

FDA Webinar: of Voluntary Consensus Standards; Final Guidance

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

Coordinator: Good afternoon and thank you all for holding. Your lines have been placed on a listen-only mode until the question and answer portion of today's conference. I would like to remind all parties the call is now being recorded. If you have any objections, please disconnect at this time. And I would now like to turn the all over to Irene Aihie. Thank you. You may begin.

Irene Aihie:

Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn page at www.fda.gov/training/CDRHLearn, by Friday, November 2.

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 you FDA CDRH webinar experience. The survey can be found at FDA.gov/CDRHwebinar

immediately following the conclusion of today's live webinar. Again, thank you for participating and this concludes today's webinar.

Scott Colburn: Hello and welcome to the Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices webinar. My name is Scott Colburn, Director of the Standards and Conformity Assessment Program.

Before we start, I want to congratulate all of the staff in CDRH and CBER and the many stakeholders who have contributed to this guidance and the many areas where scientific research, standards development, conformity assessment, and regulatory science intersect.

Also of note is the publication of our 50th Federal Register Recognition List this week that incorporates many of the areas we will discuss today. Also, just a few hours ago we recently opened our Accreditation Scheme for Conformity Assessment Web site that we encourage you to go to and learn a little bit about this new draft program that's taking place under the MDUFA IV negotiations.

I also want to wish everyone a happy belated world standards week that took place last week and congratulate the American National Standards Institute on its 100th anniversary. It is an exciting time for standards.

In today's webinar I'll be going over the evolution of this guidance document from the 2014 draft and the changes that were incorporated in the 2018 final. We'll look at the areas that we discuss regarding the Declarations of Conformity, what we talk about when we discuss the 'General Use' of standards, how FDA does a review of a Declaration of Conformity, and what is the supplementary information FDA talks about versus the supporting

documentation we receive in how standards are used, and finally well turn over to some questions and answers at the end.

The take home message from stakeholders who commented to the draft guidance were for the Agency to follow least burdensome principles when requesting test reports, provide consistency across the center with regards to data requests, test summaries, or complete test reports, and to provide increased transparency about how standards are applied across review offices and divisions.

Of particular concern, reducing paperwork with regards to form 3654 which required a form for each standard used within a submission. We have heard your comments and will be addressing them and talk about them throughout this webinar.

At the end of the webinar for any type of submission you will be able to determine whether or not to provide the Declaration of Conformity or elect to use the standard in general use. If you elect the option to provide a Declaration of Conformity or DOC, you will learn what elements to provide and the supporting documentation to include, if any, or whether to provide a complete test report.

If the option to use the standard is the general way as a reference, you will learn also what and when documentation should be included and when it should not.

We are here today to discuss the guidance entitled The Appropriate Use of Voluntary Consensus Standards in Premarket Submissions that was issued on September 14, 2018. The FR notice of draft guidance was issued on May 13, 2014 and the guidance proposed two policy changes that were basically the

overarching principles discussed in this draft. First was that the Declaration of Conformity would no longer be acceptable when the submitter deviated from the normative requirements of a recognized consensus standard. The second proposal is for promissory statements indicating future conformance with a consensus standard to no longer be used in the form of a DOC.

The comment period closed August 22, 2014.

We received several comments from many stakeholders that included standards developing organizations, regulated industry, industry advocacy groups, and consumer advocacy groups. Some comments related to the first policy change, that of deviations within the Declaration of Conformity. Others were related to promissory statements specifically requesting to maintain the ability to promise within the context of a Declaration of Conformity and stating that testing should be done before market.

Several other comments were in the general category, but we also received several regarding the use of Form 3654 being burdensome and how that affects the communication of the standards used in the submission as well as discussions on transition periods when we do withdrawals to standards that are being superseded by new ones recognized.

We'll be discussing about these different areas of comments throughout the rest of this webinar.

With the final guidance we incorporated the 21st Century Cures Act which amended section 514(c). We clarified that deviations may be made to a standard but not within the context of a Declaration of Conformity. This would be general use as described in the guidance.

We also clarified our position on promissory statements in that if you choose to rely on a recognized standard or a guidance for any part of the device, design, or testing you may include either a Declaration of Conformity or a statement that testing will be conducted and meets specified acceptance criteria before the device is marketed.

Because the Declaration of Conformity is based on results from testing, we believe you cannot properly submit a Declaration of Conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the act.

We adopted for use ISO/IEC 17050-1 and -2 which clarifies the content of a Declaration of Conformity and the accompanied supporting documentation that underpins the extent of Conformity and how it was assessed. Also, we are now also including the transition period for all standards that are withdrawn and replaced with newer version.

Lastly, form 3654 is eliminated because the elements of the form are addressed by the Declaration of Conformity that we'll be discussing as outlined in ISO/IEC 17050-1 and -2

The 21st Century Cures Act of 2016 (Pub. L. 114-255) modified Section 514(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to clarify how the FDA will process requests for recognition of voluntary consensus standards. Any interested party may submit a request for recognition of an appropriate standard established by a nationally or internationally recognized standard development organization. Specific changes included: adding a 60-day timeframe for FDA's response to recognition requests, directing FDA to publish on its website its rationale for recognition of all, part, or none of a standard that is subject of the request and issue a statement to the requester of its rationale for that determination. The statement will

include the scientific, technical, regulatory, or other basis for the determination, requiring training for all FDA reviewers of premarket submissions, and requiring FDA to provide periodic training on standards. Of note, FDA has a draft guidance document titled Recognition and Withdrawal of Voluntary Consensus Standards that is open for comments until November 13, 2018, where much of this is outlined.

So what is a Declaration of Conformity or DOC? The DOC is an attestation from the submitter that the device conforms to all the requirements of an FDA recognized consensus standard at the time of submission. If the submitter declares Conformity to an FDA recognized standard, a Declaration of Conformity must be included in the premarket submission.

The purpose of a Declaration of Conformity is to reduce the amount of supplemental data and information that is submitted to FDA.

So what does this mean? FDA expects that all testing required by the consensus standard will be performed and conformance to the consensus standard will be met before premarket submission. All normative requirements have been met and most testing conducted on a finished device or a final finished device.

In the past, the composition of a Declaration of Conformity was based on ISO/IEC Guide 22 which is no longer in publication and has been updated and replaced by ISO/IEC 17050-1 and -2.

What is a finished device? Under 21 CFR 802.3(l), a Finished Device is “Any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.” A Final Finished Device is any device that includes all manufacturing processes for

the “to be marketed” device, including packaging and sterilization, if applicable.

