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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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PUBLIC WORKSHOP – APPROPRIATE USE OF CONSENSUS STANDARDS

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M E E T I N G

(1:00 p.m.)

MR. COLBURN: Hello, and welcome to the Appropriate Use of Consensus Standards Public Workshop. My name is Scott Colburn and I'm the Director of the Standards and Conformity Assessment Program, or SCAP at FDA. I'm joined here today by Dr. Terry Woods, whom I'm sure many of you already know and who serves as SCAP's Chief Engineer.

I'd like to thank all of you for joining us today, as we discuss how FDA can make use of the consensus standards in device submissions easier and more efficient. Before we begin, there are a couple of housekeeping items we need to address. First, please keep your microphone on mute unless you are speaking, which we will permit and encourage later in the program.

Second, we ask that if you wish to speak, please use the "raise your hand" function. That way we can call on you and your microphone can be unmuted. Finally, if you prefer not to speak but still have a question, or something to contribute, you may use the Q&A button. Note that the chat button is disabled for this workshop. If you want to comment or submit a question in writing, you must use the Q&A button. I'll remind you of those options -- excuse me. I'll remind you of those options again later in the workshop.

Whichever method of communication you choose, please know that we welcome your input. This event is called a workshop because we hope and expect to hear your thoughts and responses to today's working questions.

We have 2 hours today to address the workshop overarching goal, soliciting input on how FDA can enhance the use of standards in device submissions, and how ultimately we

can improve the appropriate use of voluntary consensus standards in premarket submissions for medical device guidance, a long handle for an important foundational guidance that we affectionately refer to as the Appropriate Use Guidance.

The agenda will proceed as follows. Terry will first share the background presentation with us, after which we'll turn to three working questions designed to obtain feedback from you. These questions are: How can the FDA advance the use of declarations of conformity to FDA-recognized standards; two, how can the FDA make it easier for medical device submitters to include the correct supplemental documentation for the standards they cite, and three, what tools and resources do medical device submitters need to encourage the appropriate use of FDA-recognized standards in their medical device submissions?

I plan to conclude the workshop after we address the working questions. Now I'll turn it over to Terry, who will walk us through some background information to prepare us to discuss our working questions later in the workshop.

Terry.

DR. WOODS: Thanks, Scott, and good afternoon, everyone. I'd like to begin by sharing SCAP's vision and mission. Our vision is as follows. The Standards and Conformity Assessment Program leads the medical device community in the enhancement and use of consensus standards in the design, development and evaluation of health technologies across their lifespans. SCAP solves problems, and anticipates opportunities to protect and promote public health through the use of high-quality, regulatory-ready consensus standards. As I will share with you in the following slides, all our work at SCAP is centered

on advancing both the quality and the use of consensus standards.

Next slide.

SCAP's mission describes how we support our vision. SCAP drives the development, recognition and appropriate use of regulatory-ready standards for medical devices throughout their lifecycles. We produce and implement clear policies and programs to optimize the appropriate use of standards in regulatory processes. We anticipate the need for, and lead the development of national and international consensus standards, and advance initiatives to enhance confidence in conformity assessment activities.

Our work fosters innovation and standardization in technologies that provide platforms for regulatory science to meet novel challenges, and we provide leadership and outreach in global harmonizations. Finally, SCAP serves as a resource for FDA staff, industry, other regulatory authorities and standards development organizations. What this mission means is that SCAP takes a total product lifecycle approach to standards. We work to promote standards, their quality and their use. In our next slide, you'll see that we've organized ourselves to do just that.

Next slide, please.

SCAP has three key main functions, depicted here across the total standards lifecycle: Standards development, standards recognition, and conformity assessment. We have 16 SCAP staff, and are able to tap into the expertise of hundreds of volunteer standards liaisons across FDA, to drive these three functions. SCAP itself is run like a standards development organization, with transparency and precision, and with an eye always toward anticipating future medical device needs.

Our overarching goal is to encourage the development and use of high-quality standards that are fit for regulatory use. Let's first look at standards development. FDA believes that contributions from regulatory authorities to standards developments are critically important to promote individual and public health. Building regulatory needs into standards means they will be more useful, for manufacturers as well as for us.

SCAP manages about 400 center staff, who in addition to their day jobs, whether that's device evaluation, postmarket analysis or regulatory research, participate in more than 600 standards development organization technical committees, subcommittees and working groups. Sometimes, we're the only regulator at the table.

A key component in this standards development work is our Specialty Task Groups, or STGs. STGs align with our regulated device areas, from horizontal aspects like quality systems and risk management, to the vertical or specific device areas, such as cardiology, orthopedics and radiology. STG members are experts in regulatory policy, engineering, medicine and science, from different offices across FDA.

The STGs serve as internal advisory committees to SCAP. Our STGs use the consensus process throughout the lifecycle of standards, from identifying the need for a new standard all the way through standards development or revision, and finally, formal recognition.

Now let's talk about our Standards Recognition Program. The term recognition refers to the mechanism by which FDA identifies a published standard to which device manufacturers may declare conformance in order to meet a relevant requirement. It is a formal, rigorous and transparent process that I'll discuss in greater detail in the next few

slides. The important thing to take away from this introduction to our recognition program is that if a manufacturer declares conformity to a recognized standard, the amount of supplemental documentation used for the device submission goes way down. More on that in a moment also.

Currently, we recognize more than 1,400 standards, a number that increases by 5 to 10% every year. An internal standards utilization study demonstrated that an average of seven standards are cited in each 510(k) submission. And finally, on to conformity assessment. Once standards are recognized, now what? We need to put recognized standards to work, which leads to another important element of our total standards lifecycle, conformity assessment.

A key priority of our conformity assessment work is to promote the use of declarations of conformity in device submissions. And we have implemented a new program, the Accreditation Scheme for Conformity Assessment, or ASCA to do just that. We won't have time to discuss it in great depth today, but its goals are to enhance confidence in medical device testing, promote consistency and predictability in premarket review, encourage effective use of FDA resources, and support international harmonization. We encourage you to visit the ASCA web pages to learn more about how ASCA can streamline the conformity assessment aspects of device review. We'll share the links later in this presentation.

Next slide, please.

I promised you more information on our recognition program, so here goes. You can find this information and more on the SCAP web page, and in the guidance entitled,

"Recognition and Withdrawal of Voluntary Consensus Standards." As I mentioned on the previous slide, recognition is FDA's formal identification of a standard to which it is appropriate for device manufacturers to declare conformance, in order to satisfy part of a postmarket review requirement.

Now, our Standards Recognition Program is a central part of what we do. And to repeat, we run the recognition program like an SDO runs standards development, in an open, inclusive, and transparent manner. Why do we recognize certain consensus standards in the first place? Well, it signals to product developers that FDA considers the standard to be appropriate for use.

If a manufacturer elects to conform to one or more recognized standards to meet a premarket review requirement, they can submit a declaration of conformity in their submission, which generally reduces the amount of documentation that will be required. This should help streamline the conformity assessment elements of the device review. We'll talk more about declarations of conformity in a bit, but I wanted to introduce them and their advantages here.

Before I go into how FDA staff approach recognition decision making, note that we can recognize all or only part of a standard. And since we are committed to transparency, we publish our reasoning or rationale for each decision. These decisions can be found in our Recognized Consensus Standards Database, which is available to everyone. There is also a database for standards we specifically choose not to recognize. And finally, we keep an eye on standards and revisions through the standards development work I talked about earlier. That way we know when to update our recognition database, or even withdraw

standards that are no longer suitable for recognition.

Next slide, please.

Here's how the recognition decision-making process proceeds. First, someone submits a request for recognition. This can be anyone, inside or outside the FDA. We acknowledge the request with a formal communication and convene the appropriate specialty task group, which is the group of experts I mentioned before, to formally review the standard and make a recommendation to SCAP.

SCAP then decides whether to recognize the standard or not. If we do recognize it, we'll state the extent of our recognition. In other words, will we recognize the complete standard, or only part of it? Finally, we will add the standard to the Recognized Consensus Standards Database, when the next update is published, which is typically twice a year. We include the scientific, technical, regulatory or other basis for our decision. Currently, we use the *Federal Register* list to inform the public about updates. At this moment, we're in the process of a second update cycle for this year, which will be List 59.

Next slide, please.

This is a screenshot of the landing page of our database. You can see it's searchable using several different criteria, including a standards development organization, a designation number, a recognition number, and the title or keywords. Above the Search box, there are links you can use to access the previously published FR lists as well.

Next slide. Previous slide, please. Previous slide. Let's see, can you go to slide 10, please? There we are.

You will also find other important information in the Recognized Consensus

Standards Database. For every standard we recognize, we publish what is called a Supplementary Information Sheet, or SIS, containing the information listed on this slide. The SIS is designed as a tool for stakeholders who may use and cite a recognized standard. I won't read all the elements listed here, but I will draw your attention to the last one, relevant guidance documents and other publications. It is extremely important that manufacturers consult these related documents to learn more about expectations for conformity with a standard.

Next slide.

Here, we have an example for ISO 4823, a dental standard. It includes the extent of recognition, in this case, it's a complete recognition, the rationale, examples of applicable product codes and additional information.

Next slide, please.

ANSI/AAMI HE75 for human factors is an example of a standard that has a partial recognition. It does not feature acceptance criteria or test methods, and so when citing this standard, manufacturers will need to submit complete test reports. More on what to submit shortly. But notice, in particular, that on this SIS, we direct users to consult a key guidance on usability testing.

Next slide.

All that being said, use of consensus standards is voluntary. FDA strongly recommends it, for all the reasons we just talked about, but their use by a manufacturer is voluntary, unless a standard is incorporated by reference into a regulation, which is a rare thing for medical devices. If a manufacturer wishes to demonstrate conformity to

expectations in other ways, that's up to them to decide. They will just need to justify their approach.

