stating pass/fail or in or out of specification, what did the standard say? It said the laboratory shall take uncertainty into account.

So from a practical perspective, this isn't anything new, but it's allowing for clearer definition of what that means. So when you've got a specification, it's really easy if you're clearly in the middle of the range or if you're clearly out of the range. Where things get squirrely is right up against the specification limit, and that's where measurement uncertainty needs to be taken into account.

And in the working group, we felt that it was a really bad idea to do that at the test report stage. So we put explicit requirements in to deal with how that uncertainty is characterized and dealt with in these statements of conformity at contract review before the laboratory undertakes the work.

This is another place where risk comes in, and this is the one element of risk in the standard that's actually more quantitative. There are ways to calculate how the decisions are made with respect to conformity with a specification. You can quantify the probabilities of false accept or false reject. And so that's part of the documentation of the decision rule.

So what's this mean? Clearly, in the standard, it always has been and still continues to be a statement of conformity with respect to an individual result or set of results and only for the individual item tested or calibrated. To say it as bluntly as possible, for those of you that are up to speed in the ISO 17000 definitions around conformity assessment, this is not an attestation. This is a laboratory making ideally, based on the decision rule, a quantitative decision. Here is the number, here is the range; we are going to say it's in or out of that range. This is not a certification decision on the item tested or calibrated.

So what I'll say, what this means here is -- Scott made the point, and I think it will be

emphasized through the course of the 2 days and as the pilot goes on -- terminology is really important. So if we are going to go down a path where under the ASCA scheme a laboratory may be making those kinds of statements of conformity as intended under 17025, that that's distinct and clear from any attestation with respect to the device overall. That kind of conformity assessment process is outside the scope of 17025. There are standards for it. This just isn't the one.

Finally, the end of the standard has the requirements that used to be at the beginning. So it used to be clause 4 was the management system, and clause 5 were the technical requirements. The new standard has 4, 5, 6, 7, which includes all the technical stuff, and the management systems are clause 8.

When we talk about flexibility, this is the ultimate in flexibility because the laboratory is given options, two equally valid options, for establishing their management system. That's option A. If you look at that, if you're a quick counter, there are eight requirements there. Most of them look a whole lot like what was in clause 4 of the previous version of the standard.

If you choose to conform with 17025, you do clauses 4 to 7, you do option A, and you're good to go. However, there is a recognition that there is another standard that was built as a set of management system requirements. So option B allows the laboratory to establish and maintain their management system in accordance with the requirements of ISO 9001 as long as it is capable of supporting and demonstrating that the rest of 17025 is met. Two options.

If you look at these requirements, what does this mean? Again, flexibility. If you're a laboratory that's part of a larger manufacturing organization, this may allow you to leverage the management system at that corporate level provided you have done what's necessary to demonstrate the management system as applied in the laboratory supports

the consistent operation and the conformity with clauses 4 to 7. That's the key. If you're not using that management system in a way that supports how the laboratory meets those other clauses, then option B is not an option, or at least you would need to do more work to ensure that you're meeting the requirements.

Now, this last bullet I put it in here before you ask the questions and try and provoke a little discussion or thought. In other stakeholder groups, this level of flexibility is challenging, and so I think in the context of the discussion around ASCA, if there's questions around whether one option is better than the other, we need to work that out as well, because the standard means that they are equal options; a laboratory could choose either. And so as demonstrating their competence, we need to make sure that we understand what the assessment process would look like for those laboratories under the program.

Briefly, on the transition process, the standard was published right at the end of November of last year. The International Laboratory Accreditation Cooperation established a 3-year transition deadline, which means for the accreditation bodies, they have to have all of their laboratories accredited to the new standard by November of 2020. That means most of them, if they're not already assessing to the new standard, they will be very soon. And I think that's a good opportunity here because we can just jump right in and look at the new standard as being where we're going to start rather than trying to transition from the previous version.

Along the way, those accreditation documents that are issued as evidence of accreditation, so the scope and certificate of accreditation, will start referencing the new version of the standard. Transitions are always difficult, and so there's been a joint communiqué between ISO and ILAC that states that both versions during this transition period are equally valid. What that means in terms of the implementation of the pilot will be how quickly we get up to speed with laboratories being assessed and then which

standard they would be accredited to. But I think that's less of an important issue here. Just sharing it for information.