Everything you need is here. The Declaration of Conformity should include these elements:

- name and address of the applicant or sponsor responsible for the Declaration of Conformity
- the product or device identification
- the Statement of Conformity
- a list of standards or which the Declaration of Conformity applies including, for each standard, and the options selected if any
- the FDA recognition number for each standard. *Remember, you can only submit a Declaration of Conformity to a recognized standard by FDA*
- the date and place of issuance of the Declaration,
- signature, printed name, and function of the applicant or sponsor responsible for the Declaration of Conformity, and
- any limitation on the validity of the Declaration of Conformity.
 - For example, how long the Declaration is valid, what was tested, or concessions made about the testing outcomes.

If you really think about it, the only change that we have placed into the new guidance is listing the recognition number of the standard you’re submitting in your Declaration of Conformity. Everything else has remained the same since the previous guidance.

The next few slides are examples of what Declarations of Conformity may look like. And there are other examples out there as well. But one here shows everything that you would be presenting. The Declaration of Conformity calls out the elements of 17050-1, gives the name and address of the sponsor, the product and the device identification, the statement of Conformity, and lists the standards for which the Declaration of Conformity applies.

Here you see the recognition numbers, the date and place of issuance, and the signature and printed name as well as any limitations on the validity of the Declaration.

Alternatively, I'd like to show you another example. Here you'll see we also have the Declaration of Conformity to IEC 60601-2-37 under the recognition number of 12-293. But you'll see that the two other collateral standards of IEC 60606-1 or in the case of FDA's recognition the ANSI/AAMI ES60601-1 and the IEC 60601-1-2 are not included.

If you think of how the body of standards work with the particulars in the 60601 family, there's no need to include the other normative standards separately as they are already called out as being requirements that satisfy the vertical standard.

This is an example different ways one can present the Declaration of Conformity discussing the different manner to which a particular standard incorporates other normative references and/or recognized standards.

Now I will note and I am aware that the ANIS/AAMI ES 60601-1 standard is not normatively placed as a requirement in [60601]-2-37. However, FDA only recognized the ANSI/AAMI ES version and therefore FDA would expect that testing conducted to meet that normative requirement in the particular would be that of the recognized version of the standard.

Normative references -- Why are normative references used in consensus standards? Simply put, the use of normative references promotes harmonization and saves resources, referencing common elements, promotes uniformity or requirements and avoids the inevitable divergence of

requirements that result when different groups of experts develop solutions to common problems.

Using normative references in an FDA recognized consensus standard towards Declaration of Conformity can reduce the amount of documentation. Maybe less obvious is the savings in human resources as well. Smart standards writers did not reinvent the wheel; they use current standards to help the normative requirements in their existing standard. They reuse what is best in existing standards and that apply to the particular situation through the use of normative references.

So what do we mean by a normative reference in a consensus standard? Again, consensus standards generally have two type of references. First they have a bibliography which consists of informative references that are useful in understanding the requirements of the standard and may be used in conjunction with the standard.

Second, consensus standards may contain a section that details designated normative references. In ISO and IEC standards, normative references are listed usually in clause two of the standard. The purpose of normative references is stated in the boilerplate used for references – *“The following reference of documents are indispensable for the application of this document.”*

This simple statement does not say that the entire reference standard or standards must be used in order to demonstrate Conformity to the standard. It merely states that you can't apply the standard without the knowledge and appropriate use of these normative references. Plus, the difference between an informative reference and a normative reference in a consensus standard s that you're free to refer to the former, but you must refer to the latter.

How do requirements of a normative reference get incorporated into the requirements of a consensus standard? In order to incorporate the requirements of a normative reference into the requirements of a consensus standard, those requirements must be referenced within the body or normative section of the consensus standard. Thus the normative reference made at the introductory part of the consensus standard is a precursor to the statement that the actually normatively referenced requirement stated later on.

Once such a reference is made in the body of the standard, Conformity to the standard includes a requirement cited in the normative reference as well as the stated requirements of the consensus standard.

So do all the requirements of the normative reference apply? Again, and discussed a little bit earlier, the use of normative references is usually limited to that specific clause or clauses that are necessary to achieve the goals of the consensus standard they are normatively referenced into. In some cases, just a single clause will be incorporated into the requirements of a consensus standard.

In some others, the normative references are incorporated in its entirety. It is important to note that the user, tester, manufacturer, as well as the reviewer of a Declaration of Conformity and test reports understand how the normative references apply to the standard which the Declaration of Conformity is being submitted.

So does FDA recognition of a standard mean that all the normative references are automatically recognized? No. Normative references are recognized by FDA only to the extent that they are used within the FDA recognized standard. Such normative standards are not automatically recognized as

independent entities unless it is felt that independently the use of those standards would also be useful to support the relevant parts of the Act under 514(c).

Knowledge of the normative reference should be used to apply a recognized standard. Normative references do not typically reference the entire standard. Rather, the normative references are typically limited to a specific clause or clauses. The citation of the normative reference should provide information on the extent the reference is limited or applied.

So as we all remember back in the 80s the statement “Where’s the beef?” When we’re talking about a Declaration of Conformity, ISO/IEC 17050-2 Conformity assessment part two - Supplier’s Declaration of Conformity, the supporting documentation sets forth the requirements for documentation to substantiate a Declaration of Conformity.

There are circumstances when supplemental documentation is necessary to support a DOC or Declaration of Conformity. The type of information a sponsor should submit and the FDA needs to review as supplemental documentation will vary based upon the specific consensus standard.

However, the following general principles should govern the need for and review of supplemental documentation. At a minimum, the following questions should be asked of the standard -- a description of the object under test and whether that is a final device, final finished device, or an attribute of the device; a description of the test method or procedure and whether Good Laboratory Practices or Quality System Regulations were followed; the results of the testing and acceptance criteria; and an assessment and results of how the normative requirements were met, including rationales for any selection, adaptations, modifications, or concessions that were made.

So what is the difference between a Supplementary Information Sheet and supplemental documentation to a Declaration of Conformity? The supplementary information sheet is CDRH's determination of how the recognized standard may be used in CDRH's regulatory activities. For example, a supplementary information sheet or SIS may describe the select the sections or clauses in the standard that are excluded from FDA's recognition.

Supplemental documentation describes how the medical device conforms to the FDA recognized standard. For example, supplemental documentation may describe the acceptance criteria and rationale for selecting those criteria to demonstrate the essential performance of a medical device.

Specific guidelines exist to help determine whether or not supporting information should accompany a Declaration of Conformity.