Now, standards may be cited in any type of submission, including PMA, 510(k) and others. And as we discussed, if a standard is recognized by FDA, a declaration of conformity may be used. But generally, use of a standard is also an option, with any standard, recognized or not. Just keep in mind that additional documentation will be needed.

Next slide.

So what is a declaration of conformity? A declaration of conformity is an attestation from the manufacturer that the device conforms to all the requirements of a standard. It confirms to FDA that all normative requirements have been met, that all testing has been conducted, and that those tests were performed on a finished or final finished device. If the submitter is declaring conformity to an FDA-recognized standard, a declaration of conformity should be included in the premarket submission. Using a declaration of conformity generally reduces the amount of supplemental documentation needed in a submission, which in turn supports a least-burdensome approach to regulatory review.

Next slide.

Before we turn to a discussion of when and what types of supplemental documentation may be needed, recall that use of recognized standards and the submission of a declaration of conformity are voluntary. That means manufacturers may also use other, non-recognized consensus standards under the General Use provision, as well as user-recognized standard without a declaration of conformity.

Also, in some cases, when deviations are made to the methodology in the standards,

a declaration of conformity may not be possible, so it will fall under general use. In these cases, since declarations of conformity are not submitted, complete test reports should be included as part of the submission. These reports will require review by FDA, which adds time to the review process.

Next slide, please.

Let's talk more about what we mean by supplemental documentation. Supplemental documentation is information needed to support a declaration of conformity. You can see here that it's pretty clear when supplement documentation will be needed, when neither test methods nor acceptance criteria are called out in the standard, and when a manufacturer has deviated from a standard. In these cases, FDA will want to see the complete test reports. And if a manufacturer decides to cite a non-recognized standard under general use, even more documentation will typically be needed, for example, the verification and validation of test methods in acceptance criteria.

Next slide.

This table, adapted from the current Appropriate Use of Voluntary Consensus Standards guidance document, outlines when and what sorts of supplemental documentation are needed when a standard is cited in a device submission. As you can see in the first scenario in the yellow box, sometimes a standard includes a test method, but no acceptance criteria. In those cases, a complete test report is not needed, but supplemental documentation should include the acceptance criteria the manufacturer tested to, and a summary of the results.

Next slide.

Our next scenario is the opposite case. A standard may include acceptance criteria but does not specify a test method. As in the previous case, a complete test report is not needed, but manufacturers should submit supplemental documentation about the test methods or protocols they chose, and why they chose them.

Next slide.

The third line in the table, outlined in red, is our worst-case scenario. Neither test methods nor acceptance criteria are included in the standard. For those standards, manufacturers need to submit the complete test report.

Next slide, please.

As you can see in our final scenario, outlined in green, when both test methods and acceptance criteria are called out in the standard, and manufacturers use and apply them as written, FDA doesn't need any supplemental documentation. This is the best-case scenario, as it can save manufacturers and FDA a significant amount of time. One caveat: Sometimes standards offer choices in test methods. When that's the case, manufacturers should let FDA know what they chose, and why.

Next slide, please.

In summary, when are complete test reports needed? It's simple: When a declaration of conformity is not submitted; when there are neither test methods nor acceptance criteria in the standard, and when the sponsor has made deviations or adaptations to the recognized standard.

And so with that, I'll turn it over to Scott, who will lead our discussion of our working questions. Thank you very much.

MR. COLBURN: Thank you, Terry, and thanks for doing the hard part of all of this for us.

It's time now to switch gears, hand the microphone over to you, our valued stakeholders. But before we do so, I see that we have two hands up, and we're going to take those questions from you before we go into our first question for the panel. So, I'm going to ask the group if they can get the question from, I believe it's Kathy Meddick (ph.). She's muted, now we can unmute you.

MS. MEDDICK: Hi there. I didn't actually submit a question.

MR. COLBURN: Oh, we had your hand up. Your hand must be very tired by now.

MS. MEDDICK: Oh, sorry about that.

MR. COLBURN: Okay. And I see the other hand went down right now, so that's all right. We just wanted to -- at least we know the system's working.

So, all right. What we'll do then, we're going to jump in. We have three questions to ask you today, and we really encourage you to share your thoughts with us in response. As a reminder, you have two ways you can speak up. First, you may raise your hand, just like we did, and we know that works, in the Zoom screen, and we'll recognize you, which you can be unmuted. Please know that when you do that, you may be showing up as broadcasting for this video.

Secondly, you may wish to click on the Q&A button and type in your question or comment, and we will be monitoring both. Again, we want to try to keep this as, you know, interactive as possible. So before -- let's go on to the next slide, then, and read our first question.

Question 1 is simple. Given how important declarations of conformity are to the appropriate use of recognized standard, how can we at the FDA encourage manufacturers to use them more often? Or, phrased in a different way, what are the obstacles that get in the way of submitting a declaration of conformity?

All right, I see we have one raised hand, Hevia Shaw (ph.). Can we bring that person in?

MS. SHAW: Hi. I have a question about what -- can you say that one more time? If a standard has acceptance criteria but not test method, what is required in supplemental documentation?

MR. COLBURN: So, all right. Well we can try to go back there and talk about, you said if there is a test method included but no acceptance criteria?

MS. SHAW: Actually, the other way. If the standard has an acceptance criteria but no test method, what is required in supplemental documentation?

MR. COLBURN: Yeah, so typically, and again, we're talking possibly about maybe a thousand different standards, so this would be a high-level general overview, but if you don't have the test method included but the standard has maybe called up the acceptance criteria to meet what the area that's being focused on, you would, you know, supply in your declaration of conformity -- what you're doing is you're not necessarily needing to justify the acceptance criteria, because that's included in the recognized standard. But we probably are going to need to see the methods or protocols, possibly, depending on the standard that you use to support how you came to the results in the, already in the standard portrayed. Does that make sense?

MS. SHAW: Okay. So just a test protocol, but the same acceptance criteria?

MR. COLBURN: Yeah. So you'd want to make sure you're at least discussing the method, maybe even adding in the protocols. And as always, you know, if this is something that would be newer, or a brand new standard, there's nothing wrong with ever trying to contact the review offices to try to get maybe a little bit more specificity, too, on what is the level of information.

Also note that, sometimes in our Supplementary Information Sheet, we also cite relevant other tools, such as guidance documents or other areas that may also help outline what's the type of information that would be able to support that declaration of conformity.

Speaking -- just kind of revisiting the topic of declaration of conformity and what we want to, you know, hear from our stakeholders here, a declaration of conformity is, in most simple terms, a communication tool. We have recognized a standard to which you may submit a declaration of conformity. When you communicate to us that you've utilized the standard via a declaration or attestation, in that way, you're communicating that you used the standard in accordance to how we've recognized that, whether it's a complete or partial recognition, whether we've cited please, you know, look at such-and-such guidance document, or even a specific area of a guidance document.

When utilizing a standard and calling it out towards a declaration of conformity, you're communicating to us that you're using it in the manner which we have tried to describe it through our recognition. And that helps us a little bit more in not needing to see every piece of data or information if you were just calling out the standard and citing it, or

calling it out in what's called general use, which Terry talked about earlier in her discussion.

So that, I just want to kind of put that in the most simple terms. And then based upon the construction of the standard, the chart that Terry shared that's also in the Appropriate Use Guidance gives a really high level overview of what may be necessary in that supplemental documentation to support your declaration of conformity.

MS. SHAW: Okay. And another question was, if a standard has acceptance criteria and test methods both, but the test method is not feasible for the device, so you go ahead and take the acceptance criteria but develop your own test method or protocol, would you declare that as a general use?

MR. COLBURN: Yeah. So that is more of a deviation, I guess, to a standard, that you have, you know, modified the standard and how it was recognized by putting in place your methods and stuff, which are not in the standard. So that way, you'd probably want to do more of a general use, and provide all of that information that would be supporting the document.

You could also try -- you know, that would be the most -- I think that would be the easiest way to communicate to the review team that, you know, you've modified the standard and had to replace, you know, the test methods, for whatever reason you would justify.

Terry, I'm also going to see if you would concur on that one --

DR. WOODS: Yeah.

MR. COLBURN: -- to see if that makes sense as well

DR. WOODS: Yeah, I think that makes sense. And I guess maybe with that, we can

move on to our first question and answer in the Q&A. Zachary asked, "Creating the pool of consensus standards is part of the process, but a number of them are actively being revised to address changes in safety information. This often leads to the FDA listing being out of date. What efforts are being made to maintain them to the current revision of consensus standards?"

Well, Zachary, so what we do there is again, we work with the SDOs to have the -- you know, to publish the most current version. There is a transition period for each of the recognized standards, so that you can reference the previous version and the current version.

The other thing is, this is all voluntary. And so, you can use a more current version of a standard if you -- you know, if there is a standard that's published before we've recognized it. Another thing that's happened to keep the recognition lists much more up-to-date is now, as soon as the standard appears in the recognition list on the website, you can start using that standard.

And so the *Federal Register* notice will come out somewhat later than that, but you can go ahead and start using it for declarations of conformity as soon as it shows up in the database. And again, you know, they come out two times a year. Someone else asked how often. There's a spring list and a fall list. And so roughly every six months, we update that with the newest versions of standards that are recognized. And I guess with that, we could go on to the next comment.

MR. COLBURN: Sure. Yeah, and we are looking at your feedback as well, not just questions but feedback on how we can advance the use of declarations of conformity from

our first question to the FDA-recognized standards. There is a comment from Allison (ph.), "Is there a template provided from FDA for a declaration of conformity?" And I'm going to try to hit this standpoint from two different levels. One, our Appropriate Use guidance talks about what's the information that would be provided in the base declaration, the seven or eight elements that are outlined in the Appropriate Use guidance are called out from the of ISO/IEC 17050-1, which is the main elements discussing what are the standard or standards all the way down to the supporting documentation of the signature from the responsible person.