I'll close with a couple of pieces of information that Scott asked me to share. Again, part of our role is to make federal agency use of standards of conformity assessment as consistent as possible to reduce the possibility of complexity and redundancy. So we're right in the middle of the process of putting out two documents. One is a revision of our ABCs of Conformity Assessment, and that's sort of what the title implies, the basics around conformity assessment. The other document is intended to be considerations for federal agencies like the FDA or any other agency that's considering putting a conformity assessment program in place.

We've enjoyed a lot of interaction with industry, with the conformity assessment community, with other federal agencies, but we're still in the process of generating these documents, so feedback is still very much welcomed and needed. The timeline for this is that we hope to have drafts released -- we had drafts released in December of last year. We're in the process of analyzing those comments, and we're targeting publication for the beginning of the next fiscal year, government fiscal year, so that would be October.

We have a lot of work to do. There's a lot of really good comments for us to revise and change things. So if you are interested in having input into these documents, please find me or preferably find Amy Phelps because she's engaged in the revision of these documents.

Scott, I think we have a couple of minutes for questions, but if not, thank you very much.

Any questions?

UNIDENTIFIED SPEAKER: Here's your opportunity.

MS. GEORGE: Elisabeth George with Philips. Quick question: You talked about the

two options up there, of the option 2 being ISO 9000. What about a customer test lab that actually is, you know, our own test lab that might be under ISO 13485 system rather than the 9000, which is probably why nobody raised their hand because most of us are the 13485?

MR. MERKEL: I would say a couple of things. That would not, from the -- well, I'll take a step back. According to the standard, that wouldn't be a given. From an accreditation standpoint or in terms of demonstrating conformity with the standard, what I would say is the alignment of that standard with 9001 and the fact that not only for option B but specifically in option A, the requirements around key aspects of a management system were changed to match what's in 9001, which then should also match what's -- there are a number of other management system standards that laboratories or their companies may conform with.

And so I think both the alignment of the option A requirements as well as the relationship between 9001 and those other management systems should mean that it shouldn't be that difficult. There isn't going to be anything that you're seeing in option A that you're probably not already seeing in those other standards.

CAPT COLBURN: Yeah, partly in relation to this last question, the medical device working group at the IAF was -- we added a whole scope of -- for companies that wanted to get -- or organization types that wanted to get 13485 certified. One of them that came up was testing labs. Can they get 13485 certified? And we do allow for that in the IAF, but we also note that they really should be accredited to 17025.

I think when you ask the question about risk -- with medical device experience in 14971, the definition we use for risk, which I noted is correctly stated in our definitions that we received today, is a little different than that which we see in the 17025 environment, where you're dealing a lot more with uncertainties.

And I think the real focus here with the ASCA program, the way I see it anyway, is that when we go to a testing lab and we get something tested, we're going to be able to trust that that conformity assessment was done with a high level of confidence. And that means that those uncertainties that you're talking about are understood and out there on the table for us to look at. And, you know, from the dental perspective, we're not all that concerned about whether a ruler is, you know, a millimeter off. It's not the end of the world. But with more critical, life-saving products, of course, it is.

So having that all contained within the 17025 framework, having those uncertainties available to us to digest and then put into the context of a 14971 risk management process, that's really I think where I see the benefit of the ASCA program would be.

MR. MERKEL: Sure. I appreciate that. And I think just to build on that, those of you that have read 17025, it deals with all types of laboratories. And bridging the gap between what's in 17025, not just with respect to the management requirements but all the requirements, when taken along with the test methods or standards that will go on the scope of accreditation, filling that gap between the two, if necessary, is really what these scheme requirements would do. But it's critical again to get the input from all of the stakeholders here and an understanding of how 17025 would best be applied in a given technical area.

And hopefully with this revision of the standard, we now are up to date with the current lingo around conformity assessment and around standards more generally. And so aligning all of those different sets of requirements hopefully should be a little easier to do.

All right. Well, thanks. There's my contact information, and this has also been shared with Scott and will be made publicly available. So thank you very much.

(Applause.)