Supporting information should accompany a Declaration of Conformity when:

- an FDR recognized consensus standard describes a test procedure but does not include performance limits or pass fail criteria. The submitter should provide an assessment of the results and how Conformity was determined, When the FDA recognized consensus standard includes choices related to for example, what is to be tested, which test methods to use, or the performance limits to test Conformity, or when it describes a process like risk assessment, the submitter should include an explanation for those choices and the selections made.

Supporting information should not accompany a Declaration of Conformity when: the FDA-recognized consensus standard includes both a test method or procedure with the predefined performance limits or acceptance criteria.

FDA should not request the data related to the specific consensus standard identified in the Declaration of Conformity when those exist. When there is more than one standard, for example -- one a test method and one with acceptance criteria -- or when the FDA recognized consensus standard is a design standard. These are the areas to which a Declaration of Conformity by itself under ISO/IEC 17050-1 should meet the required elements to support the Declaration.

During review of a premarket submission in which a Declaration of Conformity has been submitted, FDA will review the Declaration of Conformity and determine whether the following have been met:

- the elements in this guidance as well as ISO/IEC 17050-1 are present,
- the standard or standards identified in the Declaration of Conformity are recognized consensus standards,
- there have been no deviations made to the normative requirements of the FDA recognized standard identified,
- the FDA recognized standard in the Declaration of Conformity are or is applicable to the medical device under review,
- the supporting documentation - if determined to be necessary per ISO 17050-1 - is provided according to ISO 17050-2 or equivalent,
- the data or information submitted to support such Declaration demonstrates that the device is in Conformity with the normative requirements of the standard,
- the Declaration of Conformity does not include a promissory statement.

If any of the elements above are not met, FDA will review any explanation provided by the sponsor to determine if it is adequate to support the Declaration of Conformity or may request additional information to meet those requirements.

So why Can FDA Rely on a DOC? Let's talk about the reasons we can rely on the Declaration of Conformity. We know Declaration of Conformity is an official statement and falsification of a Declaration of Conformity submitted under section 514(c) of the FD&C Act is a prohibited act.

Under section 501(e)(2) of the FD&C Act, a device is adulterated if, among other conditions, it is declared to be in conformity with a recognized consensus standard unless the device is in all respects in conformity with such standard. 21 CFR Part 58 Good Laboratory Practices establishes quality and reliability of how labs will conduct non-clinical laboratory testing.

The Quality system regulation in 21 CFR part 820, by which a manufacturer must also establish and maintain procedures for validating a device design and monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.

By note, this is also similar to requirements in other quality system standards such as ISO 13485.

And laboratory accreditation under ISO/IEC 17025, ISO/IEC 17043, and other areas within the ISO/IEC 17000 series as well as ISO 15189 for clinical laboratories -- these series of standards set forth a system for how labs will be operating when they are accredited through these schemes and how it supports the adequacy of a Declaration of Conformity.

So let's talk a little bit about complete test reports. Complete test reports are requested when a Declaration of Conformity is not provided or the standard has neither test methods or predefined acceptance criteria or deviations have been made to the recognized standard. In any of these situations, FDA would expect to see a complete test report so that it could understand those adaptations or modifications to testing in the product or device.

This table from the guidance document outlines FDA's expectations regarding submission of supplemental information for different types of FDA recognized consensus standards. Use this table during your reviews or the submission and development of your submissions to help indicate that supplemental information that may be necessary to support how you're appropriately using the standards.

'General use' of a consensus standard in premarket submissions is when a submitter chooses to conform to a consensus standard in part or in whole, but does not submit a Declaration of Conformity.

Reasons for general use of a consensus standard vary but may include: the manufacturer's chosen to use a recognized standard without submitting the Declaration of Conformity; the manufacturer has deviated from the FDA recognized consensus standard methodology to adapt its purpose to test the device, or the manufacturer has chosen to use a non-recognized consensus standard or an older version of the standard that is no longer recognized.

Standards may change before, during, or after review and this is where we talk a lot about transition. Before review [of a submission], standards may be updated or revised and the newer version recognized during product development. This may present challenges to submitters. FDA values and encourages early interaction with submitters to ensure scientific issues are addressed prior to the submission of a marketing application for a device, including the discussion of the changing standard.

The submitter is encouraged to engage with the agency regarding the strategy for addressing the differences between the two standard versions and whether those differences significantly affect the evaluation of safety and effectiveness. This is because it may not be necessary to comply with all parts

of the revised standard, only those parts that significantly affect the evaluation of safety and effectiveness.

During review: Generally while a submission is undergoing active review and in the interim, a consensus standard is updated or revised and recognized, FDA will continue to review that submission based upon the previously recognized version.

If the updated or revised consensus standard addresses a new safety or effectiveness issue that is relevant to the final decision of that submission, and if that information is not described elsewhere in the submission, FDA may ask the submitter to either meet the portions of the new or updated standard that addresses that safety or effectiveness issue, or provide alternative data or information along with scientific rationale for why the alternative addresses the issue.

After review, just as standards may be revised before submission they most certainly will be revised after clearance or approval is granted. Changes in the recognized consensus standard do not retroactively affect the product's clearance or approval status.

Similarly, once a consensus standard is recognized, recognition of its revisions is not automatic. In general, FDA actively assesses the impact of new consensus standards and revisions of existing standards on the premarket review process and recognizes these standards as appropriate. As new or revised standards are recognized by FDA, the recognition will be published in the Federal Register and listed on the CDRH Web site.

FDA performs the activity twice annually or more often. Superseded standards that FDA has withdrawn from the list of recognized standards

cannot be subsequently used towards a Declaration of Conformity. If a submitter receives clearance or approval based in part on the Declaration of Conformity, but the standard is withdrawn from recognition, the cleared or approved device remains legally marketed and remains eligible for 510(k)s as a predicate device.

However, any new device citing such predicate in a 510(k) submission cannot similarly rely on the Declaration of Conformity to the standard no longer recognized. In these circumstances, FDA would likely recommend that the submission use the newer, currently-recognized version.

Which brings us to transition periods. As we discussed three areas where transitions could apply to the premarket review. [FDA] looks at transition periods where standards have been withdrawn and replaced by newer versions. We look at the impact of that standard and try to specify the amount of time to which the outgoing standard should remain, in effect, a recognized standard until it is officially withdrawn. That information is contained in the Supplementary Information Sheet or SIS below the extent of recognition.

Standards that do impact large broad areas such as the Quality Systems Regulations or other major horizontal processes will typically receive a longer two to three year transition. We also do consider the ISO/IEC implementation withdrawal dates listed or if other standard developing organizations make recommendations and try to take other information that is available to the Agency to take into account the impact or a transition period during the recognition of a newer standard.