The second part of that declaration of conformity is under ISO/IEC 17050-2, which is the supporting documentation that would support how you would, you know, advance that discussion on how you made the attestation of conformance to that standard. So those are the main areas that the appropriate use covers.

Now in our pilot program that we have for the Accreditation Scheme for Conformity Assessment, we took an opportunity to provide examples of what a declaration of conformity and the Summary Test Report that would accompany a declaration of conformity if you so choose to use a testing laboratory that is a part or has been granted *ASCA Accreditation.* With that, we provided examples to the series of standards that are included into the ASCA pilot program. And that provides the opportunity for us to see more consistent how the areas of the standard were tested, and how the discussions that we're looking to see as the minimum amount of information to support a declaration of conformity can help us make those determinations through the course of the review.

The thing of the ASCA program is that we have a connection with the conformity

assessment bodies to be able to work with them, provide education, learn from them on how they are testing, also working with the accreditation bodies to build a relationship, and with that, confidence in our understanding of how they test, which provides a little bit more assurance to how we look at the information that's contained in those reports.

Anything else you'd like to add on that one?

DR. WOODS: That pretty much covers it.

MR. COLBURN: All right, so I think we've hit the next one that says about updating the database two times a year. I guess we could say, in general we try to update those usually late June or early July, and then again probably coming up here in a few weeks, is when we'd aim to do that. There are certain circumstances too, where some standards come in that is of high priority to the Agency, and the leadership is asking we get those into the recognition database earlier. And those do also happen. And we try to announce that through channels, like *CDRH New* and others. So we do try to keep that.

The *Federal Register* notices are the thing that accompany later, but as Terry mentioned, we do have the ability to show our intent for recognition through the recognition database, and then follow it up through the *Federal Register* notice when that goes through that process.

Take the next one?

DR. WOODS: Sure. I guess there's a question about standards that aren't recognized by FDA. The companies use the standards, but does FDA recommend using them in the declaration of conformity in the premarket submission. Now, if a standard isn't recognized, you are perfectly free to use that in your testing and your device design development and in

your submission, but the declaration of conformity only works for recognized standards. So again, if it's not recognized, you're still free to use it, but you would not use that in a declaration of conformity.

MR. COLBURN: One of the advantages that Form 3514 provides, though, is right up front, the review team gets to see which standards are a part of the submission, and what is the method that you are utilizing those standards, whether it's towards a declaration of conformity, a declaration of conformity with, from the ASCA program, or in its general use. And as Terry mentioned, you can also put in standards that may not be recognized. And we do try to look at metrics from that from time to time to see, are we seeing a trend of standards that we have not recognized, that may make sense to do so in the future, based upon how members are using, but we have not yet received a formal request for recognition.

DR. WOODS: Right. And I guess, seeing the comment from Pam Martin (ph.), saying, "Add the supporting information required for the DOC into the Supplementary Information Sheet," that's precisely the kind of information we're trying to hear from you. You know, what is it that we can do to make it easier for you to use declarations of conformity. So again, thank you for adding that comment. We will definitely take that into consideration. And again, let us know, you know, what other things can we do to make it easier for you to use a declaration of conformity to recognize standards.

MR. COLBURN: Pam, I'll add on to that, for your comment there, you know, I think though, the pie in the sky is that every standard helps outline what a test report should look like. And so, I know we have standard developing organizations on the line. Our call to you

would be to work with your technical committees to try to make sure, do the standards lend themselves to a declaration of conformity, first and foremost, but secondly, is there a way that you could communicate how that test report would be appropriately constructed.

We know certain areas, like in the IECEE, there are test report forms developed, and certain other standards also have examples of what needs to be included in the test report. But the more that the standards development can do that, the easier I think it is, because we would want to ensure that how we would look at assessments of conformity in the test reports would be similar to how you would use them in other jurisdictions as well. And if it's built into the standard, it's a lot easier for that to take place, when we can recognize it in that form, versus taking the more arduous task of trying to build that into our own Supplementary Information Sheet.

And just a quick note about the Supplementary Information Sheet, the information that we put on there is pretty on a very high level, but it's not intended to be guidance. It's not a guidance document itself, otherwise they would go through a very long process for clearance. So there is a minimum amount of information that we can provide that would not already be contained within the standard, or something cited within an existing published document.

Go to the next one, maybe. I do see one here that I think is pertinent, before maybe we go to even the second question. It says, "Who should sign off on the declaration of conformity from a company? Does FDA have any suggestions or comments?" And that's a great question. We know, over the last couple of years, we have worked with a number of different organizations to try to have this discussion on, you know, who should sign it.

Really, from our standpoint, it's who's a responsible person at the company. I think it even outlines that, within the declaration of conformity information that's in our guidance document. That could be a number of different people, depending on how your company is set up. We know too, though, that there is some concern about signatures, and that's just something that we're continuing to try to advance with our policy as well as within our stakeholder community. So, if people do have questions or thoughts on this, this would be something we wouldn't mind hearing from.

Maybe we could open a live one. If you would --

DR. WOODS: I guess I see one more --

MR. COLBURN: Okay.

DR. WOODS: One more in the chat. "What can SDOs do to help expedite the recognition of standards? Any advice on new technology such as AI in getting acceptance by FDA?" And I guess Scott addressed that a little bit. But what we're hoping that the SDOs can do is, at the individual committee level, at the level of each individual document that you're working on, think about what information is needed for a declaration of conformity or for general use.

So, if you can, you know, beef up the information in the test reports, think about the information that needs to be included, either in a declaration of conformity or in general use of a standard, and add that. You know, I know the holy grail for test methods is acceptance criteria. And, you know, I've been in many discussions, trying to come up with acceptance criteria for specific standards, but anything the individual task groups can do to come up with acceptance criteria, or make it that much easier to minimize the amount of

information you have to submit to FDA. So again, it's the thinking about making standards regulatory ready, defining the test methods as well as you possibly can. Think of acceptance criteria. Come up with perhaps standard formats for your summary test results, or for your test reports. Those are things that, you know, every SDO and every specific working group for a document can do to help make standards more regulatory ready.

MR. COLBURN: Okay. Why don't we take a comment from the audience, then? If we could unmute Jamie (ph.), who I think is up at the top of the list.

JAMIE: Hi Scott and Terry. Can you hear me?

MR. COLBURN: Yes, we can, very well.

JAMIE: Okay, good. Well thank you so much for hosting this forum. I do have some thoughts, both about the question about DOC, and also what you said about updating the database also made me -- we had a thought about that was well, which I thought I would take this opportunity to mention, which is, as you note, right, although the primary updates are twice a year, you also do update throughout the year, for well, very important standards, right.

And given what both you and Terry were saying about the fact that the moment it appears in the database, that they then can be used, per FDA recognition, that it would be helpful, I have heard, to have that information pushed out to industry as soon as possible. So, and you mentioned using various forums, existing forums such as, you know, website and that kind of thing. But one of the ideas that was suggested to me, and I wanted to pass on to you was the idea that you could have a subscription, a subscriber type of email list, right. FDA has many of them, and they're sort of general ones for standards, right, but that

you could have a specific one where you would push out notifications any time, to this list that people would opt into any time that there was a potential, or there was a change, an addition of a standard or a change, right.

And important changes can be important too, of course, to the database. So that was just an idea I wanted to share, and then did have a response to your first question about DOCs, and opportunities for increasing use.

MR. COLBURN: Oh, thank you, Jamie. And I know we're always looking to find better ways to communicate when an update has been made, or a significant update's been made to the recognition database. And we do try to communicate that, you know, through a few channels that go outward. I think the hard thing is, I know the Agency's large, and it puts out lots of information, and things can get missed, and they get shuffled under maybe, you know, 24 hours of communications. But that is something we do want to continue to do.

I do like your idea of, you know, can we tie a subscription service towards, you know, the database somehow. And I think as, you know, FDA continues to go through enhancing its database shuffles or some of the capacity buildings that we could look into, so I appreciate that. You said you had another way of us looking at the declaration of conformity, so why don't you continue?

JAMIE: Yes. Well it's more sort of thoughts that have been generated about potential, right, just some potential maybe challenges to increasing use and, you know, just to get the discussion started and, you know, potential opportunities. Because I know you are very much always looking for ways to improve standards, given your deep commitment

and love of standards, which is originally --

MR. COLBURN: We call that being a stand nerd.

JAMIE: Oh my gosh, I'm totally feeling that one. Love it. So, in any case, what some of the things that have been mentioned is, and you denoted in your explanation, right, is that there are, you know, some quite a few restrictions to when you can actually use the DOC, right. And there isn't really a mechanism, or at least I've been told, to say, you know what, the standard -- we really don't believe the standard is applicable to our particular product, or there's some very specific reason, right.

So, that is a potential limitation. The other limitation is, there was a question about the signing of the form, that -- and you mentioned there are some concerns surrounding that form, right. I think that language of the attestation is viewed as quite prescriptive, right and, you know, there's not really as much of a caveat as you see in certain other ones, about to the best of your knowledge. And I think that's also potentially an issue as well.

The other thing that some people have mentioned to me and, you know, I assume that these are isolated incidents, but we have heard some reports of, is that even when there is a DOC, that there may be a request for the entire test report, and to examine the entire test report. And therefore, right, if there's a perception that even if you use a DOC, the entire test report will be requested, that there might be less of an inclination to use the DOC.

So just some food for thought to start the discussion about some of the things that were reported to me.