CAPT COLBURN: Thank you, Warren. I appreciate that.

All right. So we're going to transition now into some public -- so we had a few people that registered for public speaking. I've been informed that two of the three have shown up. So we will definitely start into that.

And I believe our first presentation is from Steven Margis, and he's representing IFIA, the International Federation of Inspection Agencies.

Steven?

MR. MARGIS: Thank you, Scott. I guess, first of all, I will tell you that I am not a medical expert. I'm a conformity assessment expert. At UL, I'm the Director of Conformity Assessment Programs. I also am the U.S. alternate to the Conformity Assessment Board at the IEC. So hopefully we can bring some conformity assessment expert -- to you.

I will say just briefly, as a personal note, as someone who's gone through a major procedure just a few years ago, thanks to the FDA and all of you in the room and all that you do for the medical society here in the United States to make sure that we take care of patients everywhere.

So with regards to IFIA, first of all, for those of you that are not familiar with IFIA, IFIA is a large, multinational organization that 63 members that are global and SMEs that are consisting of independent conformity assessment bodies. We've talked a lot today about 17025 and testing. What I'm going to share with you a little bit is about the fact that conformity assessment goes wider than just testing, and it's been alluded to a few times, and this would be an opportunity for us to speak to that briefly.

Within this larger organization of IFIA, we have a Medical Device Committee consisting of these seven organizations. And when the call for comments for the ASCA document came out, we provided comments. For those that would like to look at these comments a little bit more closely, they're available on the FDA website. But we wanted to take a moment to share with you some of our thoughts that we put in those comments to

hopefully elicit some thought from you as we go into the breakout sessions. We hope that they'll help stimulate some of the discussion in those sessions for an active and vibrant discussion.

So some thoughts from the conformity assessment side of the house as a stakeholder group with the proposed draft ASCA program. So some of the needs or some of the observations that we made that we'd like to bring forward are the need for clearly identifying incentives for manufacturers to participate. This was already alluded to earlier this morning. We believe that it's key and critical that if we're to have a vibrant program, for us to have an environment that encourages people to use the program, we're going to have to identify incentives. Those incentives may come through metrics, such as streamlining reviews, reducing cost. There are many different opportunities that are in front of us, but for it to be a successful program, we're going to have to itemize where those value propositions are to encourage and support the vibrancy of the program.

Second, develop and set clear accreditation parameters, in this case, to prevent a downward spiral of quality. An open-ended accreditation program often leads to people racing to the bottom. It was alluded to a moment ago by Warren about the fact that different requirements that come up will be defined by the scheme. And we support that. We believe that the scheme is critical in identifying what is the breadth of organizations that can perform the accreditation activities; what kind of competencies do they need?

In the old world of accreditation, you had 17025 and 17065 and 17020, and people had skill sets to those different criterias. The world as it's evolving is now recognizing that that's not enough. And many of those documents and one of the trends that's happening in CASCO is that those documents now refer to "as stated in the scheme." And that's a common theme and kind of language that you will see.

In this particular case, it's a perfect juncture because we're in the process of helping

contribute some feedback to the FDA to write where are those places that we need to define what is the scheme defining for the accreditor to look at; what type of skills and competencies does the accreditor need to have? And by doing that and identifying how many times the assessments will have to occur, how they will occur, by whom they will occur, we will be able to prevent this risk that is sometimes prevalent when it's not further defined. So that's a trend that will hopefully play to our favor as ASCA matures.

The next one, develop clear acceptance criteria for test laboratories. When we say test labs here in the context of the ASCA draft, I would offer for us to consider to step back from those words. We heard a wonderful presentation on 17025, and it talked about the strengths, but it also talked about some of the shortcomings when it comes to medical.

When we talk about risk management, when we talk about activities that sit outside the realm of test and testing operations, we need to consider what other solutions are out there, and CASCO has many. There are many different conformity assessment solutions. So while we're responding to the question about test laboratories, when we go into the breakout sessions, I would encourage everyone to consider -- take a step back from those words and look at the broader situation of conformity assessment and how could conformity assessment from customer laboratories to independent laboratories provide solutions that will get us to the ASCA objectives that were stated this morning.