Why? This allows a submitter to continue to test and develop without additional retesting, allows time to revalidate processes under 21 CFR 820.75(b), and allows testing laboratories time to revalidate new test methods.

A promissory statement or note is defined as a statement in which the submitter indicates that the device is not yet known to be in conformance with consensus standards at the time of the premarket submission but will conform to the consensus standard before marketing. Promissory notes are used in certain situations such as installation requirements, chronic or long-term testing or postmarket testing.

Although a promissory statement describes a situation where a submitter states that they will conform to a recognized consensus standard in the future, submitters may not use a Declaration of Conformity with a promissory statement. I'll say that again. Submitters may not use a Declaration of Conformity under 514c with a promissory statement. Submitters may only use a Declaration of Conformity to a recognized standard if conformance has been met prior to the submission.

Pending recognitions and the intent to recognize -- this is something new that we introduced to this guidance document. Within this guidance, FDA has declared its intent to recognize a standard when the Recognized Standard's Database is updated. The database is refreshed once a week usually. The Standards and Conformity Assessment Program will update the database when the sender has developed a Supplementary Information Sheet (SIS) to a newly recognized standard that the Agency intends to recognize. And will include a recognition number so stakeholders can begin to use the standard.

A list of pending recognitions will be included in the subsequent upcoming Federal Register Notice that we put out once or twice a year.

The dates of standard is entered into the recognition database. It is the effective date of recognition that you would apply in the use of that standard.

This slide is just a list of resources that are utilized by both the CDRH Standards and Conformity Assessment Program as well as the agency's use of standards and across the federal government.

At this time, this concludes the content in the webinar. I want to thank everyone for joining and I guess we will open up for questions.

Coordinator: Thank you. And at this time if you would like to ask a question, please press star 1. Please unmute your phone and record your name clearly when prompted. And if you would like to ask a question, please press star 1. One moment please.

Scott Colburn: So while we are waiting for the first question, some of the questions that come in have been regarding transition and when we put out a transition dates that we listed on the most recent recognition list that came out on this week regarding transitions of 12 months for certain standards.

And I'll be quite frank and transparent with you. This is an area that we are still building a base of knowledge to help understand the impact and do encourage stakeholders to contact us if they feel the transition date that was selected may not follow the principles that we have in our guidance.

We understand that many cases standards that are vertical based or product specific, in our eyes, tend to possibly require less time for appropriate transitions. But we also may not take into account some of the research and development activities that are going on at the early stages of the design control process. Information like that is helpful in our understanding of applying the appropriate amount of transition applied. That is one area that I think is real important.

Another one is where standards have been updated that are not yet cited in the parent standard where a 'Declaration' is being submitted -- and I discussed this a little bit. It is appropriate to use a newer standard, say an ASTM test method that specifies the durometer on how would you assess the hardness of a material, that is not yet incorporated into a product specific standard and a new version of that test method has come out? Can you utilize that test method and still be in conformance with the recognized standard?

This is one of those where it does depend and you need to make sure you assess the impact of the newer standard and the use of that newer standard and where its normative references are incorporated appropriately still meet the requirements of the standard to which you are submitting a Declaration of Conformity or the general use to.

And so these are just a few examples of how you can make that assessment because, as we know, normative references that exist in a parent standard may be updated during the course of or immediately after the publication of another standard and that test laboratories -- especially those in the accredited environments -- may be using those newer standards to maintain the current state of art or practices that are currently being utilized at that time.

So I will pause to see if we have any questions.

Coordinator: And as a reminder to ask a question please press star 1. Our first question today is from (Vivian).

(Vivian): Hi. My question again is related to the transition period. So when a revision of an existing standard is out there, I see you know that a transition period is posted in the location that you mentioned. But when it's a brand-new standard

that gets, you know, recognized is it -- I'm trying to understand -- is it the expectation that from the time it gets posted from that date that you know we would start showing compliance? Or what the expectation from a transition period is for new standards that come.

Scott Colburn: So (Vivian) I'll try to answer the question from two different directions. And one would be if you are developing a new product that would require FDA to evaluate. Standards first and foremost that are recognized, are voluntary, and are not requirements. We feel that they are tools that are suitable to help tell the story of what you are trying to explain in your submissions. So the use of them are voluntary.

But when a new standard does become recognized, we do hope that manufacturers will use them as appropriate to support their submissions that are coming in. So that would be one way to help and I think create a common line of understanding between the review staff who are familiar with the standards that are recognized and what would be coming in.

The second side of that question though is -- and I received a similar question on this just this week from a manufacturer -- is what happens to a legacy product when the new standard is being recognized and are we expected to be in conformance of that [newly recognized]standard?

And I believe I described that earlier in this webinar where a legacy product is not required to have to demonstrate to the agency that you have updated your file to the newer standard. However, I do note that in many cases the Quality System Regulations and/or quality system standards do ask for a process improvement or quality improvement where you do assess newer standards/methods to see if you're maintaining the state of art activities that would support the quality of a device.

(Vivian): Okay. Thank you.

Scott Colburn: Next question?

Coordinator: Thank you. Our next question is from (Eric Kellnas).

(Eric Kellnas): Hi. This is (Eric). Thank you. For 510(k)s I just would like to confirm that the Form 3654 is no longer required and would not be looked for under the review to accept criteria. And they would just be looking for, you know, the DOC and supporting evidence. Thank you.

Scott Colburn: Yes, thank you (Eric). I've been looking forward to repeating that question as many times as I can! We've been talking about Form 3654 since the development of this guidance. So yes, Form 3654 has been deleted. It is no longer on the RTA -- refuse to accept checklist -- that I think was updated 2016 where it removed that requirement and well as in this guidance.

Because we had seen so many different ways the form had been utilized, and its intent was actually never fully incorporated to collect standards data the way it was when first developed. The form has hence been deleted and we are recommending that you just clearly identify through the tools in this guidance whether it be a Declaration of Conformity or citing the standard in its general use or even using tools such as Form 3514, which is the cover sheet and has an area which you can outline what standards are being used. Those are the areas that will give the information that should be sufficient enough for the review staff to understand how/where the standard is being used.

So in short, no the form is no longer required and I even tried to look for it online and I couldn't find it!

(Eric Kellnas): Excellent. Thank you.

Coordinator: Thank you.

((Crosstalk))

Coordinator: The next question is from (Andy During).

(Andy During): Yes, good morning Scott. Thank you very much. My question -- the committees that I'm participating in have had and continue to have representation from the FDA helping to shape the standard as it's being developed. So I'm wondering one, would that participation on a committee still necessitate somebody requesting the standard be recognized or could we assume that the goal is to recognize that standard -- the goal of participation and consensus with the content would be to FDA recognize the standard?

