

**FDA Webinar: Recognition and Withdrawal of
Voluntary Consensus Standards - Final Guidance**

**Moderator: Irene Aihie
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1:00 pm ET**

Coordinator: Welcome and thank you for standing by. At this time all participants are in listen-only mode until the question-and-answer session of today's conference. At that time you may press Star 1 on your phone to ask a question. I'd like to inform all parties that today's conference is being recorded. If you have any objections you may disconnect at this time. I would now like to turn the conference to Irene Aihie. Thank you. You may begin.

Irene Aihie: Hello and welcome to today's FDA Webinar. I am Irene Aihie of CDRH's Office of Communication and Education. On September 15, 2020, the FDA issued the final guidance Recognition and Withdrawal of Voluntary Consensus Standards. This final guidance explains the updated procedures the FDA intends to follow when the FDA receives requests for recognitions of consensus standards and withdrawals recognition of a consensus standard.

Today Donna Walsh and Jianchao Zeng, both Senior Standards Advisors in the Standards and Conformity Assessment Program within the Office of Strategic Partnership and Technology Innovation here in CDRH, will present an overview of the final guidance documents. They are both joined by center

subject matter experts to assist with the Q&A. Following the presentation, we will open the line for your questions related to the information provided during the presentation. Now I give you Donna.

Donna Walsh: Thank you Irene. Good afternoon everyone. My name is Donna Walsh and I'm a Senior Standards Advisor in the CDRH Standards and Conformity Assessment Program. Today my colleague Jianchao Zeng and I will be sharing with you information regarding the recently issued final guidance Recognition and Withdrawal of Voluntary Consensus Standards.

Next slide please. Our agenda today begins with an overview of the role that is played by the Standards and Conformity Assessment Program or S-CAP with respect to FDA recognized consensus standards. We will then take a brief look at the types of comments that came in on the draft guidance from our stakeholders.

We'll review the main facets of the final version of the guidance which incorporates that stakeholder feedback. Then we'll have a question and answer period. And then we'll wrap things up with some concluding remarks before the end of the Webinar.

Next slide please. So let's get started with our overview. S-CAP supports CDRH's mission by driving the development, the recognition and the appropriate use of regulatory ready standards for medical devices throughout their life cycle. FDA encourages the voluntary use of recognized consensus standards in premarket submissions. Doing so offers several advantages such as increased predictability, a more streamlined premarket review and increased clarity of regulatory expectations, all of which can help facilitate market entry for safe and effective medical products.

In addition, declarations of conformity may be used with recognized standards reducing the amount of supporting data and information that needs to be submitted to FDA in a pre-market application. So the use of voluntary consensus standards is a key element of regulatory science. When manufacturers cite FDA recognized consensus standards the review process can be more efficient.

And when declarations of conformity are made to recognized standards less documentation is typically needed. And at the same time, the utilization of consensus standards, which are written under conditions of transparency and inclusivity while effectively being crowd sourced among experts around the world, this enables medical device quality to be enhanced which benefits both clinicians and patients.

So let's review what is meant by recognition. Recognition is FDA's formal identification of a standard, reflecting a determination that it is appropriate for manufacturers of products to declare conformance to that standard, in order to meet relevant requirements including premarket submission requirements.

Next slide please. In order to promote the use of consensus standards, S-CAP prioritizes the following recognizing standards through our formal Standards Recognition Program which we will discuss in greater detail in a few moments, encouraging the appropriate use of recognized standards in device premarket submissions, and actively participating in the development of national and international voluntary consensus standards. So how do these priorities translate into reality? Well here are some numbers to describe the depth of our commitment to standards.

We have 17 internal advisory Specialty Task Groups or STGs in 23 specific device and scientific areas. At last count there were about 400 CDRH staff

members who participate in around 600 national and international standards committees across 29 standards developing organizations.

There are currently roughly 1400 recognized standards in our database and more than 90% of those are complete recognitions meaning that a standard is recognized in its entirety. Over the past few years, we've typically had a 5% to 10% increase in requests for participation in new standards development activities each year. And based on a past survey that was done there are an average of seven standards cited in each 510(k) submission with a wide range as you can see here on the slide.

Next slide please. So now that we've provided an overview of what S-CAP does we're going to shift gears to talk about our newly published guidance entitled Recognition and Withdrawal of Voluntary Consensus Standards. The final guidance formalizes several aspects of our Standards Recognition Program and provides clarity on other aspects. It was written with significant feedback from our industry stakeholders on the draft version which we'll review next.