In here, we talk about compliance judgments, elimination of the need for additional reviews for declarations of conformity. The terminology, as we said, is going to be key. The clarification of statement of conformity that was just made is a critical one in the overall process. And understanding what deliverables are being provided by whom, what level of independence do they provide, and what values do they provide to the overall process of ASCA to reduce times or reduce cost to create values for the service are critical.

Moving on to the next one, as additional standards are considered for recognition,

what are the competence requirements? How will they be considered? In some cases, we have to recognize that all accreditation bodies do not have full technical competencies. In many cases, accreditation bodies are fantastic and are very strong in their pursuits of understanding and portraying quality principles and how organizations operate. They don't always have the capabilities or competencies to have the technical side of it covered. So, as a result, there has to be some consideration for when accreditation bodies are used, when new standards are introduced, how will those conformity assessment interests be addressed or covered.

Standardized report formats: We've heard from many different portrayals along the process so far in the journey of ASCA about different kinds of reports that we're seeing. We're seeing descriptive reports. We're seeing tabular type format reports. We're seeing reports that have selection processes for how you identify a conclusion, pass/fail, not applicable, maturity levels, whatever the conclusion may be. But because they're being portrayed and introduced in so many different ways, it provides a lot of challenges for the reviewers that get these myriad of documents. So one thing that we've proposed and we consider is that the need for standardized reports can provide value to all of us in the process.

As I said, I sit on the IEC Conformity Assessment Board, and within the world of IEC conformity assessment, there are certain types of test reports called TRFs, test report formats, that are used. They may or may not be the perfect solution for ASCA, but they provide an example or a case study, many of which exist across the globe, that we can look at the pros and cons of and hopefully find one or a myriad of them that together can be joined to make a solution that works for ASCA.

Establish peer review requirements: With a myriad of conformity assessment providers, we want to make sure there's some level of base understanding and knowledge

on requirements. This can be done through things such as lab comparison programs, proficiency testing programs. There are many different approaches to it. When we go outside of the testing environment and talk about risk, there are case studies that exist, again, in IEC conformity assessment about task forces who speak and talk about risk management and how risk management is applied and in what ways it can be documented and shared so that the appropriate communications and deliverables support the kinds of decisions that are being proposed.

For each standard, set clear expectations for evaluations. There's a word there that most people might gloss over, "evaluations." Evaluation is a little different than testing. As we heard a moment ago, the act of testing, the act of performing that laboratory exercise of performing the test in a particular way to get a repeatable result, that test sits in a bigger world of conformity assessment where you have to determine if the test is appropriate; you have to determine if the test is applicable. And evaluation is stepping back and looking at the overall requirements that may exist and determining which ones will apply in the interest of creating a deliverable that may go beyond just a test report, without throwing additional terminology in for the moment.

And then, finally, provide clarity in cases where new technology is introduced. When we talk about new technology, I'll lump it together with just a general statement on standards management. As new standards introduced, are the new editions appropriate for regulatory use? That's already been stated. When we talk about a standard, what about the normative references that exist in a standard? If a standard is a particular and it references collaterals or it references base standards, do they by virtue get accepted and adopted into the overall pool of standards that we're talking about?

It's not a simple situation. It's a challenge. And it will have to be looked at case by case, of course. But certainly when standards management is being considered, you have

to consider not only the core standards you're looking at but the related normative references, and we have to decide when we're talking about standards, are we looking at national adoptions or are we talking about international-based standards as they're written in an IEC format or some other format?

So these are all considerations that were brought up in the comments to the ASCA proposal. We ask that everyone consider some of these when we're looking to help to work together towards a solution that will meet the objectives of ASCA.

And I thank the FDA for the time.

(Applause.)

MR. MARGIS: Scott is asking if anyone has any questions, we could take a question or two. Is the question is everyone hungry?

(Laughter.)

MR. MARGIS: We have a question. Yes?

DR. RAGHEB: Kind of a simple question perhaps -- Tony Ragheb from Cook -- this word "standard format for reporting" has been mentioned. Now, I can remember a time when I used to have to do thesis format approval to get a doctoral thesis through. And they lay the template on the page, and they wanted to make sure the margins were in a certain place, the page number was in a certain place. They'd lay a template over your table of contents. That was format. It didn't matter at all what you had written in there. You could have the content from somebody else's thesis when you went to get format approval. I don't think that's what you're talking about when you say report format, but could you give us a little more flavor for what you are talking about, please?