Scott Colburn: That's a great question, (Andy). And that serves a number of purposes. So yes, as many people know we do participate on several working groups and committees across almost three dozen standard developing organizations. I think on a little over 600 different working groups. But we don't know all standards that are being developed.

And as technology is being broadened and we're looking into areas such as, artificial intelligence and other areas like nanotechnology or cybersecurity, those are the areas that we don't typically have personnel or expertise to be involved in all those standards. And they may be appropriate for requesting a consideration to recognition. Those are the ones that we typically hope to hear from our stakeholders on considering for recognition.

Where we do have participation, one of the roles and responsibilities for us is to receive continuous feedback throughout the development of a standard that would help formulate the appropriate recognition and we hope that engagement with the standards organization will take place of that.

Now, we are not, a speedy jackrabbit or anything so you may not see immediately upon publication within the next week or two the intent to recognize through the database, but if you don't see anything for maybe a few months, feel free to contact us. But it does take time for us to go through the internal process to make sure we are making the appropriate decisions before we would go out with the intent to recognize the standard.

We are hopeful that we won't need to receive for every committee we're sitting on, additional requests for recognition in that realm.

(Andy During): Okay. Thank you. And can I follow up? Just wondering if that participation would also lead to a fewer parts of a standard that may not be included in the recognition. I mean, if we're actively participating and there's a general consensus on the content, would we expect the standard to be likely recognized in full?

Scott Colburn: Well, that's obviously the main goal of participating in standards so FDA can provide the perspective into the committee. But as you know, standards are consensus based and maybe the issues that were brought forth by the agency didn't override the consensus of the group.

And there are cases where if we have existing guidance or regulations and the content of a standard, especially international or global standards, may not be in alignment with current policies we have in place. And that's where you'll more likely see potential [partial] extents of recognition but we would be

pointing for the rationale for such partial recognition to an existing policy or regulation or guidance document that would help show where you would go to satisfy that section that is not recognized.

But to your point, the goal is always to try to build an internal level of understanding to what we can bring forward to the committee to help address those issues in the hopes of having a complete recognition.

Just as a statistic note, out of the over 1,200 standards we recognized, I think there's around 130 -- give or take -- standards that we have a partial recognition on. So that is not the norm to have partials. It's more the exception.

(Andy During): Thank you, sir.

Coordinator: Thank you. Our next question comes from (Jenny Foo).

(Jenny Foo): Hi, Scott. I just had a question about the use of ISO-IEC 17050 in regards to the Declaration of Conformity. Do you actually list that standard itself on your Declaration of Conformity?

Scott Colburn: No, we don't. I mean, and I believe every whenever I go on Google and search what is the Declaration of Conformity, they all follow - this template. It's a guide to the elements of a Declaration of Conformity.

It follows virtually identical to what has always been conducted. Even when this program kicked off in 1997 using ISO Guide 22, this guide just came in to become ISO/IEC 17050-1 and then the supplemental information or supporting documentation in the -2.

You don't need to dictate that (use of ISO/IEC 17050). The review staff will be looking at the appropriate elements to ensure a Declaration of Conformity has met those necessary factors we outline, but if you just follow the guidance and the content, that should be more than satisfactory.

(Jenny Foo): Okay, good. I thought that would be kind of obvious but I just wanted to double check. Thank you.

Scott Colburn: The goal has not changed. Really the one major change I would say -- and it's not a major change. It's just a very helpful tool and it also allows us to receive some metrics of understanding -- is adding the recognition number of the standard that you are listing on the Declaration and that allows us to make sure and get us to a quicker resolution that the appropriate standard was selected towards the purpose of a Declaration.

Coordinator: Thank you. Our next question is from (James Hanes). And please limit yourself to one question.

(James Hanes): Hi Scott. Good afternoon. This is (James Hanes). My question is in regards to the applicability of the consensus standards to drug device combination products.

We work with products that are regulated a drugs and are reviewed by (CDER) and (CBER). And was wondering if this could be applicable to the device constituent portion of the combination product. Thank you.

Scott Colburn: Yes. So (James), great question. Thanks for the easy one. So with the use of standards in combination products, I would first recommend discussing this with who the lead center is of review and deciding, if it's s (CDER) led review versus CDRH review to get that question answered up front.

Obviously if it's a CDRH level review or lead review and you're using standards towards a Declaration of Conformity, this guidance applies directly. Although we do have great relationships with the majority of the areas where combination products are interfaced (with the use of standards) and we're doing consultative reviews and standards may apply, the level of information of supporting documentation may vary based upon the type of document that you are submitting and that is being reviewed.

And I would first recommend that if the lead center is not CDRH always ask the question if you do know who is working on that part from the CDER side, because I don't want to speak for CDER and their policies as they too are also looking at how they can benefit from use of standards. So I think a lot of principles do seem to apply, in many cases across different areas of the agency. However, it's always best to start with the primary center and the review team to ask those questions upfront.

Coordinator: Thank you. Our next question is from (Lauren).

(Lauren): Hi. Yes, I'd like to ask if there is a consensus - excuse me, if there is a recognized standard for your product but there are some elements of that are not applicable, can you issue a Declaration of Conformity and then have the justification in the report that you have? Or do you have to do it in an alternate way?

Scott Colburn: So just to make sure I understand the question correct, it's when you are utilizing a particular standard but not all elements of that standard apply, can you still submit a Declaration of Conformity? And I think I can give the general answer but I think you may want to always feel free to ask that

question of the review branch or review team that is in that - may have a little more knowledge on a particular standard.

In general, many standards may be designed in a way that you have to use selections or use certain options based upon the technology of the product that you are testing under. Certain areas may not be applicable, and in your Declaration what you may want to provide is the justification that would dictate why a certain section was not applicable and provide the appropriate justification to that as well. That would be the key in understanding why you didn't test to a certain subclause or normative requirement in the standard simply because the design or technological features based upon your device.

(Lauren): Thank you.

Coordinator: Thank you. Our next question is from (Christina Hart).

(Christina Hart): Hi. What is the role of recognized consensus standards for items that are listed as 510(k) exempt?

Scott Colburn: So we in general I know the culture's always been thought of in terms of recognized standards are for those that are only ones that we would receive submissions on. But in actuality that isn't a true fact.

We do recognize standards for many devices that are exempt from regulation - - not regulation, but are 510(k) exempt. Both in the class one and class two areas.