Next slide please. When looking at the types of comments that came in on the draft version of the guidance the commenters told us that the recognition process should reflect our Center's least burdensome principles and that all aspects of the process should be clear and transparent. The comments also requested additional clarity on the use of transition periods including the rationale for recognition and other updates in the supplemental information sheet as well as a distinction between when a standard may be used in a submission versus when it is formally recognized.

And as Jianchao will explain once a standard appears in the Recognized Consensus Standards Database it may be cited in a premarket submission even if formal recognition

-- by publication in the Federal Register -- is still pending. Now please note that your comments on the guidance are still welcome. Final guidances remain open for commenting as long as they are in effect.

Next slide please. And now I will turn the presentation over to Jianchao to review some key elements of the final guidance in greater detail.

Jianchao Zeng: Thank you Donna. Next slide please. The next few slides summarize some of the main points of the guidance including specific information related to stakeholder requests for standards recognition including who may submit a request for recognition and what should be included in the request, the FDA's response procedures for such a request and how we intend to respond in writing with our decision within 60 calendar days. It discusses how the extent of recognition is determined to be complete, partial or non-recognition. The FDA will make public the rationale of our decision to either recognize or not to recognize a particular standard.

Next slide please. The guidance offers practical advice on the processes we follow and expectations for requests as well as key elements of the recognition program. It specifically addresses the value and the utility of consensus standards in product submissions, the elements of a request for recognition, updates to the supplemental information sheet including the extent of recognition and the rationale for that decision, updating the Recognized Consensus Standards Database with standards we intend to recognize, official recognition which occurs upon application of a Federal Register notice, and our procedures for withdrawing recognition of a standard including a possible transition period.

For example, when a newer version is published and FDA decides to recognize it the recognition of the older version of the standard will be

withdrawn. However, we may provide a transition period to the older version during which a declaration of conformity may still be accepted. Next slide please.

Let's talk about the practical aspects of the recognition process first. In order to request that a standard be recognized by FDA -- and anyone can submit such a request -- the elements listed below on this slide should be included. Your name and address, the title of the requested standard, the standard's reference number and date, a proposed list of product types for which a declaration of conformity should routinely apply, the basis for recognition which may be scientific, technical or regulatory, and a brief identification of the testing, performance or other characteristics that a declaration of conformity would address.

Next slide please. Once a request or recognition has been received it triggers the following steps. An acknowledgment letter is sent to the requester. The standards program S-CAP organizes a formal review of the standard with the appropriate Specialty Task Group, STG. The review team makes a recommendation to the S-CAP regarding the standard recognition either recognition (which may be complete or partial) or non-recognition, along with a rationale for the recommendation which could be grounded in a scientific, technical or regulatory basis.

Next slide please. As I mentioned earlier the guidance formalizes some aspects of the recognition program. Recognition decisions should be made within 60 calendar days. The decision including the rationale will be sent to the requester. Pending recognition, FDA's determination will appear in the Recognized Consensus Standards Database.

Official recognition occurs upon publication in the Federal Register notice. Non-recognitions will be listed in the Non-Recognized Standards Database. Once again, I want to emphasize an important point. Official recognition occurs when the recognition list is published and a notice appears in the Federal Register. However, a standard may be included in a declaration of conformity as soon as it appears in the Recognized Consensus Standards Database as that indicates our intent to formally recognize it and therefore recognition is pending.

You do not need to wait for the Federal Register publication. You may cite a standard in a declaration of conformity as soon as it is included in our database.

Next slide please. Let's go back to something we briefly mentioned earlier, the Supplemental Information Sheet or SIS. Each recognized standard has its own SIS sheet in the Recognized Consensus Standards Database. It includes the following elements: A recognition number, the date the SIS was entered into the database, title of the standard including the SDO and the designation number, the US identical adoption if applicable, scope or abstract of the standard, extent of recognition whether it is a complete or partial recognition.

For example, currently we are recognizing both the IEC 60601-1-11 (a standard on medical electrical equipment and the medical electrical systems used in the home healthcare environment) and the US modified adoption ANSI/AAMI HA60601-1-11.

While the ANSI/AAMI version HA60601-1-11 is a complete recognition, the IEC version 60601-1-11 is a partial recognition due to differences in definition of home healthcare environment between this standard and FDA's guidance. The SIS sheet also includes the rationale for recognition, transition

period if any, Specialty Task Group (STG) as well as additional items such as public law, CFR citations and product codes (if any), relevant FDA guidance or supportive publications, and FDA technical contact information.

Next slide please. Periodically we need to withdraw recognition of a standard but we do not do it lightly. Typically it happens when a newer version of a standard is published and FDA decides to recognize it after a review. On rare occasions we may determine that a standard no longer meets our expectations or is no longer appropriate for meeting a requirement, and therefore we need to withdraw its recognition.