MR. COLBURN: Sure, all right. Thank you, Jamie. Yeah, we know the -- you know,

and this is an area we really want to continue to work on, and so everyone here is going to hear from us, and from different venues of how we can help use -- you know, someone being comfortable in using that attestation, that declaration of conformity, and what are best ways that we can do it.

I know there's two ways that we're trying to now approach this as well. While we usually think of the use of standards in premarket submissions, we know there is a litany of devices that don't go through the premarket process, or there's ways that you may use an updated standard or, you know, based upon changes to the device, it may not constitute a need to submit. Or maybe the standard itself is updated, and you've chosen to utilize the most current version.

You know, so a lot of those things may not come through a premarket submission, but how do you still maintain, as part of your device master file, and all of the quality system documentations that you have, as part of your -- you know, on the risk management file, how do you make sure that you're demonstrating that you're in conformance with a standard, and are you using a declaration of conformity to do so even in those venues where it's not accompanying maybe a premarket submission?

So we're looking at, what are the differences that a premarket submission may have in it versus what you may have just in a normal update to a file. So I think these are things that we want to continue, and if there are people that have other thoughts on that too, we would appreciate it. I think --

JAMIE: Thank you, Scott. And that' interesting about what, you know, exempt ones.

MR. COLBURN: Yeah. Well, it's just, you know, there's a lot of products out there

that use standards that don't necessarily submit. But, you know, if an inspection were to take place, how would you be also, you know, demonstrating that you're using that standard in accordance with how it was recognized, or if you had to make the appropriate modification, you know, and what is that attestation of such as well.

So I think maybe we can go to the next -- do you want to go to the next live person, or we can maybe go to Zack, or Zachary.

There you are. I think you're live.

MR. FOWLER: Hi. Zachary Fowler, I represent Linde, and I'm also part of the CGA, Compressed Gas Association. So I'm here really on their behalf, as I represent and attempt. Really, this is -- it just, to kind of tie my first question that I had to your question, actually. One of the challenges that we have heard from our industry membership has been that because the listings on the website are actually out of date, per our consensus standards, it's difficult for us to want to use a declaration of conformity because we don't feel that if we do it to a current revision, that it's going to be accepted, because the version that you have posted is unrelatable.

DR. WOODS: So, Zachary, I mean one thing you could do is request that we consider the standards for recognition if, for some reason, we haven't recognized the most current version, or the version that you think is, you know, is the most representative. Contact us. There will be an email address on the slide toward the end that just -- send us an email and request that we recognize, again, the most current versions of those documents.

MR. FOWLER: We are preparing a request, actually right now.

DR. WOODS: Great.

MR. FOWLER: We have a task force to review all of our standards and submit a request for recognition.

MR. COLBURN: Yeah. No, thanks. Yes, so and again, that's a great call for our, you know, the ability. Anyone can request a recognition of a standard. We do try to be aware of the standards that are coming out, as they do, from a majority of the standard-developing organizations that we're engaged with, but we're not involved in everything. And while we do get, I think 85, 90% of standards that come through, there are certain areas that we're not necessarily as engaged with in the development of the standard.

So if you do see a standard that is published, yeah, that we recognize or one that you think that should be recognized, we do have that process, that you can formally request recognition. Or you could even just ping us if you think that was something that maybe we would have normally been recognized but maybe it just didn't come up. I would say, give us a few months or so after a publication, because we do work in cycles. But you can always give us a heads up that there is a newer standard that maybe you'd want us to consider in the next cycle, or you can do a formal request, that we have outlined in our websites.

Why don't we go to the next hand up as well? Tony, if we can do that one, and then we'll get a few -- so Tony, I think we're going to try to keep going.

TONY: Do you have me?

MR. COLBURN: Yes, we do.

DR. WOODS: Yes.

TONY: Great. It's admittedly duplicative. I put it in the chat too. I was just wondering, if you took a look at current circumstances in standards and in testing needed in

support of medical devices, what percentage of that do you think could have a declaration of conformity that standards exist that have methods and acceptance criteria? In my experience, I feel like it's the vast minority, actually, but I have only the perspective that I have, so I just wondered what yours was.

MR. COLBURN: Yeah, and that's great. And that, we could hold an all-day debate, probably, on trying to weigh, what is a declaration of conformity to a standard that may not have, you know, either methods and/or acceptance criteria built in. And Terry may have thoughts on this too. But, you know, I think the most important thing, and I'll go back to what I originally said what a declaration of conformity is, is it's a communication tool, first and foremost, saying this is the process that we're using, and we're using it in accordance with how you recognized it, which may also incorporate the use of some of the guidance documents that cite the use of those standards.

Even when it doesn't have the -- sometimes, you know, it doesn't have methods, or it doesn't have acceptance criteria, that's the supporting documentation that you would need to support your declaration of conformity. And I feel that's still a stronger communication than just citing general use to a recognized standard when the review team may not have any advance knowledge of okay, you used the standard but did you, you know, did you deviate from it outside of what the standard allows? And that is an unknown factor which may require additional resources to do reviews. And consultations may also advance some additional information questions back for clarification.

And that's what we're trying to do is see, you know, if we can raise the understanding on how you communicate it to us, how you appropriately used the standard.

That hopefully reduces some of the burden for us to then dig into, how did you support the attestation of conformance. Does that help a little bit?

TONY: It does. And if we did that, if you snapshotted right now, where do you think that would get us? Do you think it would get us to even 50% of the testing that's submitted that could be supported by a declaration? Because again, my perspective is, I think it's way less than that.

DR. WOODS: You know, Tony, it's hard to say what fraction. I think, part of the, you know, the beauty of the recognized standards is, even when you've got a test method without an acceptance criterion, us recognizing it means that we have looked at that test method, and we believe that the method itself is, you know, has value and we understand how that method is performed. So there is value to declaring conformity to a standard that has a test method but not acceptance criteria.

You know, again, sometimes for horizontal standards it may be hard to come up with acceptance criteria that are applicable across the whole range of devices for which that test method could be used. But again, recognizing the test method means that we understand, and we're in agreement that that's a reasonable way to do the test. And then you can give us the rationale for the specific acceptance criterion.

I guess you can also think of it as kind of part of the evolution in the standards development process. You know, first we can recognize it with either the -- you know, you've got the acceptance criterion, or you've got the test method, but as the SDOs, or as we all work together within the SDO process to come up with additional generations of that standard, we work further and further -- you know, we can get closer to evolve it to have

both test methods and acceptance criteria or to -- you know, with each iteration, I think we work to make the standard more regulatory ready.

So, it's not just a, you know, an on/off declaration of conformity with test method and acceptance criteria, but we can start with standards that we think are valuable, and then keep working to make them more useful, is -- you know, again it's part of that evolution, or the total standards lifecycle that we were talking about.

MR. COLBURN: Thank you, Terry. Great question. All right, so I think we'll try to maybe get into some of the questions that have been brought in, then. And some of these are a little repetitious, so we may skip over a couple of them if we felt like we've hit them. So I want to see -- I see a lot of different questions regarding either transition, or when there's a new standard that's been revised but not yet recognized by the FDA, but the company may have already complied with it. And in this situation, what does FDA recommend to do?

Should you use the FDA-recognized standards number from the older revisions? And so specifically, that situation, you would only cite a recognized standard in the current edition of to which it's being recognized. A newer version may have additional considerations, or parts of a scope, so we don't want to put a new one in place before it is recognized. We want to make sure you're citing the recognition number with the version of the standard that you're using.

If you have a newer version that you feel strongly about, and you don't see it recognized, you could always again, request recognition, or ask, you know, the review team if you want to, also what their thoughts would be on that. Again, we try to stay as current

as we can with recognitions, but also know that changing from one version to the other version needs to be a little more transparent. And we need to take into account the burden of switching versions of a standard.

So in many cases, when you see a newer version, you'll see a transition date. And this answers a few other questions that are in the portal as well. And our transition date is intended to communicate that we are recognizing, for a period of time, both versions, while the one that's being superseded times out. So you may see a transition time for a particular standard for 1 year, or 2 years, or maybe 3 years. And what goes into that consideration is what do we feel the impact on the newer version of that standard would have on someone being able to utilize that appropriately in a coming submission.

In terms of how you cite that standard, though, we know that sometimes you do testing, and then it's getting close to the end of the time. The important thing is that, in your submission, if you have testing in a standard that was conducted while it was still recognized, but when you maybe submit it, or during the course of the review, it actually transitioned out, you can still utilize that older version of that standard for the declaration of conformity if you demonstrate that testing was done while it was still recognized. So there are ways to do it but, you know, as always, never hesitate to contact someone at the Agency to help answer that question as well.

Is there another one, maybe, you want to hit, Terry? I know there was one --

DR. WOODS: Let's see.

MR. COLBURN: Kevin? Okay. Let's see here.

DR. WOODS: I just read it. Sorry. Yeah, we're searching through the questions here.

MR. COLBURN: So, there's one by, I'm assuming, one of our SDOs. "What can SDOs do to help expedite the recognition of standards, and any advice on new technology such as AI in getting acceptance by FDA?" So maybe we can take that in two parts. So, any time -- Sharon, I think this is your question, we can, you know, communicate with each other on standards that would come up, especially in SDOs that have mirrored committees to other international groups, or possibly we do not have, you know, FDA or other regulatory presence, that might come into that situation, that we don't know until after the fact.

So, working with stakeholders, whether it's at the national level -- and I'm kind of speaking to this on an international podium here, but any time you're working with stakeholders and you're looking at your table of people developing the consensus document, if you don't have a stakeholder present, there's a good chance that that stakeholder may not be aware of the standard being developed. So, trying to get them early into the development cycle of a standard is critical, and that's whether it's at the national level or at an international level. I think it's important to have the right type of stakeholder.