One example I always give is the hospital bed standard. IEC (60601)-2-52 is a recognized standard. I think that's the correct number. We did that because we also knew that there was some areas in the post market domain that we were

seeing adverse events on, whether it was bed entrapment or hospital bed fires. Subject matter experts and regulators went and worked with the IEC maintenance team to update the standard to help address those areas. We also felt that it was important for us to indicate that the standard is important and should be considered, obviously still under a voluntary basis, but as a recognized standard.

And so you will see several standards that we do list that may be to exempt 510(k) type devices. And, the manufacturers have the option if they so choose to utilize those standards to support or consider what would be appropriate for use when testing.

(Christina Hart): Thank you.

Coordinator: Thank you. Our next question is from (Leonard Eisner).

(Leonard Isner): Hi, Scott. So I've got a specific question around some of the 601 series of standards of medical electrical equipment. So (60601)-2-18 which is endoscopic systems is recognized for an older - it aligns with 601-1 third edition which is not recognized because amendment 3.1 is recognized. Also, there is reference to 2-2 which is the high frequency surgical standard and that's an older version as well because 2-18 was released in 2009. And it's not going to be updated probably until the end of 2019 or so from what can I tell.

So how do you approach that when you have all these major alignments issues? Because what I was told by someone in the group of standards and Conformity assessment is you can write a Declaration but you need to basically do a gap analysis for the difference between the third edition's 3.1 and 601-1, et cetera. And sometimes the alignment of those standards in the

601 series between one addition and another gets sort of tricky because some elements disappear, some are (unintelligible), et cetera.

Scott Colburn: Thank you, (Leo). I was hoping you'd keep talking to me to answer the question that you asked. I do appreciate the question though. And the 601 series is the animal of all animals because it has such a large, broad base of particulars that reference so many collateral standards that at different times are being updated. And this kind of goes into the earlier question of how do you appropriately use the normative references -- especially when some of those normative references may have newer versions of FDA recognized consensus standards.

And I think sometimes, there's a two-way approach of how you look at it. If an FDA recognized consensus standard has older normative references a Declaration of Conformity based upon the outline of that standard can still apply. However, as I state in many presentations, conformance does not equal equivalence; Conformance does not equal approval. And the use of standards typically does not fill the entire mosaic picture that you're trying to create. There are still gaps in that.

So what is important is for you to look at that, and in the case of 601 to see how does that meet your essential performance. How does that satisfy the risks that you're trying to mitigate in your risk analysis? And is using some of the newer standards help get you closer to those areas where the gap may be less if you use the newer version of a standard?

The key thing here is -- and you'll see this theme through every question now if you kind of look back in the recording -- is to make sure that you are appropriately connecting with your review team because they will be able to

help give you what they feel would be the most reasonable and least burdensome approach to looking at that question.

Using the newer standards a lot of times does address newer issues that have come up whether it be through postmarket analysis and other areas where we have seen improvements in technology. And (those updates) just have not yet hit the newer particular standard in this case. But it doesn't preclude you from being able to utilize that newer standard if that does help you in making your story about how you have addressed certain areas of risk.

So the most important thing would be making sure that your submission in totality addresses the areas that are going to be of concern for you to be able to get your clearance or approval as appropriate. And how you utilize some of the normative references when a newer version may exist may be a way for you to help limit some of the amount of information that would have to accompany that Declaration. But when you are using different normative references or updated references, it will be very important for you to clearly outline why you did that so that it is clear to the review team when they are assessing the overall submission.

Coordinator: Thank you. Our next question is from (Debbie Brown).

(Debbie Brown): Thank you so much. My question was already answered.

Scott Colburn: I'm very glad to hear that, (Debbie).

Irene Aihie: We'll take our next question.

Scott Colburn: Yes.

Irene Aihie: Operator, are you there?

Coordinator: I am. Our next question is from (Hugh).

(Hugh): Hi. On your sample Declaration of conformance you did not list the dates of revisions of the standards. And I bring that up because there are times when the standard recognized by the FDA is an older version than the one recognized by other regulatory bodies such as Europe. And when we're trying to satisfy regulatory bodies in different geographies, how should we go about declaring a conformance? Should we try to declare a conformance to the newer one? Would the FDA accept that?

Scott Colburn: Yes, that's a great question. Actually kind of a good catch here. Could the Declaration of Conformity be a little bit clearer by adding the date? I think in the case when we drew up this example if you look at a particular recognition number, that recognition number does tell out a specific version of that standard and in that the date of the standard is incorporated to that recognition. So it is in fact kind of built into the Declaration appropriately that way.

Can you also add the date to the standard? Yes. But what we really want to make sure too is that you are using the appropriate standard to the version that is recognized and not using an older version of a standard to the version that is recognized.

So the driving tag here really is the recognition number, which will call out the version of the standard to which the Declaration would be expected to be read from. Does that help?

(Hugh): Yes. I guess the only thing is if Europe is requiring or requesting a newer version and the FDA recognizes the older version, it kind of puts manufacturers in a little bit of a bind.

Scott Colburn: So if there's good way to talk about the draft guidance that's out on the recognition and withdrawal of (voluntary consensus) standards and where we do have the opportunity for stakeholders to request for recognition of the agency a standard that you yet have not seen the newer version of.

And as I mentioned to (Andy) earlier, while we're on several committees and we try to keep our eye on all the areas where standards development takes place, we don't get that tag notification or poke sometimes until we do receive that from a stakeholder. So if you feel it would be helpful to have a newer version recognized, by all means feel free to contact the agency. And we have that information on how to do that both in the draft guidance of course, but also in our Web site it also indicates how you can contact the standards program.

Coordinator: Thank you. Our next question is from (Allison).

(Allison): Hi. I just want to echo a collective hooray for the end of Form 3654 so thank you for that. But my question is more with best practices and if the FDA has any guidance on how the medical device manufacturers can work together with their test labs to come up with a Declaration of Conformity. I know that the manufacturers themselves are the ones that sign the truthful and accuracy statement, but oftentimes my clients have a hard time understanding what they comply with and how they complied with a standard. And they really rely on the test labs for that information -- which puts them sort of in an awkward situation when they're putting together the DOC.

So do you have any ideas of how to best go about that?

Scott Colburn: (Allison), first thank you. Yes, we are all very happy with deletion of Form 3654!

But to your question about how can we improve an accurate and appropriate the Declaration of Conformity especially when you're working with testing laboratories that may not even be within the manufacturer's organization but a third party organization and how can we improve that. There's a couple ways now that I see natural improvements.