For example, a CLSI standard (point-of-care blood glucose testing in acute and chronic care facilities) was initially recognized on list 36 in July 2014. But subsequently it was withdrawn on list 37 in October 2014 because it was in conflict with an existing policy. If you have not already, please take a look at the Appropriate Use guidance for more information about withdrawing a recognition.

Next slide please. On the previous slide we talked about when it is necessary to withdraw recognition of a standard, for example, when a standard has been revised with a newer version. In these cases, FDA may implement a transition period. In determining the length of the transition period we consider the following factors.

The public health impact of delaying the use of the newer version, and potential difficulties the manufacturers may face in implementing new changes to a standard. The transition period allows additional time for the submitter to complete product development and testing already underway using the older version. It also allows them time to validate any new test methods in the newer version before using them for a submission.

For example, a one-year transition is typically provided for a product specific vertical standard, while a longer transition time (say two to three years) could be provided to a horizontal standard, a standard that impacts multiple product types such as biocompatibility, sterility, software, EMC, usability, alarms, et cetera. The length of the transition period is spelled out in the SIS sheet before the Rationale for Recognition section. This concludes our slide presentation, and we thank you for your attention. I will now turn it over to Irene.

Irene Aihie: Thank you Jianchao. This is Irene Aihie. Operator, we'll now take questions from our participants.

Coordinator: Thank you. We will now begin the question and answer session. If you'd like to ask a question please press Star 1, unmute your phone and record your name clearly. Your name is required to introduce your question. If you need to withdraw your question press Star 2. Again to ask a question please press Star 1. It'll take a few moments for the questions to come through. Please stand by.

Donna Walsh: While we're waiting for...

Irene Aihie: Go ahead.

Donna Walsh: While waiting for the question and answers to begin one common question that we are asked, sometimes relates to Form 3654. "What role does Form 3654 play in my premarket submission?"

Well this form has actually been discontinued, and we found that it was never really used quite as we intended which was to collect data on standards use and submissions -- for example, with testing done by a third-party, were there any deviations? But instead people were incorrectly using Form 3654 more as

a declaration of conformity. And so because it created more confusion we no longer use it. But Form 3514, which is the CDRH Premarket Review Submission Cover Sheet, contains a section specifically for listing any standards used in your submission.

Irene Aihie: Thank you Donna. Operator, do we have any questions in queue?

Coordinator: Yes. Our first question is from Patricia Lehman. Go ahead your line is open.

Patricia Lehman: Hi hello. This is Patricia Lehman from Intuitive Surgical. Thank you so much for this Webinar -- very informative and for the opportunity to ask questions. I would like to know what the criteria is for the information put in the database when a standard changes revision and the agency publishes what the grace period would be. What's the criteria to actually have that information for some standards that get revised and not others?

Jianchao Zeng: So I will try to answer this question. So maybe Donna and Scott may add. So I think you are asking about the transition period. So as we mentioned that typically we provide a one year transition period to a product specific standard and two to three years or longer transition period for a horizontal standard that has multiple - that impacts multiple product types.

Patricia Lehman: So is this a horizontal...

Jianchao Zeng: Does that answer your question?

Patricia Lehman: So you wouldn't provide that information? There wouldn't be no transition period for horizontal standards? Is that what you're saying?

Jianchao Zeng: There will be the - yes in some cases we provide a transition period to horizontal standards which is a longer transition period than the product specific standard.

Patricia Lehman: Okay. I guess the - my question is if it's not listed, if a standard is revised and there's no information on the database that there is a transition period the agency would expect that the manufacturer would conform to the very latest revision that's recognized?

Jianchao Zeng: Correct right. If no.

Patricia Lehman: Okay.

Jianchao Zeng: ...transition period is provided that means that...

Patricia Lehman: Okay.

Jianchao Zeng: ...the older version is withdrawn and without a transition time.

Patricia Lehman: Okay understand.

Scott Colburn: Hi. This is...

Patricia Lehman: Thank you there.

Scott Colburn: This is Scott Colburn. I'm the director of the program and I want to just kind of expand on this because there's different situations that come into play when people ask about transitions. And first and foremost, please always realize that the use of a standard whether recognized or not is a voluntary aspect.

These standards are not incorporated by reference into statute or regulation where it is required for them to be used. The recognition provides a communication from the agency to a stakeholder on this is our current thinking on a tool that we think would be appropriate to use.

That being said, you know, when we recognize a standard for the very first time we will recognize it without a transition period because there is no other standard that that new recognition superseded. Even if that standard might be the third or fourth edition of it, if it's the first time the agency has recognized it, we will just recognize it because it's voluntary. It isn't required to be used in any sense.