MR. MARGIS: Yeah, that's a very good question. I would say it goes beyond your statement on structure, and it's more framework, if I could change the word slightly, in that the structure of the document is important for a reviewer because it's important for the

repetition and for the timeliness of the review to make sure that the types of materials that you need are available. But as far as layout and structure, we're not just talking about columns and putting content in particular boxes. We're talking about is there a common harmonized way of reflecting results, are we reflecting critical data? If there's critical data to be reported, is there in the format a way to say that for a particular clause here are the two or three minimum elements that I need to be able to make an assessment or a judgment? Those types of things go on beyond just the structure into the framework of not only what does the document look like but what materials are critical to the reporting within that document.

Within a medical space, clearly this is a lot different than it has been in the old days for a vacuum cleaner or a refrigerator, where you have very simple data and your files or your dossiers are very compact to user manuals and some drawings and schematics. In your case, when you have so much supporting requirements and evidence, there has to be the core document for the assessment analysis, and then there has to be a method or a mechanism for the supporting evidence.

So hopefully that helps answer that question.

Scott, I think you had another presenter?

Thank you.

(Applause.)

CAPT COLBURN: Thank you, Steve. Yes, we have one more presenter.

Grant?

Grant Ramaley we've heard ask a few questions. He also asked if he could provide some public remarks, and again, we thought these would be great to get us going and start thinking at these different levels and areas of discussion before we go into breakout.

So introduce Grant. I surprise you? You're thinking it was later? Surprise.

MR. RAMALEY: Yeah, this is a little surprise actually. I submitted this last minute, and I wasn't sure whether it was going to get on the table.

But I'm Grant Ramaley and also work with the Dental Trade Alliance. And they are active members of the International Accreditation Forum. We work with ILAC as well and participate in some of the international organizations, harmonization convergence activities.

One of the statements that you see here, "Certified once, accepted everywhere," is kind of the goal of the whole thing.

So originally I created this for a U.S. Department of Commerce presentation on accreditation to kind of look at the two largest, I would say, technical mutual recognition agreements on earth. I hope these -- slide animations are not really working, but ILAC actually is involved in accrediting about 60 -- well, this is outdated -- so 52,000 left. Now it's up to 68,000 labs, and they are currently about 8,000 inspection bodies that are accredited under the ILAC MRA. And NVLAP, which is part of NIST, is signatory to that arrangement, so we're quite pleased that the U.S. DOC is involved in that.

So we'll see how all these animations go. They're not looking that pretty but -- so one of the ways that, of course, that we are -- one of the goals here is that when we're going to get a product tested, we're going to all use a testing lab, and we of course use them for all kinds of regulatory submissions for U.S. FDA. We use them in the ASEAN MDD, CE marking, that sort of thing.

So how can regulators and industry trust that testing was done right? And this is really -- I'm really proud of what Scott is doing here. I mean, and honestly, when we worked on doing the international accreditation program for 13485, it took us about 5 years to get it done. Anytime you work with an organization as big as ILAC or IAF, you're working with as many as 100 different stakeholders from every single continent, and there's a lot of

give and take, a lot of balloting, a lot of work that goes into that.

But simply put, and many of you already know this if you are having your products tested, you go to a testing lab, and you have an EMC test. The question is, is that testing lab a member of the ILAC MRA? And so this is just one of the things that I tried to educate different companies about, is if you're going to use a testing lab, check the ILAC MRA and see if that testing lab has an accreditation certificate. If they have an accreditation certificate, that means that that test report that you're going to get is going to be attached to the ILAC MRA.

So as you can see here, this is A2LA. This is an accreditation certificate to this keystone compliance, which is an EMC lab. So that would be a good lab, one of the many that you could go to.

So these are also different -- I want to go back here. These are countries that are backing the IAF 13485 program. We had some really good news this last April, that the Inter-American Accreditation Cooperation signed the IAF MLA for the sub-scope of 13485. So Latin America and the United States and Canada are all members of IAAC. So if you have a 13485 certificate that can get an IAF mark on it, that will be recognized by the other countries. I have some of these brochures for the program.