Then working with the stakeholders, in this case regulators, early on would help not just expedite the recognition of a standard, but also help that standard become what's called regulatory ready, or regulatory grade, which is an area where we look at. How do those standards help meet the needs of what FDA and other regulators are looking at, to help support the appropriate use of that standard towards whatever the intention is from the scope?

So having involvement is very important. Now many regulators have very limited

resources and budget to be able to collaborate, but I think it's important to find whichever way is feasible to do that, to enhance the opportunity for regulators to communicate early into that standard, to optimize its use for regulatory purposes once it is published and hopefully recognized by regardless of the jurisdiction.

The second, maybe Terry, you could take on, advice on new technologies too on how does FDA, how do we look at that, how do we look at it from an acceptance point of view?

DR. WOODS: Well I think, you know, again for the new technologies, they're trickier to write standards because they're, by their nature, new technologies. But I think if, you know, if there is a group that comes to an SDO and is willing to write a standard, then that's something that we could absolutely -- you know, you could submit to us for consideration for recognition. Again, the -- you know, once the individual device community has decided that there is a need for a standard, then we're more than willing to take a look at that published standard and see if it's something that we think could be recognized.

MR. COLBURN: I think there's a couple of other ways too that we can look at this. One is -- and usually, and we'll use artificial intelligence and machine learning as an example, we know that there are several SDOs working at both the national and international and regional areas on this. And we know that there are a number of different departments within, say the federal government that are coordinating on this approach. But we are trying to do that. That's -- you know, in fact we are trying to coordinate.

There are specific activities that we're trying to do in conjunction with other agencies within the department and with other departments across the federal government. In addition, we're trying to work within other regional and global regulatory

groups like the IMDRF and the Global Harmonization Working Party, for example, on how can we develop a solid regulatory voice on some of these newer technologies, to help the early advancement of some of this into standards.

The earlier we get engaged on trying to help in those things, the better it is for a standard to have some acceptance abilities in the, when they publish, and hopefully then we can help fold those in to how we would address that for recognition.

Maybe what we can do is go on to, now question 2, see what we have for question 2 and see if some of our comments go into that. We're trying to monitor -- we have a lot of comments and then we have another thing, but what we're trying to do here -- so this is a little bit more -- what do you think we can do to make it easier for medical device submitters to include the correct supplemental documentation for the standards they cite. So how can we make it easier for manufacturers to identify and submit the correct supplemental documentation?

So we'll look for some newer comments that maybe you can come and ask us. Provide or feel free to raise your hand if you want to make a few comments. One of the things we do know, that we are trying to work on, is how our Supplementary Information Sheet is, first of all, clear. And can we identify a little bit more, within a standard, how it promotes itself towards the use of a declaration of conformity? And that is something that we're looking to try to do. But as I mentioned earlier, our Supplementary Information Sheets are not guidance documents, so there is a very, you know, finite limitation of what we're able to communicate through there.

So that kind of goes back into what I said earlier about making sure, how does the

standard communicate its appropriate use towards the types of information that's necessary to support the standard itself, and then can we work a little bit further. And this can be done through a number of different ways. If it's an ISO or an IEC standard but we're unable to build that into that construct, could it be done through a national adoption process or can we find other ways that we can build into that?

Thinking about this early, in the earliest of stages, I think, is also what can help us build the possibility of making standards stronger and towards of how they communicate their appropriate use and getting the right type of supplemental documentation. FDA also tries to help this by utilizing some guidance documents, and I think a good example is the human factors guidance document. The human factors standard itself is, you know, a very hard one to say yeah, we recognize that, but how would you declare conformity to it when it uses risk management and many other facets and asks, you know, for useability studies and, you know, the protocols.

It'd be really hard to try to guess, what do you need to supply as that information. So FDA wrote a guidance document, that in there cites, what is the information that we need in a human factors study. And that's how we applied that into the recognition of the standard. And I believe that approach is very similar to what we have from a few other questions too, in areas like biocompatibility, for example, or other types of guidances we've published. Where standards are a part of that, we do try to make sure that we tie that in as close to the standard as possible to help direct manufacturers, what would be the approach in which you would convey that documentation to support the standard as recognized.

Terry, do you have thoughts?

DR. WOODS: Let's see. I guess I'm looking at one question, just to clarify. Someone is asking, "If a standard isn't recognized by FDA, but a company has used it, does FDA want us to add it to the DOC or not?" No, the declarations of conformity are only for recognized standards. So you can use any standard that you want in your device submission, but you only include a declaration of conformity to recognized standards. Standards that aren't recognized, you can use, but you don't declare conformity to them.

I guess someone else also asked, "Where do you find the SIS sheets?" Again, at the, you know, a later slide, we'll have a link to our recognized standards database. When you click an individual standard in that database, the supplemental information sheet will pop up with that.

MR. COLBURN: And so I think we'll take one here that kind of hits a little bit about declarations of conformity. And it says, "To advance the use of declarations of conformity to our recognized standards, alignment with E.U. standards would be helpful, you know, for E.U. manufacturers are required to keep the product state of the art, but in the U.S., the standards are usually older. Manufacturers usually test to the latest standard to stay compliant with the E.U., so the declaration of conformity is not usually used in U.S. submissions."

I found that very interesting too, because our understanding is that the E.U. does not have very many standards in its -- that it recognizes, currently. And we do try to make sure we maintain the most recent version of a standard recognized within a couple of months of it coming out. But that said, years ago, we used to be told that we're recognizing standards too quick, and the older version is something that needs to stay recognized. So that's why

we have the older and newer versions recognized for a period of time, sometimes up to 3 years, even more as circumstances dictate that need.

That said, if there are newer standards that have been published, and that we are not yet recognizing, we would appreciate knowing. Typically, E.U. standards, we don't see recognized in our database, unless they are independently individual standards that are not in an ISO, IEC or other U.S. or other international organization, because we know many of the E.U. standards are those that went through some sort of agreement and became an E.U. standard from the ISO or IEC adoption process, for example, (indiscernible).

So what we want to do is make sure our -- you know, I want to make sure we understand the issue. But if there are standards that you don't see as recognized, and I think Terry mentioned it earlier too, we do have a portal for you to request for recognition, and we'll take that into account and respond.

Another one? There are a few more questions. So, someone asked a question about the Form 3514 again, and whether if something is not recognized, would you include it in 3514, and the answer is yes. And here if it is not recognized, if you cite it in there, I think that's still very helpful to the reviewer, as well as to our program, to know what standards are being utilized that might not be recognized. You just wouldn't be supporting that through a declaration of conformity and you would be citing general use in that form.

You got it, Terry.

DR. WOODS: Let's see, someone said, "You should communicate with us on questions around standards. What are the easiest ways to connect with us? Do we need a full-fledged meeting or can you send us emails?" You know, and that depends a little bit on

what it is that you're trying to ask. If it's a more general question, not about a specific device application, then you can send our standards email address a question, and we will try to get back to you. Or you can -- again, we can see if it's something that needs to be a conversation or something that we can address by email. If it's a question about specific standards to be used in a specific device application, then you need to go to the review team that's working on that specific device.

MR. COLBURN: Okay. So I think what I'm going to do is I'm going to read the third question but then go from some of the current comments. So that way, people keep filtering in some newer comments if they want. And if we go to the third question, it asks, you know, we'd like to know what tools and other resources manufacturers need to encourage the appropriate use of standards in submissions, and what would you find most helpful.

So I'm kind of looking at what other tools and resources could be developed, not necessarily by FDA as well, but you know, what could we do through any number of other networks that we could have in building this. And actually, that's my preference is that we try to work with our, you know, through that public private partnership or working with SDOs, or other organizations, in developing the tools that then can be used more broadly, you know, with other regulators, with other agencies, rather than something that is, you know, just coming on to the FDA.

We do have an example, and it kind of comes from a recent comment on, you know, what are -- you know, is there ways that we can get examples of declarations of conformity. And I think that is one of the things we are striving to try to do. But we need your help in

doing that was well, to ensure that we are doing something that would not just work at FDA but work in the jurisdictions that you may be needing to use that declaration for or, you know, which could be in the U.S. or external.

But do -- you know, one person asked about, you know, our example that we provided about the ASCA program, the Accreditations Scheme for Conformity Assessment. And on our website, if you go to the ASCA website, and click on either of the two program-specific guidances for basic safety essential performance, or biocompatibility, or it might be titled biological evaluation under the ASCA program, towards the end, we actually provide an example of a declaration of conformity, and the Summary Test Report.

Now realize that those Summary Test Reports are specific to how that standard would be utilized under the ASCA program. But it does provide an insight to what we were looking at, in getting to the Summary Test Report, which may be different than the supplemental documentation, or supporting documentation you need for a declaration of conformity. Realize that the Summary Test Report is based upon our knowledge already of knowing those testing laboratories included in the program and the confidence that we have in understanding their competence in testing, and how they approach that as an organization.

So our concerns or questions usually are alleviated already by having that relationship. So we are looking at a minimum amount of information to help support the declaration of conformity, with the knowledge of already understanding that laboratory a little more. Applying this to the other almost 1,400 standards in the program that aren't in ASCA, we do want to take an approach of looking at, how can we communicate better what

goes into a declaration of conformity but most importantly, what goes into that supporting documentation for the declaration of conformity.

And that kind of goes back into working with our standard developing organizations first to see if tools can be developed there, or seeing if there's other ways that we could enhance existing guidances that we have. Our hope is to build, with the communications that we get from this workshop and future discussions, ideas on what we can do to enhance that from a higher level. But to be able to do it across all the different standards would really be best suited when we work together on that approach within the organizations that develop the standards.

And Terry, I don't know if you have other thoughts on that. Not to put you on the spot.