The second part -- and this is the more common aspect -- is when a standard is recognized and then withdraws a previous edition that is already recognized as well. And that is when FDA will look at the standard and determine the impact of such standards transitional needs that was outlined in the slide that was discussed by Jianchao. You know, what is the impact of that standard towards the manufacturing changes, how does that impact possibly quality systems? What is the impact if that standard is traditionally done in a laboratory that needs to be accredited to such procedures, you know, because there's time that that takes?

Those are all elements that we take into consideration as well as we look at the public health advances that that standard may be addressing. If that standard is looking to try to help address a particular public health issue that we're seeing we will want to try to drive or encourage manufacturers to utilize the more current version. But they are still allowed to use the older version. In most cases a manufacturer may still be expected to address the differences in how public health, you know, situations are being addressed in the risk management file.

So there's different situations that can apply. So what we do is we try to identify that transition date and give it an appropriate thought process to make sure both that we're looking at it from the public health responsibilities that we have as an agency as well as some of the challenges for implementation. And then we do try to take into account that \$1 million question which is, what are other agencies from other jurisdictions around the world also doing to try to help with the harmonization aspect of that internationally as one of our responsibilities?

Patricia Lehman: That clarifies. Thank you so much.

Coordinator: We show no further questions at this time. But again, as a reminder please press Star 1 on your phone and record your name if you have a question. One moment please.

Irene Aihie: While we wait for further questions...

Coordinator: Our next...

Irene Aihie: ...Donna - oh the questions are coming in.

Coordinator: Our next question is from Ron. Go ahead your line is open.

Ronald Reitan: Thank you. This is Ron Reitan with Boston Scientific. I'd like to revisit this topic of transition periods as well. You mentioned earlier that your default period for vertical standards might be like one year.

And there are a number of product standards vertical standards for rather complex products and I'm going to bring active implants into that mix --

pacemakers, defibrillators, cochlear implants infusion pumps,
neurostimulators.

A revision to those types of standard certainly involves a great deal of complex issues with likely retesting a lot of verification testing, validations. One year in my own humble opinion is a totally inadequate period of time for such things. And I'm wondering if you're criteria which you haven't elucidated yet actually takes into account those level of difficulties for a revision to those types of standards?

Jianchao Zeng: Thank you Ron.

((Crosstalk))

Scott Colburn: Yes.

Jianchao Zeng: Thank you Ron.

Scott Colburn: Go ahead Jianchao.

Jianchao Zeng: Thank you Ron. Thank you for the question. Yes this is a good question. Actually, we had a lot of discussions on this.

The one year the typical one-year transition is in general given to product specific standard. However we are open to discussions on a case by case basis for difficult products as you mentioned for - to discuss the possibility of extending that period. So it's - but it's not a kind of a general case it is a case by case that some - is a discussion on the case by case basis.

So we did have this situations happen before and then we did extend the recognition for that purpose. So Scott you want to add more?

Scott Colburn: Yes and Ron this is a great question because vertical standards are impacted differently depending if they're a part of a larger series. And I think you're alluding to the IEC 60601/80601 family of standards where a lot of times impacts that come in on newer versions or amendments of those standards are based upon updates to more horizontal standards like the base or other collateral standards.

And in those cases, we see those more as horizontal impacts to a product standard which usually is impacting a series of product standards. And we tried to address that more from a horizontal aspect because we understand that there are larger things that come into play when looking at that.

But there is a difference between that and say maybe I'll just throw one out like a ASTM specific test method that's addressing just one aspect of a material characteristic. That is something that may be something that isn't needing as long as a transition period to address and that may see a shorter transition period.

So we do try to take into account what are the impacts to the changes being made to a product specific standard if they're coming in from horizontal aspects that would impact certain things that would take a longer time for a manufacturer to adequately prepare for. And so I kind of hope that helps illustrate a little bit of what we're trying to take into account when we look at appropriate transition periods.

That said we may not always get that right in our communication. And we do encourage you to contact us and we can have that discussion. We have also

been asking the standard developing organizations to have those types of discussions as well both at the national and international level so that way we can kind of hear and appreciate that during the development of the standard. And that allows us to communicate that into the agency to make sure we're doing an appropriate mechanism of communicating when that transition period should be set.

And more importantly if someone chooses to use the older standard how they might need to make sure that any changes between the two that would impact the safety and effectiveness or some aspect that's important to the overall regulatory review is addressed somewhere in the submission if appropriate.

Ronald Reitan: Thank you, Scott. If my line is still open here just a follow-up. I was referring primarily to the ISO 14708 series of standards which as you know consists of a general standard and several particulars for various device types. And a change to any one of those in my humble opinion would necessitate a longer transition period.