And the other thing is, is the European Accreditation Cooperation which covers about 30 different countries, including the EU, they're -- they just signed the IAF MLA for the sub-scope of 13485 as well.

So, anyway, if you're not familiar with IAF or ILAC and the two largest trade agreements that they have, just come and ask me some -- go onto their websites and check. The goal now since there is -- there are signatories of IAF MLA for 13485, you should be asking your CB if you can get the IAF MLA mark on your certificate, that you heard that the accreditation bodies are able to support that now. And so we expect to see that happening.

That's going to be the currency that a lot of the regulators are being encouraged to accept.

The Saudi FDA recently spoke to me and said that that's the only 13485 certificate that they're willing to accept, and the Therapeutic Goods Administration has already posted on their website that they will accept IAF MLA marked 13485 certificates. So, again, it's taking advantage of that certified once, accepted everywhere.

And it's all about accreditation, what's underwriting all of those certification activities. And I'm really proud of the work that the ILAC has done and IAF has done, and the more we can get regulators to work through that process, the better.

Thank you.

(Applause.)

UNIDENTIFIED SPEAKER: Any questions?

MS. STERLING: Thanks. Joan Sterling with Intertek. So as an organization with many accreditations, as most of the laboratories and cert bodies in the room are, we all know that all accreditation bodies are not created equal. So from our perspective, we really encourage the FDA to make sure they know who they're choosing as their accreditation bodies as being qualified on the standard, not only the standards but also the necessary regulations.

So while this is a nice group of organizations that theoretically can help test labs and cert bodies help their clients gain market access, the real key for us is that the regulator, if they're not going to do accreditation directly, is careful in who they select to make sure that they're competent to accredit to the needs for the FDA in this program.

MR. RAMALEY: Yes. And, again, what I was commenting to Scott, the amount of work that went into the IAF program, we had four notified bodies. We had regulators from Europe. We even had Jan Wilson (ph.), I think, from FDA participated. So we developed the competency requirements. And to be honest, we tried to keep it level with what the

regulators were requiring, but they were a little bit tough for some of the accreditation bodies to live up to.

And, in fact, the program was published in 2012. And when it went into effect, there were some immediate results. There were 9001 auditors that were being used for 13485 audits, and they were immediately told you can't do that anymore. But all the way up through the accreditation body structure -- right now we have ANSI or ANAB is participating in the IAF MLA for 13485. I've met their accreditation assessor, a very sharp woman with experience in medical devices.

That's the direction that things go when you establish criteria like this. It may take a while to get everyone's competency levels up to that point, but for manufacturers, what you can do is you can find a CB that is accredited by ANAB, and then you know that you're going to be getting a better accreditation assessment. For example, Intertek, someone who has got the competency skills to be able to accredit them under that program.

So, yes, that's absolutely true. A lot of accreditation bodies will not be offering this support for the IAF program for 13485 because they don't have the competencies yet. But some of them will, and it's just up to the manufacturers to find out which ones are supporting it.

(Applause.)

CAPT COLBURN: I'm not going to show that slide yet because then people will start leaving the room before I'm done.

So just a couple more things. So this, you know, will conclude the morning session. But to help us prepare for the afternoon, this is when we start breaking out. And I have no clue where people are intending to go. And our facilitators would like to know a little bit is there someone that's going to show up to my room.

So just real quick as a show of hands, just so we get an idea to make sure we have

the right rooms for the right sessions, for those who are intending to go to the biocompatibility session, which will be in the breakout room A behind you, could you just give a show of hands.

All right. Good. So we know there's more than just FDA people there. That's good, right, Jen? That's great.

And then for the 601 main plenary, which will maintain itself in this room, I'm assuming the rest of those will be in that session. But after the afternoon break, we're going to break out further into the specific standards.

So I wanted to get a quick look to see who's intending to attend the 1-8 alarms session. Some hands. We knew that would be a smaller group, but that's good.

All right. And then the EMC 1-2 group? A few more. We figured a few more for that.

And then, boy, how many are left for the -1 left? All right. So we have enough. And that will maintain itself in this room.