DR. WOODS: Pretty much -- I understand. I guess, going to another comment, someone said, "As a regulatory professional, one of the things I remember needing most earlier in my career, examples of DSCs and also the information to be included in summaries of reports, when those were needed to be submitted. Does general industry have access to the examples from the ASCA program, and if so, where can we find them?"

Yeah, anyone has access to the ASCA information. We have -- again, if you look at the slides after the program is over with, there is a slide on ASCA resources, that has links to all of the ASCA information, and we encourage you all to take a look at that.

MR. COLBURN: All right. So someone did list, "It would be helpful, for example, on our recognition database to write a list of the submissions that have been cleared or approved, utilizing the standards in that database. Include recognized consensus standards

used as part of a design submission."

I'm not too sure if I fully understand that. I mean, first I would think that would be -- I mean, it would be very interesting to see, you know, a way for, especially trying to select a predicate or something, knowing what others have been cleared, using that. There are a couple of ways that someone can navigate, though, to understand what types of standards would be applicable.

In our recognition database, we do try to cite the appropriate regulation and even product code for vertical-based standards that are, you know, associated in their scope to a particular type of device, or device family. For horizontal standards, like sterilization and software and, you know, risk management and biocompatibility, et cetera, many material standards, those are horizontal standards that we don't necessarily assign to a particular device area because they could apply to thousands and thousands.

In reference to tying them to known or previously cleared submissions, that would be an extraordinary lift because those databases -- you know, to be able to monitor that. And I think too, there are certain levels of information that wouldn't be appropriate to share in that aspect. But I would say that when you're looking at predicates, many predicates do have a summary, a 510(k) summary that may list the types of standards that were utilized in their clearance for that approach.

And that is a very helpful tool, I think, if you are looking to try to do a substantial equivalence designation. You would see, in a summary, a 510(k) summary possibly, the standards that were utilized. Maybe those standards have since been updated, if it is a clearance from a couple of years ago, but it would point you into that right direction, and

we would be able to do that as well.

Another thing we're trying to do, from a historical standpoint, let's say a standard was superseded by a newer version, and I'll use ISO 594-1 and -2, which is the Luer standard, which has been superseded by the ISO 80369-7. And I think at the end of 2023, the 594 standard will no longer be recognized.

But we are looking to see, is it possible or would it be helpful if we were to consider adding a historical reference in the Supplementary Information Sheet to previous versions of standards that were recognized in the past to help provide a historical lineage, so to speak, of understanding, if you had an older predicate you're using, that used an older standard, but that standard no longer exists and was superseded by a different version, would that newer version be -- would that be helpful to have in the supplementary information sheet. And that is a concept we are looking to see, if that would possible, to help those who are looking to -- you know, that come across that type of situation.

Who do we have next?

DR. WOODS: Let's see. We have someone asking, "If a device is marketed based on an approved standard-based FDA submission, does the change of a standard version require resubmission?" No. Once your 510(k) has been cleared, or your PMA approved, the device is legally marketed, and you don't have to redo testing just because the standard has been updated. If you make a modification to the device and do a new submission, then you need to look at the new version of the standard and consider whether or not the change requires you to repeat that testing.

MR. COLBURN: I'm going to throw a different curveball onto that too, though and

say, you know, so in our appropriate use guidance, we do talk about what happens when standards change. Do I need to first, use that newer version, and if so do I need to resubmit? And there's a couple of things that you should always be looking at. One is, you know, if you're trying to figure out, do I need to submit based upon the change to a medical device, we have guidance on that. And it walks you through what would be the trigger that would indicate that maybe you should resubmit. And then to Terry's point, you would want to make sure you're using the relevant standards.

But, you know, every medical device has its lifecycle, and part of our initiatives with the total product lifecycle is looking at, you know, what happens, you know, over the years of your device, you're collecting information, you're using the risk management tool to determine, you know, potential changes. You're going to see new test methods coming out that maybe would help describe what you're trying to understand, what's your device's performance.

And that's all part of how you operate in your quality system as well. So I think if you, you know, are questioning, you know, do I need to use this new standard, I think you have to work with your organization in totality and look at, what are we doing from a quality systems standpoint, how are we assessing the risks, based upon newer information that's coming in, the real-world evidence that we're getting? And does that speak for us to need to consider testing to the newer standard?

Based upon, you know, that, that will help you answer that question. And then, you know, from always looking at your product and seeing if you need to make changes to an already cleared medical device, following that guidance on when to submit would help you

indicate whether you would need to have that in a submission that comes forward. But to Terry's point, once you have a 510(k) that's cleared, just because a new standard comes out doesn't mean, first that you have to retest to it, in our rules, or have to submit, notify us of that in the 510(k) world.

DR. WOODS: Let's see, we did have a comment suggesting, in the SIS for a particular standard, recognized standard. "It would be helpful if there was actually a link to the guidance documents that would be associated with that standard." And that's definitely something we can take into consideration. We list the relevant guidance documents, but you're right, it would be easier to be able to then just click the link to the guidance document and get there. And that's something that we'll definitely consider in our thoughts of how to make the SIS sheets more helpful to people.

MR. COLBURN: All right. Oh, we have a hand raised. Jamie has hand-raised again. Why don't we go live?

DR. WOODS: Yes.

MR. COLBURN: And again, if anyone wants to ask a question or provide some comments actually, it's what we want to hear. Feel free to use the hand-raise function.

JAMIE: I'm back. Hello to you too. This is such a fun discussion. So just to follow up on the discussion regarding the SIS, right, so first of all, I really like the idea that you just provided about putting in some of the historical information, which I think is consistent with the recommendation I'm about to make of as much information as you can provide in the SIS as possible. But yeah, that historical information, particularly with the example, you know, 80369 versus 594, number changes, right. So you wouldn't necessarily think to look

for that if you don't have the history.

So I think, I like that idea as well as the idea we just heard from someone in the audience about, you know, actually having the link there. It's, you know, just one less step. But the one I was going to suggest, in addition to that is, particularly when you're looking at a partial recognition, right, any information you can provide about why, essentially, what is recognized and what is not recognized, and specifically, if you don't want something, what you do want instead.

Now, you're going to -- I know you're going to tell me that it cannot be -- you know, that there are issues with it having it be guidance, but again, I do think that that is something that we would really find helpful.

MR. COLBURN: Thank you, Jamie. And that's, I will say, is probably one of the constant improvement processes that we've been working on for a number of years. And I would say I think we've come a long way, too. One of the things we really try to ensure, is that if we are not recognizing a complete standard, if there's an issue with a particular area, that we call it out clearly. But we try to, you know, provide the rationale for that partial, or for that section not being -- maybe it's in conflict with an existing regulation or guidance. If so, cite that, and try to lend -- you know, draw a line, essentially, right to where is the replacement for the part that's not being recognized if that replacement is critical.

There are a few partials that we have, that we specifically don't recognize because it's not underneath maybe our jurisdiction, or it's not pertinent to what we're looking for. But I think, in the majority of cases that you're referring to, we do -- one of our goals is to always try to tie that in to some sort of something in the public domain that is known, so we

can say, you know, this is what we feel is necessary, with the rationale to support that.

If there are areas that you feel that are not clear, again feel free to always try to contact us. And we can try to -- you know, that we're going on, is our goal is to make sure that the recognition of standards, if anything, helps provide some clarity on how to use the standard. But if we find that in how we recognize it that it creates more questions than answers, then yeah, we need to continue addressing that so it becomes clear.

JAMIE: Thank you, Scott.

MR. COLBURN: Thank you. Okay, no other hands, what would be our next question?

DR. WOODS: Okay, here's one. "Can you submit a DOC if there are differences between the test article and the proposed device? So, should you include the rationale of why the test results are still relevant on the DOC itself or on the test report?"

This sounds like it may actually be a deviation, depending on, you know, whether or not the standard allows you to use a test article of the sort that you're talking about. So, that one, we'd need a little bit more information. So if you have deviated from a standard, then that's not something that appropriate for a declaration of conformity. But if you've done something that was a choice within the recognized standard, then you can include that in the declaration of conformity. And as part of your supplemental information, you'd need to provide a rationale as to why you made the choice that you did, or why you chose the test article that you did.

MR. COLBURN: Okay. I'm just trying to look at the things we're not answering.

DR. WOODS: I guess there's also a question about education. We, in the past have done some education and I guess information that, a request that education with examples

and, you know, specific examples should be included. That's something that we will definitely take into consideration. And again, one thing that we've all learned is how much easier Zoom -- or how we can be effective with Zoom meetings. And so we will consider, you know, what kind of additional information or education that we've done in the past that we could also share again in the future through Zoom meetings like this.

MR. COLBURN: Okay. So one thing we want to make sure, a lot of people -- you know, going back to the communication tools and stuff. A few other things that we do, as someone said, you know, a big part of this is making sure the regulatory affairs departments of manufacturers are in line and in tune with understanding the appropriate use. It doesn't just happen from bench to bedside. We have to go through many hurdles of regulatory affairs and regulators to get to that approach.

So yes, we do work a lot with different regulatory organizations, industry associations, and are always open to try to help improve knowledge on that, as we also try to do within our own organization to ensure, you know, new reviewers and existing reviewers receive information and work across their OHDs and OPEC, and with OSEL, and other organizations across the Center. Knowledge is key, and education is very important.

I would say also, you know, if you are part of a RAPS chapter, we have historically worked with organizations like RAPS, and do either the big RAPS meetings, or sometimes come out for chapter meetings to talk about topics, and on this area. So that is one way we try to reach out to the regulatory community, and then also through other tools, whether it be updates to guidance and others.