And I'm happy to hear that, you know, you're willing to take into account input from SDO, you know, ISO, IEC technical committees. Generally speaking we've seen, you know, FDA involvement in those committees in the past. And so I would hope that - by - through that participation they would see levels of difficulty that are coming into play and perhaps, you know, and not necessarily invoke a one-year default timeframe for a vertical standard like say ISO 14708-3 but rather set it appropriately upfront so we don't have to necessarily come back and have that somewhat protracted discussion.

Scott Colburn: Yes, well thank you Ron. And I think, you know, that series and kind of looking at, you know, even that version, the most recent version kind of that was the timeframe when we really started trying to address transition periods

more readily. Historically if we look back at a decade ago or more we rarely did transition periods. We really just did a withdraw and replace with a few exceptions for some really very broad standards in the 60601 series or the, like a 14971 risk management standard or maybe a sterilization standard.

Prior to the appropriate use guidance publication, we really didn't do that, but we saw the need to do so because we saw some of the struggles and challenges that were being placed. So with the appropriate use guidance in 2018 we really started making strides in making that part of our policy for recognition and then we further tried communicating it into this guidance.

So I think we're - what we're really trying to impress is, you know, for our own liaisons from FDA to sit on the committees to try to look into that as an aspect of how we should recognize the standard but more importantly or just as important to make sure that our stakeholders like our industry experts and those who sit on the standards committees also try to discuss those as an aspect of, you know, how the standards should be published or if it's an international standard and being adopted how that could be better communicated.

Ronald Reitan: Thank you for the feedback.

Scott Colburn: Yes.

Coordinator: Our next question is from (Steve Parrish). Go ahead. Your line is open.

(Steve Parrish): Yes, so good afternoon. I'm (Steve Parrish) with AbbVie. And I have to admit it's a very specific question but there's a particular standard for infusion pumps 60601-2-24 that's been out since 2012. And unfortunately it doesn't

fall on either list. It's not on the recognized list. It's not on the unrecognized list or the not recognized list.

And just thought I'd - we - those of us in the infusion pump industry have been dying to know why it's not on either list and I was wondering if anybody can provide an explanation as to why that is?

Scott Colburn: I'm happy to take the first swipe at that one if I may. There are, you know, some standards that we have not recognized that have not had a formal request for recognition. And a lot of times our non-recognition list which is new is - has really been addressing those types of standards that come in for a formal recognition and a determination for to not recognize it because it's not felt that it is suitable to support a declaration of conformity as to the appropriate decision.

The infusion pump standard that particular does have a bit of a history. And I think the agency's been trying to find better ways to communicate what's the appropriate information that would be supportive to make a regulatory determination through things like their guidance documents and so forth.

That being said we'd, you know, welcome if you feel that that is a standard that based upon the tools that the agency is providing such as guidance documents or other means that the use of the standard would help support, you know, some of the priorities that is - that are important to the agency as well as industry if we could look at that and put, you know, get that in play.

The use of the standard is not prohibited because it is not recognized. It's just that the agency feels that the use of the standard towards a declaration of conformity wouldn't be appropriate. And so for standards that one, that are

being used to not support a declaration of conformity should go through the general use platform that's described in the appropriate use guidance.

And that would permit the review staff a little bit more of (robust) of data that they would be looking at in comparison to a structure declaration of conformity that might only have a small summary test report. So this is something that we would encourage you to engage with the agency on and we'd be happy to have further discussion on a particular standard such as 2-24.

(Steve Parrish): Okay thank you.

Coordinator: Our next question is from (Sheryl Laforte). Go ahead. Your line is open.

Sheryl LaFond: Good morning, it's Sheryl Lafond's with Abbott Vascular. And I'm just curious do you have a metrics or some kind of way of identifying how much shorter your review times are or what the real visible measurable gains are for going that extra mile with the declarations of conformity to some of these standards?

Jianchao Zeng: Yes I can take a quick - a answer to this. The short answer is that it we don't have specific number but we did try to measure in some way to see whether a standard - the recognition or a declaration of conformity how much it will be able to streamline the review process.

So it is - so in general the use of recognition standard would be able to help with the reviewers to understand the design and the testing process. And then of course yes, if it is a standard that is recognized, both the manufacture and the reviewers understand the test method and the pass/fail criteria.

So we understand that it will help the review process and has streamlined the process instead of we're asking additional questions multiple times back and forth. So the answer is that we don't have a specific number but in general we feel that that's the benefit of using the recognized standard.

Sheryl LaFond: Of course. Thank you very much.

Scott Colburn: I'd like to just add - yes I'd like to just add a little bit on because the use of a declaration of conformity which is the premise of what we have under Section 514(c) in the act which is what developed the recognition program really was designed to try to help from the least burdensome principle to make it a little easier.