And we'll give for those that'll be breaking out after lunch the directions of where those rooms will be for the 601 group.

So we will then transition. I want to thank everyone who presented already. Warren, I know you have to leave, so I want to thank everyone and our public presenters as well as those who participated in asking questions.

When we go off for lunch, I want us to -- and actually, I'm going to kind of click back to slide 64 and 65. Steve, you did a beautiful job in a section here. And I think the recommendations that you wrote here are things that we should be taking into perspective as we work into our breakout sessions to try to look at how can we build the program.

We're going to be speaking more on the technical tongue as we relate to the standards, but the purposes of what we build in the program and the scope, I think these

are some of the things we should be looking to drive, you know? How can we develop and set clear accreditation parameters? What are the incentives for manufacturers? What are the incentives for accreditation bodies and testing laboratories and all the other organizations here as well, because if there is no incentive, no one is going to come. And then I will be submitting my résumé to get a job somewhere else.

And so we want to make sure that we're also making this work. How does it work for everyone? And the FDA, of course, is a stakeholder in this.

So I want us to -- you know, these were I thought very nice slides that kind of put this back in the picture what we were talking about a year and a half or so ago when Amy was saying, well, it's all nice and dandy, but someone's going to have to want to do this, Scott. And so we wanted to, you know, find some ways. And she assured me, and I'm going to use her term, that there was oodles of examples of ways that we can do this. And know that's why with the people here we can build this out.

So these were very important. I want to thank, you know, Steve for kind of outlining these in the comments, bringing that perspective forward.

So we do have lunch. I was told it will be here by 12:05-ish. I'm hoping they got here early. So those who ordered box lunches, if it's not here, it'll be here shortly.

We'll go ahead and break until 1 p.m. And then for those who were -- you know, we'll start off -- anyone dealing with 601, we'll hold a plenary here. Biocompatibility will be in the room behind us. For those who are online, we do have specific Adobe Connect for biocompatibility that is different than the one who -- if you're listening to me now. And then after the afternoon breakout or afternoon break, we'll be breaking out further, and those two rooms for EMC and alarms have WebEx meetings associated to those.

So for even our colleagues here, if you have someone who you think might want to listen in, the information for all that is on the main agenda website, and you can be able to

dial into those.

There are chatrooms that are associated, where people who are listening in can submit a question, but those chatrooms aren't designed for ask a question, get an answer type chatroom, but we are looking at these, and we're trying to see where they would fit in appropriately and maybe help drive some of the conversations. So we do have staff that will be monitoring each of the breakout sessions to try to help collaborate that in to make sure we're capturing something, because there's a lot of expertise who's here virtually that we do want to take into account.

So, with that, are there any questions? Heck no, it's lunchtime, right?

(No response.)

CAPT COLBURN: All right. Well, thank you very much, and we'll see you in your rooms at 1 p.m.

(Applause.)

(Whereupon, a luncheon recess was taken at 12:03 p.m.)

(Breakout sessions.)

(On the record at 4:37 p.m.)

CAPT COLBURN: Hello, everyone. So real quick here, what we're going to do, we're not going to come back and have a summary right now. A lot of the separate groups are still having really good discussions. We're starting to discuss now and work -- you know, in the alarms group, they're starting to talk from the lab perspectives, like how are they being assessed to 17025 in that specific environment, and they're going in through some discussions. I know EMC had a number of really great topics.

So we're going to go ahead and break for this day from this group and reconvene back into breakout sessions, in the three separate sessions for 601 tomorrow morning from 9 to 11, and then we'll come back and do a summary. Sound good? Or whatever the

agenda says there.

So thank you very much. I want to just put my appreciation out to everyone who's been participating, and you know, I'll be around for a little while if we still have some questions. We still have I think a lot for tomorrow to discussion. So thank you very much.

(Whereupon, at 4:38 p.m., the meeting was continued, to resume the next day, May 23, 2018, at 9:00 a.m.)

C E R T I F I C A T E

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

PUBLIC WORKSHOP -

ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA) PILOT

PLENARY SESSION

May 22, 2018

Silver Spring, Maryland

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.

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SHAYLAH LYNN BURRILL

Official Reporter