The parts too, that we want to look at, in terms of, you know, what we can do is, you

know, we'd like to again, keep hearing from you on areas of education that you think would be important for different areas within your organization as a body. And we know we work closely with some, again trade associations and standard developing groups, which helps hit different stakeholders within an organization, just like we do internally with our own.

Let's see, I think what the next -- we did that one already.

DR. WOODS: That one we already did.

MR. COLBURN: Yeah, we did that.

DR. WOODS: Yeah.

MR. COLBURN: One thing I did want to say too, we do try to update when we make a change to our recognition, to CDRH New. So if you're subscribed to get the CDRH New, when we make updates to our recognition, it does go through portals like that. So, while we don't have a subscription to the current recognition database, we do always go through channels like that, and in any other means possible as well. Again, we'd be interested in seeing any other comments about the three questions, to see, you know, what else could we do to help advance the use, make it easier for you to use standards, and what are the types of tools and resources.

And that's back into that subset. So, did we hit the one about DOC for recognized that's partially, what do we do for a clause or section that's not recognized?

DR. WOODS: No.

MR. COLBURN: So, we'll keep hitting questions that are being asked, but again, please continue to submit comments. Well, let me go to Tony here first.

Tony, you have your hand up again.

Why don't we unmute Tony?

TONY: Yeah, it's a little bit, again repetitious from my previous question and comment, but I was thinking, I don't think it's anything to sort of be ashamed of, if that's the right word. Everything has to start from somewhere, and everything has to try to best move forward from where it is. But I think sometimes an assessment of where things stand helps us understand what work we need to do to move forward.

So again, I just want to offer the comment that I think that we have a lot of work to do in this regard. And the reason I think that is, I think it's actually the vast minority of testing right now that needs to be submitted in support of a medical device, that it's possible to do what you're saying. I just think, I think the standards just are not there for the vast majority of testing, that have methods and acceptance criteria and circumstances that can support the use of a declaration of conformity.

And maybe that's just -- it doesn't answer how to get there, but it answers where we're maybe starting from, at least in my experience.

MR. COLBURN: Go ahead.

DR. WOODS: Tony, I mean, I think you're right. There's a lot of room for improvement in SDOs. That's some of what our 400 liaison reps that we have are going out to SDOs, working on individual documents to make them again, more regulatory ready. So you're absolutely right. You know, while we are where we are, this is not a process that's going to be finished in, you know, a year or 2 years. It's something that we need to all collaborate together with, to continue working forward to, again to get test methods more well defined, to get Summary Test Reports or the test reports within the test methods

better defined, to come up with acceptance criteria when we can.

Again, you know, it's baby steps, and we had to start with the state of things where they are, but I think we're -- again, now we're at the point where we can work with this evolution of standards to get them to be more useful, both for manufacturers and for FDA. Because again, you know, it's the -- everything we can do to give people assurance that the test methods are appropriate and the results are what we need is going to help get devices to patients more quickly. And that's -- you know, at the end of the day, that's what we're all trying to do.

And again, I think the, you know, the voluntary consensus standards process is an amazing forum for us to work in, because that is a place where FDA can work collaboratively with industry, you know, that's not a device-specific application at the time. And we can collaborate and come up with the best way to assess devices to show if, you know, they do what they're supposed to do.

MR. COLBURN: Yeah. I would like to add on to that too. I think, Tony, I think you're spot on. I think many of our review staff would agree with you too, that most standards may require that, you know, a pretty large chunk of information needs to support the attestation of conformance or the understanding that you're using. So what is the value of a declaration of conformity? It gets asked secondly, but it goes back to the communication that it does provide.

And I think, you know, we have seen a struggle with, you know, how standards have come from simple methodologies with endpoints built in, and they're not tied in to risk management and all these other tools. You know, standards have become a lot harder to

pin down in that way, because we're trying to have them keep up with technologies that are always rapidly evolving.

I think one of the ways -- and this is to speak to all the stakeholders here is, you know, we need to connect more with the other stakeholders that use standards, not just regulators, and not just users of products, and not just the manufacturers, but also the testing organizations, and those who are looking at how they develop the competencies to demonstrate that they're competent in doing testing, and what could go into a standard to help communicate consistent across-the-board testing procedures, qualifications that maybe need to be considered.

These are some of the things that we identified when we built, when we worked with IMDRF a little bit, as well as in our assessment of looking at the vast types of standards, testing approaches that are conducted across our recognized standards. And when we started building the ASCA program, we really started uncovering areas of understanding, the approaches, the rigor in conformity assessment done from an inspection body or, you know, accreditation bodies and what lab tests to go through, the responsibilities that manufacturers have under their quality system to work with a testing organization and ensure that their quality system meets the needs because they're doing testing for your product.

And there's a lot of aspects to that, that I think a standard could benefit from, in how it constructs itself to communicate what's necessary to support the types of testing that are being conducted in this. So there's a -- that's a big, big ask, but I think that's something that we're going to see in this next generation of standards development, where the previous

generation incorporated risk management and all these ways to try to maintain, you know, what is safe, how did you mitigate risks, how are you managing appropriate changes in a standard to keep up with technology.

But I think if we incorporate more of the stakeholders and the conformity assessment world with standards development, we can strengthen our standards in ways that will help reduce the burden on regulators and the regulatory affairs professionals that are trying to use standards to communicate. That was a lot of words.

TONY: Thank you.

MR. COLBURN: Yes, thank you.

DR. WOODS: Okay, someone else is making a comment that the appropriate use guidance of how to use consensus standards is not particularly clear. And I guess I wouldn't --

MR. COLBURN: Wouldn't disagree.

DR. WOODS: -- wouldn't entirely disagree with you. Again, you know, we do the best job we can, at the time. And so when we came out with that guidance in, I think it was 2018, you know, that was our first effort. We appreciate the feedback, and again, any more specifics you can give us, that will help us rethink and try to make things more clear. I guess we've heard that we would like to see examples. We would like -- again, you would like more clarity.

And so, anything specific you can tell us about what would make it more clear would help us to do, you know, to do a better job in reconsidering and reformulating what that guidance says, and get the information to you so that it does make sense, and it makes it

easier for you to submit declarations of conformity.

MR. COLBURN: But I think the key, too is, you know, we also want to know, you know -- so you could flip that question around and say, well what's the value of a declaration of conformity if I'm giving everything all the time? That seems to be what's working for me. I'll flip that question right back around too and say, what's the value of recognition?

It is recognizing standards of high value to you and what we do, or would another approach be, you know, something of higher value. We're recognizing that a declaration of conformity again goes back to what I'm saying. It's a communication tool that indicates that we're aware of a standard and, you know, we're with you on the journey to try to understand how you're using it appropriately for its regulatory use.

You know, after that, you know, what do you need to support that document goes back to the construction of that standard. And there are certain types of standards, certain design specification standards that may, you know, you could claim conformity to. To Tony's point, I think they are a little bit few and far between in some cases, depending on the product that you have, in others maybe not so much. But the key thing is, we're trying to find ways to work with the standards development and performance testing cycles to have a clearer communication of, that goes further and deeper into what is it that you need to support.

Maybe it's a complete test report, but maybe if that complete test report has a format that can be utilized that helps us get consistent approaches and it helps us understand differences in the device technologies and the approaches that are used, that

helps us lower burden on everyone involved as well as it helps you lower burden as well.

Jamie has her hand back up. Why don't we go back to Jamie?

DR. WOODS: Okay.

JAMIE: Thank you. Sorry, not trying to be obnoxious, just do -- you know, we are passionate about standards. So, to the -- Terry, to your question, to your point about specificity and what would make the guidance more helpful or more clear, right. This wasn't one of your original questions, but we do have a thought about this, which is in regard to transition periods, right. One of the things that has been sometimes challenging for our members is not knowing in advance how long those transition periods are going to be, and sometimes finding that they are quite short, sometimes less than a year.

And I think, you know, our recommendation continues to be that there should be, you know, in general a presumption of a 3-year transition, unless of course there's some, you know, pressing health justification for which you would provide, you know, an explanation. But another idea we had was, you know, potentially like a provision of a comment period during which those who are, you know, really well familiar with how a new standard is going to affect the particular manufacturer, given of course that FDA knows many things, but perhaps, you know, no one can know everything, that it might be helpful to have a comment period where we could opine on the specifics of the transition period for a particular standard.

MR. COLBURN: Yeah. Well thank you. Transitions has been a topic for a number of years. And I know we've tried to take some approaches to be as judicious in how we go into the discussion of what is an appropriate transition period. And I did touch upon it a little

earlier on, on what we try to do, whether it's a 1-year or a 3-year. A presumption of 3 years, I think -- you know, I think what we would like to hear -- maybe Jamie, I could put you back on the spot and say, can you give --

JAMIE: Yes, you can. Let's hear it.

MR. COLBURN: -- some examples of why a long transition period would always be best from a presumption, in the recognition versus a, say 1-year? I don't know. If you could give us a few examples, so that way we can hear that.

JAMIE: Let's see here. I'm trying to remember some of the specific examples that they gave me, right, because of course the members are much more close to this than I am, right. But I think one of the -- 10993-2 apparently had a very short period. I mean, I think the general idea, right, is that development cycles are quite, can be quite long, right, that you're developing a medical device, right, so they can be quite long. And it can be difficult, essentially, to incorporate a new standard, particularly one for -- right, there are particular ones.

And it is, I think, sometimes very dependent on the particular facts of that particular device, where a standard will potentially impact design and testing, and acceptance criteria. So I think that's the reason for the presumption. I mean, you have seen some significant international bodies use -- standard development bodies, organization use that, right, as their baseline.

But I think the idea is essentially that it's -- we have a fairly -- you know, there's that development cycle, and you need to know in advance. And it can be very difficult, particularly if you don't know it's coming. Now again, hopefully everybody should be

involved in developing the standard, but that it can be quite -- you know, it can be challenging to do things in a short period of time.