But back in 1997 when that provision was written standards were designed a lot differently too. They were more objective based and a lot easier to navigate from a test report standpoint.

And today we know, you know, through other avenues such as risk management stuff, standards are very complex. So there is a challenge in finding out what is that right element of information that's necessary to support a declaration of conformity.

We are - this is a topic that's of the utmost interest for our - for the agency and really for all regulators as to what's the right balance with the least amount of information that's necessary to support a declaration of conformity. And we're doing this in a couple different parts.

One is we're looking to try to do additional training such as like an industry basics that we're aiming for later this winter. We also have the accreditation scheme for conformity assessment pilot platform that's looking at different

approaches too of how we can bring that information into a more succinct and focused amount. And this should hopefully be a least burdensome approach.

The goal is really trying to make sure that there's clear communication between how it - a recognized standard is being utilized or tested to and how that is able to report a regulatory determination in a way that would reduce additional information questions and back and forth because that's where, you know, any extra effort in developing a declaration loses itself if we're asking questions on that aspect.

So I encourage you to kind of keep an eye on further information and communication from the program on this topic and also welcome any questions you have by just sending an email to us and we'd be happy to take that on.

Sheryl LaFond: Thank you.

Coordinator: The next question is from Jeff Eggleston. Go ahead. Your line is open.

Jeff Eggleston: Hi. This is Jeff. I work for Medtronic and earlier you indicated that requests for changes to the transition period will be considered on a case by case basis. What is the desired method to make this kind of request? Who does a manufacturer direct the request to and if the response is going to change and the transition period will be made what is the timeframe that we can expect before the change is seen in the database?

Jianchao Zeng: So Jeff thank you. So I think I have a quick answer to your question and then maybe Scott or Donna can add. So if you have a request for example to extend your - a transition period for a specific standard, a vertical standard, product specific standard you can send an email to the CDRH standards staff email

box or the contact information on the slides so that we can initiate this discussion either by email or by meetings so that we are discussing your request and wanted to know the justification behind it and then so we will understand it better.

And so basically we wanted to have or maybe consensus between us to see what is the appropriate time that we could extend that one year into something longer? So once the - a decision is made either to for example if we decide to extend that one year to another time, so then that would be putting to the next recognition cycle because the extent of recognition, change to the extent of recognition needs to be published in the Federal Register notice as well. So that would be put to next recognition cycle.

We usually have two recognition cycles, one in the spring and the other one in the fall. So if the discussion happened during the summer for example, so then the result will be reflected in the fall recognition cycle. Does that answer your question, Jeff?

Jeff Eggleston: Yes it does, thank you.

Coordinator: We show no further questions at this time. Again if you have a question please hit Star 1, record your name. One moment please.

Next question is from (Mark Swanson). Go ahead. Your line's open.

(Mark Swanson): Hi. This is (Mark Swanson) and I apologize. I think I should know this - the answer to this question but I'm not sure. Is there a formal recognition for process for TIRs or TRs that goes along with the consensus standards?

Jianchao Zeng: Yes so (Mark) thank you for that question. So as seen - if you search the standards recognition database you would be able to find a few TIR or TR Technical Reports or Technical Information Reports in the current recognized standards database.

So although we say that this is a standard database the TIR is not at the same level as standard, but some TIRs and some TRs are really helpful for the manufactures and other stakeholders. So we also review them for recognition.

Scott Colburn: Yes (Mark) this is...

((Crosstalk))

(Mark Swanson): So some of those TRs and TIRs might be associated directly with the application of a standard. Do you need a separate request for recognition of those or are those to be reviewed at the same time?

Jianchao Zeng: It's a separate document so I mean that would be a separate process. But for TIRs that are associated with a separate standard, we probably would not recognize it as a separate standard that - so it is associated with the standard. So we prefer to for example to list it under the guidance and supportive documentations of the recognition of the standard itself instead of recognizing this separately. So that would be probably more useful for the user.

Scott Colburn: And (Mark) this is Scott Colburn. I want to kind of just elaborate on Jianchao's answer a little bit too. Remembering that a standard that is recognized under Section 514(c) is one that would be able to be utilized towards a declaration of conformity. And we know some TIRs and other types of similar documents are more guidance based. They're helpful tools in the use of a certain standard.

So what we do is we first and foremost try to evaluate the document to make sure is it something that one that could independently stand on its own towards a declaration conformity? And if so it would then make sense to give it its own recognition number. If it's a tool that would help on the understanding say of, you know, the risk management or other standards that have, you know, documents associated to it, we would reference it underneath relevant guidance and work towards that.