One is that under a laboratory's accreditation and if they're being accredited under ISO/IEC 17025, the 2017 version of that does permit under the accreditation for them to be able to either establish or work with how a Declaration Conformity may be able to more accurately reflect how a device was tested.

Secondly, and as I mentioned earlier, we have a new pilot program we are just at the very beginning stages of developing and over the course of the next few months and future you will see more information on the Accreditation Scheme for Conformity Assessment Pilot Program that FDA is working on.

And one of the objectives is to actually work with accreditation bodies and accredited testing labs who have contracts from manufacturers to certain standards that we recognize. And how can we improve the genesis of how the appropriate use of standards can apply and receive better Declarations of Conformity, supplemental test reports, et cetera and where can we improve those areas.

So I think we will see in natural order (of improvement) through both the evolution of the new standards in the ISO 17000 series as well as what we're hoping to receive from the Accreditation Scheme for Conformity Assessment or ASCA pilot program, the opportunities for us to help engage and provide the regulatory science perspective as well as opening up those areas of communication where previously we never really discussed or worked with testing laboratories or even accreditation bodies on those topics.

And hopefully that will help stakeholders -- especially some of the small business manufacturers who may not have a long history of developing those types of documents.

Coordinator: Thank you. Our next question is from (Anash). (Anash) your line is open.
Please check your mute feature

(Anash): Hi, Scott. My question is about the reference made in the guidance document that the use of this guidance is not limited to the abbreviated 510(k) but it can also be used for other 510(k).

So when we list this -- this is a standard form 3514 -- do we also have to provide DOCs for the traditional and special 510(k)?

Scott Colburn: Thank you, (Anash). That's an interesting perspective on that area. So the reason why that statement was in there, believe it or not there are certain areas where people feel Declaration of Conformity would only apply to an abbreviated 510(k). And that is definitely not a fact. A Declaration of Conformity can apply to any type of premarket submission as well as many people have Declarations of Conformity in their own files for products that are not going through a premarket review process.

So yes, that statement was there to just try to make sure and help improve and increase the amount of recognized consensus standards that we see. We did an analysis to try to understand how standards were being used a few years back and we saw that over a third of standards that were cited in 510(k)s that were cleared were not cited towards the Declaration of Conformity at all when in fact they could have been and potentially lessened the amount of information or amount of review that may be required to help assess the appropriate use of that standard.

So the message that the guidance was trying to improve is that the appropriate use of standards through a Declaration of Conformity can be to any premarket submission as appropriate. It isn't limited to any one particular type of submission.

Coordinator: And as a reminder to ask a question please press star 1. And our next question is from (Thomas).

(Thomas): Yes, thank you for taking my question. In one of your slides you emphasized Conformity versus compliance. Can you give a little bit more explanation what's the difference between compliance and conformance?

Scott Colburn: And I can't remember exactly what slide that was. But I will speak to that.

So a Declaration of Conformity is an official attestation that a device is in conformance with that standard. Conformity and conformance is a legal attestation that demonstrated you have tested the product prior to submission.

(Thomas) I just want to make sure. You talked about compliance was the second aspect?

(Thomas): Yes.

Scott Colburn: Compliance. So, we do receive from time to time where someone will say well, we are in compliance with that standard. And compliance is not an official term that brings us into understanding if you actually did a full attestation of conformance to that.

And we receive that from time to time. That would fit into an area where you might say yes, we are in compliance with the standard but maybe we made the following adjustments or we used it as our guide, so to speak, but it wasn't necessarily conformed to as published or as recognized to support a Declaration of Conformity.

We want to make sure that when people are submitting the Declaration of Conformity that they are making that attestation of conformance under the ISO/IEC 17050-1 & -2 series.

(Thomas): Thank you.

Coordinator: Thank you. Our next question is from (Amy Panzic).

(Amy Panzic): Hi. I just was wondering if what FDA's current thinking was on when submitting like a 510(k) with the intent to declare a standard rather than submitting with conformance to the standard.

Scott Colburn: And (Amy) just real quick are you kind of referring to the area where we discussed about promissory statements or promissory notes versus a Declaration of Conformity?

(Amy Panzic): Yes. So traditionally maybe we would say prior to commercial distribution we would make sure that we've tested and we comply 100% to you know, 601-1-2 rather than in a submission stating we intend to declare compliant to the standard without submitting like actual testing.

Scott Colburn: Thank you, (Amy). Yes, so I just wanted to make sure I was clear on it. So ye that is the difference between submitting a Declaration of Conformity and a promissory statement that in effect says what you alluded to -- that you're indicating that you promise you will be in conformance to the standard prior to market and are making a promise that you will meet the criteria as outlined in the recognized standard.

This is an area where you saw a shift from the draft guidance to the final guidance here. And the first thing -- and again going on the same theme -- make sure that you are speaking with your review team to understand that is this particular standard or standards that you're looking to take this approach to satisfy the ability for you to appropriately provide the amount of information through the use of that promissory statement to indicate that you can still get through the regulatory pathway where a determination of substantial equivalent or approval can be made.

Not all standards are be appropriate obviously for a promissory statement. In fact, I would probably even tee it up enough and say most standards may not be appropriate. But there are standards that, based upon the design, may require that the product be placed into its final installation area, whether it be in a hospital setting or maybe there's real long term testing for certain types of shelf life or others, that a promissory statement may be appropriate. But again, I would recommend unless you have some sort of historical reference from how you've done that in the past to connect with your review team just to make sure that that would be appropriate for you when you're submitting.

(Amy Panzic): All right. Thank you.

Irene Aihie: We'll take our next question.

Scott Colburn: For (Annie)? (Annie) I can't hear you. You may need to unmute.

(Annie): Hi. I have a question regarding the applicability of the guidance for the use of IDE devices. So let's say there's a device used in a clinical study where it complies to a 60601 third edition. And the subsequent 3.1 edition comes up. So is it required that any ID devices used following the division of this standard needs to comply to 3.1 or this is a similar rule similar to (unintelligible) marketed device apply for the IDE devices as well?

Scott Colburn: (Annie) I'm not too sure if I caught that entire question. Can you repeat it one more time? I apologize.

(Annie): Sure. So I had a question regarding the applicability of the standard of the guidance for the IDE devices.

Scott Colburn: Okay.

(Annie): So if there's a device that is being subject to the clinical trial and let's say complies to 60601 third edition. And then when a 3.1 edition revision comes up, is it required that the IDE devices used in the IDE subsequent to the implementation date conform to the 3.1 edition? Or does a similar rule like they have mentioned after review appearance or an approval of a device once it's legally marketed it's not necessary to go back and update the device file to comply with the portion of the standard.