It's certainly something where I would be happy to go back to the experts and ask them to provide additional justification, but that's my understanding.

MR. COLBURN: It's a real important topic, and it's one we're really trying to make sure too, that we're being least burdensome in our approaches but are still trying to address any public health advances that are being brought into by the use of that newer standard. But I think, to your point, you know, how can we best, you know, make sure that there's an expectation or approach. And we could, you know, dive a little bit deeper into, you know, an upcoming advancement, or guidance or other communication on this topic.

Some of the things too, I know that your experts have said too, you know, in order to consider using newer standards, you know, you go through that whole risk management process. You know, there's potential changes that may impact the risk management file that even the -- you know, areas of the quality system, how things that are going into play. And that takes time.

In addition, especially -- let's use biocompatibility or EMC as an example, organizations that test to those have to become accredited to the newer standard, which sometimes takes time as well. So that whole process does potentially take time. But realize too, that when we're recognizing the standard -- this is more speaking towards the submissions coming in versus the already cleared devices that are using the risk management process to determine when they should consider using, or if they should consider using a newer standard.

So that part, I know we get sometimes spliced in half on people worrying about a newer recognition that's timing out faster, but they were never intending to submit anyways. So we have to make sure we understand how to appropriately use standards throughout the product lifecycle that is, of the medical device.

But I do think this is an area we would like to work more with in the standards development process as well. Now, I know certain SDOs like ISO no longer allows us to put in recommendations for authorities having jurisdiction on how they should use the standard. IEC seems to let us. Other SDOs try to do it. But if we're engaged in that process as a regulator, and this is, you know, something that we also try to teach, is try to learn what would be an appropriate transition by speaking to the members around the table, those who are closest to the standard, to give us an indication too of what it would really take for you to need to transition.

One thing that usually, you know, would knock that type of process off is if we really feel that the use of the older standard would potentially create a risk to public health or in the, you know, quality and performance that we're looking at. That is usually not the case, because then we're typically looking at withdrawing that standard even before the newer something, or turning it into a partial.

But I would say, you know, it's really important for users to understand, what were the changes from one edition to the other. If they're very minor changes, sometimes we do a shorter transition period, but maybe we're assuming something that we shouldn't, as well. So, those are things too that you can always contact us on for reconsideration. We have had that done a few times and had to extend a transition where it seemed

appropriate. So, always never be afraid to contact us.

DR. WOODS: Now, you know, same --

JAMIE: A follow-up on that --

MR. COLBURN: Okay.

JAMIE: Sorry, Terry. Were you saying something?

DR. WOODS: Well yeah, I was going to say, one other thing that you and the other SDOs might go back and, or in other groups, ask your members about, in the case of like PMA devices, where a lot of the standards testing is bench testing that's done before there's a clinical trial, and so you've got that long period of time when the clinical trial is going on, so potentially you could have had new editions of standards that were published and recognized after you've done your bench testing, before the clinical trial is finished.

And so, I guess some feedback from people who have lived through that experience to us would be helpful to -- again, just that experience is something that, you know, we can imagine, but if you guys don't tell us, then we don't really know how you do work with that, where you've done your bench testing and then, you know, 2 years later you're ready to submit your PMA and there's new versions of these five standards that you used.

JAMIE: Yeah, that's a very interesting point, and certainly something to inquire about further. I did have one follow-up if I may, Scott, to your point about, right, contact you. And, you know, and there have been instances where that transition period will change. And my understanding is that some of my members have done that, with success, and of course appreciate your collaboration on that.

The only thing that has been mentioned about that is that you often -- right, the

manufacturer often will not know until the end of that transition, like almost the end of the transition period, because it's short, to begin with, whether or not it's going to be extended. So it's sort of a, well we don't know if we're going to get the extension so we need to do the work and prepare anyway. So, you know, just to the extent that that -- those -- but really it's hard, because you need to think about it, you need to go through the process, all of that kind of thing. It's just that that is potentially the challenge, is that if a manufacturer doesn't know for sure that they're going to have that extension, they're going to do the -- they're going to feel that they need to do the underlying work anyway.

MR. COLBURN: Yeah, and I -- yeah. There's those situations, I'm sure. And I think this kind of goes back to, you know, how do we create the communication lines during the standards development process that would help the regulatory, you know, stakeholders at the table understand the nuances of standards implementation and, you know, some of the difficulties.

You know, a lot of times we're looking at encouraging the newer version of a standard, of course, because we feel there might be less additional information type questions asked in a newer version, because it may address some of the current issues that have been seen in the market, or in postmarket surveillance that we have done. And so the newer version helps reduce that and reduces burden. But implementation is something that has to be weighed against that.

And that's why we always say, you know, if you're using an older version and a newer version exists, that that is acceptable, but you may need to address some of the concepts that are introduced in that newer version if, as part of your risk management file,

and that can be addressed elsewhere in the submission, of course.

So it's never the simplest answer when trying to talk about this, but I do think, going back to early communication and understanding of the concepts of putting that standard to work, and the nuances that go into that would help us in making sure we provide an appropriate transition into that. And I appreciate that comment.

JAMIE: Thank you.

MR. COLBURN: You know, and I will say, we did get a comment here that said, you know, a 3-year cycle seems pretty long, in the sense of a newer standard. And ISO and ASTM are almost -- take long -- you know, aren't much longer than that. Like, you know, you can write a standard in 3 to 4 or 5 years. And that's true too. And, you know, so we tried figuring that part out, you know, what's the best way. It's one of those, you know, we -- you're in trouble if you recognize it right away, but you're in trouble if you let the old one go too fast.

But, you know, there is a cycle that we're trying to use. I know you said you will see a lot of, two versions of a standard recognized, with a timeout for the other one. But we want to make sure we're doing that appropriately. I think that's the point, Jamie, you're making, and we do agree with that, and we're trying to continually improve that.

JAMIE: Well, thank you for that.

MR. COLBURN: All right.

DR. WOODS: Well, I see one question that we should make it clear to everyone. It says, "How can I assist FDA in revising the guidance document?" Every guidance document has what we call a docket, where you can make comments any time, for changes that you'd

like to see, or comments that you have on that guidance document. So again, the last few slides have some specific links to the guidance documents. But if you search any guidance document online, there -- on that home page that you find for that guidance document, there will be a link to the docket, where you can put any comments that you like. And we review them periodically, to help us in making revisions to a guidance document.

MR. COLBURN: Thank you.

DR. WOODS: So I encourage you to go to the docket and add anything that we haven't covered here, or things that occur to you later. And we will definitely review that in our work to revise all guidance documents.

MR. COLBURN: Yeah. Yeah, absolutely. And, you know, and if we decide that, you know, based upon information collections that, you know, an update to the appropriate guidance would make sense, you know, when that draft gets published, that is another opportunity that we receive comments on it, of course, as well. But as Terry mentioned, there is an open docket on it. And we also, you'll see later on, an email address to the CDRH standards staffer. You know, any comments or questions that you have, we're always happy to take those in, and try to learn about how we can optimize this program for everyone's benefit.

You know, I always say, this is the -- you know, we help support the medical device standards programs and, you know, for the FDA regulatory purposes, but the purposes that every stakeholder that's engaged with us as well. And we want to make sure that we're trying to do this, and leading it with you.

So, I think we're getting kind of close to the end. Maybe what we'll do is we'll go to

the next slide, and start closing out here. And we're showing -- all right, so well actually Terry, and everyone, boy, thank you all. It's been a really helpful and super discussion.

Before we close, though, I want to provide you with just the resources that we've been mentioning. On this slide, we have four of them. Our web page for the Standards Conformity Assessment Program, again SCAP is our current abbreviation of that. Then we have our web page link there, a link to FDA-Recognized Consensus Standards database, and within that are the supplementary information sheets that we spent quite a bit of time focusing on.

And look at them. Let us know, from your observation of the standards you are, you know, familiar with and utilize, you know, are there things that you think would be a little bit clearer on the approach, based upon how that standard's construction is, that we could use to improve, based upon the discussions that we had today.

Additionally, we have the links to the two FDA guidances, the Recognition Withdrawal Voluntary Consensus Standards, and the Appropriate Use Guidance. We've also listed our email address that I mentioned before, in hope that you'll use it to send any additional thoughts or questions that we were unable to get to today. And watch out in the future, again for our public comment period that will open up when we draft --you know, if we do get into the drafting of the appropriate use guidance.

Next slide.

ASCA came up a couple of times, and of course I would be remiss if we didn't mention it here and give you some resources. So if you'd like to learn more about the Accreditation Scheme for Conformity Assessment, and we hope you will, there are several

key resources, including the guidances that were published to implement the ASCA program.

Next slide.

And finally, we encourage you to refer to CDRH Learn and Device Advice on the FDA website for an absolute wealth of information and support. A lot of the questions that were asked today can be addressed by diving into those. The educators at DICE are always eager to help support all of our stakeholders to work effectively and efficiently with the FDA.

Next slide.

So, we're getting towards the end, so I think that concludes our workshop. I don't see any new hands or anything like that. If we did not get to your comments, or if you have questions, please again, that email address that is listed here today at CDRHStandardsStaff@fda.hhs.gov. You may also submit a formal comment on this meetings docket, using the link on the slide or by searching regulations.gov with the docket, #FDA-2022-N-2781.

Thank you again for joining us today, and helping us out, putting standards to work. Have a wonderful holiday season, and we look forward to working with you in the future. Thank you.

Thank you, Terry.

DR. WOODS: Thank you all for coming.

(Whereupon, at 2:53 p.m., the meeting was adjourned.)

C E R T I F I C A T E

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

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CONSENSUS STANDARDS

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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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