One of the things we're actually working to try to do is expand the capabilities of our database to maybe even allow a separate page that doesn't report the standard of a "recognized standard" but, you know, a little bit more description of that TIR where it would be referenced into other recognized standards to give a little bit more explanation for users. But that is something that we don't have yet developed but it's something we're working to do.

But in these types of documents we always want to hear from folks that have worked the development or if they think they would be helpful to either on their own right or as a part of a recognized standard be used just yes again, contact us and we'll work through that process with you. And, you know, we would kind of treat that similar to coming to a, you know, a recognition request.

Coordinator: Our next question is from Ronald Reitan. Go ahead. Your line's open.

Ronald Reitan: Yes this is Ronald Reitan again. This is a separate question about the application shall we say or declarations of conformity to standards that have just been revised and not yet recognized. A classic example of course is as you know 60601 family has just undergone revision here in August, September October timeframe. And we may have needs to demonstrate

conformity to those latest additions before they are recognized, not knowing what the shall we say, maximum timeframe is that FDA would recognize those updated 60601 standards. Where do you stand when we're in this in-between zone?

Scott Colburn: So Ron that's the opposite end of a transition question is what do you do...

Ronald Reitan: Yes.

Scott Colburn: ...before a standard is recommended I guess, right?

Ronald Reitan: Yes. And, you know, obviously we have state-of-the-art requirements for European MDR submissions as well. And that puts us between somewhat of a rock and a hard place on occasion where they're looking for the state-of-the-art standard and maybe FDA has not yet recognized it and we would like to of course avoid having two sets of paperwork at all cost.

Scott Colburn: Yes.

Ronald Reitan: So...

Scott Colburn: No I'm - yes, we try to be timely in recognizing standards but realize that we also, you know, look at this in batch cycles as well. We are looking at standards that we're engaged with and many of the ones you're referring to we are as they publish and discuss it through our process to put it up for recognition.

The thing I just wanted to put out first is that, you know, standards are not mandatory that are recognized unlike some other jurisdictions. And I, you know, while a declaration conformity itself would not necessarily be the

appropriate way to identify a new standard not yet recognized, the use of that standard itself may be appropriate just because it's, you know, most likely addressing issues of that in more recent and would, you know, tell the story that you're trying to develop in your submission letter.

But, you know, at any time that you are curious as to what agencies interest is in particular standard, you can always submit that request in to us. But we do try to be timely on standards as they come out. And we are actively looking at, you know, the collaterals and the base standards that most recently came out in this series to try to determine which ones would be recognizing the appropriate transition period, et cetera, et cetera, and we hope to be able to do that in a short time.

Ronald Reitan: So a follow-up question there Scott is does FDA have a policy in place as to the maximum time from publication of a new standard or a revision to when they would issue a decision on recognition?

Scott Colburn: We don't know. The simple answer is no. And the reason being is we don't sit on every committee. You know, I did a little study a while back. We have almost 4000 standards in the medical device community and that's probably still not the correct number. It could be much higher. We obviously don't sit on every one of those committees to have...

Ronald Reitan: Understood.

Scott Colburn: ...the knowledge of that. But what we do try to do is work with our subject matter experts throughout the development process of the standard to understand when publication will be coming and anticipated recognition request or determination by the liaison.

But we also are interested throughout the development process what issues are being raised, how are comments being addressed, are there other avenues that we need to consider throughout the development of standards especially some of the large impactful ones that might engage with current guidances and other things.

So the process of looking at recognition really starts with the engagement with that standards development process. And that has allowed us to get recognitions out, you know, within a month of standards publication whereas, you know, I member a decade ago we were sometimes waiting five, six, seven years to recognize a standard because we weren't engaged in those earlier stages.

So I think, you know, you should see a determination coming out, you know, hopefully within this calendar year. And if you have further questions too on how to apply brand-new standards into, you know, a submission you could always try to reach out to that review team, that OHT specific to see how that would be best applied. And I think they'd be able to give you a better more concrete answer for those particular types of devices.

Ronald Reitan: Thank you.

Coordinator: Our next question is from (Elizabeth Hansen). Go ahead. Your line is open.

(Elizabeth Hansen): Hi. Yes, this is (Elizabeth Hansen). And I guess I just wanted to comment on or ask for some clarification I guess with one of the comments that Donna had made during the - while we we're waiting for questions and the fact that she did say that the Form 3654 was discontinued and that we just go ahead and list the standards of conformance in our - on our coverage - on the 3514.

When so we do that going forward or when did the 3654 become discontinued? Is that with this rollout or what - at what point can we discontinue the use of the 3654 and just simply rely on the body of our work and the 35 and just rely on the 3514 for listing out our standards, conformance of standards?