Scott Colburn: Yes. So this kind of falls into the two different areas of answering that question. One will be the theme that you received is to make sure that you would communicate throughout the development of when you're going from an IDE and maybe into the next stage of what the submission may be, whether it's a 510(k) or a (PMA) type device to discuss a newer standard being recognized. Will the use of the standard as outlined as we've done through the IDE still apply for the appropriate data to support the later submission?

The other part of it too though is you have to also take into account as a manufacturer what is your responsibility and your quality system and how you should be looking at the newer standards and how that applies.

In the end again going back and discussing this with the review team is always the best decision first because you do need to take into account -- and the beauty of doing things through the IDE and with that interactive approach with the agency is that you are probably more aware of current issues that are usually addressed in newer versions of standards. And while you may be addressing those areas in your submission, if that's the case you may not necessarily need to use the newer version of a standard because you are addressing those in other sections of your document.

However, if you are not addressing any of those newer areas where there is a delta between the newer version and the older version that's not discussed, the agency may put an additional information request for you to see how did you address those areas that are in the newer standard but not addressed in previous areas.

Again, it goes back to communication and working with the review team as the primary way to address that.

Coordinator: Thank you. Our next question is from (Christina).

(Christina): Hi. Thank you very much for taking my question. My question is regarding the standard (IEC)62304 that is the list of harmonized standards.

There are currently two versions -- 2006 and 2015. Both versions have differences in the way modules are classified from the point of view of criticality. The other way the premarket submission guidance suggest a way of classifying modules according to the version 62304 2006 not with respect to 2015.

My question is if the manufacturer decides to choose conformance with 2015, what will be the expectations from the FDA when receiving and reviewing the submission of the (BMA) because the level of documentation for the modules is different.

Scott Colburn: Okay, (Christina). First I'll have to put out there that you asked the poor nurse a software question, right - 62304. But I'll try to just take this from a very broad perspective.

If I understood the question correctly, we have an older guidance that discusses the use of an older standard. And from what I'm looking at, the standard itself may even call out the date of an older standard. But there's a newer version out there. I don't have my database in front of me but let's assume that we recognize the newer version of that standard. How does that apply when there's a guidance based upon the older version?

I'm going to again stay to always communicating with the review team may be appropriate to see where the structure of the new standard may be different. The guidance document usually outlines the general things that the agency is

thinking about at that point in time. And if the newer standard has been recognized, the agency is also communicating that they feel that the use of that standard would also be appropriate.

This would be an area though that I would say you would need to probably speak with the subject matter experts or the contacts within that specific guidance document to be able to get a more appropriate answer.

Coordinator: Thank you. Our next question is from (Sue Heblin).

(Sue Heblin): Hi. Thank you. We are in the process of working on a traditional 510(k), And I was curious when you have specific consensus standards associated with the product code that don't seem appropriate for you device yet there are others that are like the 62304 and 62366 and 60601. So those are the standards that we're following for testing. And this probably doesn't matter because I think we are submitting all the test reports.

But I was just curious is it an expectation that you address those other standards that are not appropriate for your device that are associated with that product code? Or are manufacturers typically just silent on that and address the ones that are appropriate?

Scott Colburn: Well (Sue) yes, I can see where that might be a complicated question. So the recognition database does try to identify and I'll call it -- examples of product codes that may be suitable for the product area standards for the products that have product standards. Areas like (IEC)62304, and all the horizontal standards aren't assigned product codes because in many cases they would be applicable to hundreds if not thousands of product codes.

(Sue Heblin): Right.

Scott Colburn: Based upon their horizontal aspect. And so we really only try to tie in examples of product codes to try to bring that database into our database which then helps also sort what types of standards are available to a manufacturer to consider if you're unable to search for it appropriately in our database. Maybe it pops up when you're looking at a product code in your database.

Is it a complete and always updated system? No because product codes are continuously being updated. And we don't always update the recognition database to that effect. That is an area of improvement that we are interested in trying to advance. But in the end, it's really the manufacturers making the decision of which standards. It's a voluntary system so which standards do you feel are appropriate to help you make that case, make that story to help demonstrate how you are achieving what your intended use is or what you're trying to show for safety and effectiveness claims.

So really it's more of an assistive tool than a directive tool. It's really there for you to try to be helpful than more directive in that respect.

Coordinator: Thank you. Our next question is from (Margaret).

(Margaret): Yes hi Scott. I have a question related to pre-submission. Do people really need to put in the recognized standards when they're going to be used in a 510(k) in a pre-sub? Or can we either use a promissory note or state that these standards will be used in the 510(k)?

Scott Colburn: Yes, (Margaret) I'll admit I think, a pre-sub obviously is something different than a final submission. I think the information that is placed in you might not have conducted testing on certain areas. So showing what standards you

would be using. I don't even know if a promissory statement would be necessary for that effect at that statement but maybe indicating these are the standards or the test methods or the things that we're looking to utilize would be more appropriate.

This was an interesting question that maybe even bringing it to DICE or to the review team of course is there. But the pre-sub is obviously not an active review at that time. And so the expectation of utilizing full blown Declarations of Conformity or promissory statements wouldn't have that same weight, so to speak, as you would have with an active review under a 510(k) or a PMA submission.

(Margaret): I see. Which is (unintelligible) I mean for...

Scott Colburn: I'm sorry (Margaret). You clipped out for a second. Can you repeat?

(Margaret): Yes, sure. Does that mean that in a pre-sub it's not necessary on the form to list the recognized standards?

Scott Colburn: No, I wouldn't say it's a requirement in a pre-sub, (Margaret). But I state that, any time you're trying to share the information that you're using to the agency and if standards do apply, that you could have that somewhere in the information contained. But again, having what you're trying to get from the pre-sub process would look at what standards are you planning to use and is that approach acceptable.

Again, I think obviously asking the question to the review team too would be more beneficial. I admit that is not my highest area of competence and understanding that process for this specific area. But I do see where it does apply because listing the types of standards you're looking at doing is an

important tool since virtually every submission does list I think we have an average of seven or more standards in any particular submission that we see coming in.

So the discussion of how standards apply appropriately is obviously something of interest I think you would want to indicate in your pre-sub.

Coordinator: Thank you. And I am showing no further questions. I'd now like to turn the call back to Irene for closing remarks.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn web page at www.fda.gov/training/cdrhlearn by Friday November 2.

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 FDA.gov/CDRHwebinar immediately following the conclusion of today's live webinar.

Again, thank you for participating and this concludes today's webinar.

Coordinator: Thank you. This does conclude today's conference. You may disconnect at this time.

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