Donna Walsh: So we still have to, if you're going to submit a declaration of conformity you do you still need to submit that. It's not included as part of Form 3514. I don't know the exact date. Scott do you know when Form 3654 was discontinued?

Scott Colburn: Yes so this was done in conjunction with the more the appropriate use of voluntary consensus standards in premarket submission guidance that was published on September 14 of 2018, so a little over two years ago. At that time that form was officially deleted, removed and we focused on making sure people communicated their appropriate uses standards in accordance with the publication of that guidance.

Form 3514 actually updated itself about a month or in August of this year. But that is the cover sheet form for submissions. It's not a mandatory form...

(Elizabeth Hansen): Right.

Scott Colburn: ...like form 3654. But what we did with that form was, you know, the old form only allowed you to list five or six standards and then you had to write everything else, you know, on the back sheet of a paper somewhere.

(Elizabeth Hansen): Right.

Scott Colburn: The new form allows you to build out, you know, other standards that you're using, so what standard is it? If it's recognized what's the recognition

number? If you used it, did you use it towards a declaration conformity or general use and where in the submission is that addressed?

And it really is just designed to help people find where and how a standard is used. It doesn't go down the road of, you know, what is your declaration conformity look like or things of that nature. We would expect to see that in the submission elsewhere based upon the appropriate use guidance. Does that help?

(Elizabeth Hansen): Yes I guess so we - but what I'm - what I am hearing about is we're not using the 3654 any longer. That's not the form that we're using. We're simply using 3514.

Scott Colburn: Yes and 3514 isn't really designed for standard. That's just the standard cover sheet form. 3654...

(Elizabeth Hansen): Right.

Scott Colburn: ...was a form dedicated to standards use on standards data that was being collected for a different purpose but it was never...

(Elizabeth Hansen): Right. It was used for performance (unintelligible).

((Crosstalk))

Scott Colburn: ...truly appropriately assigned or well understood so that was removed when we did the appropriate use guidance in 2018.

(Elizabeth Hansen): Okay. And it was done away with. And so on the appropriate use of guidance in 2018 is the...

Scott Colburn: Yes.

(Elizabeth Hansen): ...(3654) was done away with okay.

Scott Colburn: Yes that was about yes on September 14 of 2018 was when that was kind of done in conjunction with that.

(Elizabeth Hansen): Okay.

Scott Colburn: Now...

(Elizabeth Hansen): Okay.

Scott Colburn: ...I'll admit we still do see people using it, but you shouldn't be able to download it really anywhere from the - an FDA site because I don't believe we have it existing in the - anywhere.

(Elizabeth Hansen): In the FDA Web site, okay. I still see it floating around...

Scott Colburn: (Unintelligible).

(Elizabeth Hansen): ...and so I was - I just wanted to double check and then I didn't - and I thought I didn't know if there was something that was in place of it that I had - was using inaccurately or what. So I just want to double check and I heard her talking about it so I thought well now's my chance to ask.

Scott Colburn: Thank you.

(Elizabeth Hansen): Okay, thank you guys.

Donna Walsh: Sure.

Coordinator: We show no further questions in the queue at this time. Again as a reminder please press Star 1 on your phone and record your name if you have a question. One moment please.

One moment please. I see a question coming in. And we show no questions at this time. I'd like to turn the call over to Irene.

Irene Aihie: Thank you (Dustin). Before I close out Donna, I'm going to turn the call over to Donna Walsh.

Donna Walsh: Thank you Irene. Yes, just some closing remarks just to recap. So we - the recognition and use of consensus standards is an important element of regulatory science at FDA as we've discussed today. And our final guidance explains the updated procedures that FDA intends to follow when we receive requests for recognition of consensus standards and when we withdraw recognition of a consensus standard.

So in summary, FDA will publish the rationale for our recognition and non-recognition decisions. We may specify a transition period for revised standards when appropriate. We will intend to respond to recognition requests within 60 days. And finally, when FDA makes a determination to recognize a standard we will update the recognized consensus standards database and at that point the standard may be cited in a declaration of conformity.

Manufacturers will no longer have to wait for the official recognition with the publication of a Federal Register notice. And there are more information in

the resources that will be included in the slide deck. And I now turn it back over to Irene.

Irene Aihie: Thank you, Donna. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcripts will be made available on the CDRH Learn Web page at www.fda.gov/training/cdrhlearn by Friday, October 23. If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation.

As always, we appreciate your feedback. Following the conclusion of the Webinar please complete a short 13-question survey about your FDA CDRH Webinar experience. The survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's live Webinar. The survey is also available on the last slide of today's slide presentation. Again, thank you for participating. This concludes today's Webinar.

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time. Speakers please allow moment of silence and standby for your post conference.

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