

**FDA Webinar- ASCA Pilot: Streamlining Conformity  
Assessment in Device Submissions**

**Moderator: Irene Aihie  
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Operator: Welcome. Thank you everybody, for standing by. Guests are in a listen-only mode until the question-and-answer session of today's event. Now at that time you may press star 1 on your touchtone phone if you'd like to ask a question. You also might be able to ask a question over the WebEx Q&A chat. Also, today's event is being recorded. If you have any objections of course you may disconnect. And I now would like to turn it over to Ms. Irene Aihie. Thank you so much ma'am. You may begin.

Irene Aihie: Thank you. Hello and welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communication and Education. Under the ASCA Pilot, the FDA grant ASCA accreditation to qualified accreditation bodies to accredit testing laboratories to perform premarket testing for medical device companies.

During this webinar the FDA will explain how manufacturers should prepare premarket submissions for medical devices with testing from ASCA accredited testing laboratories, share strategies for test labs to successfully

participate in the ASCA Pilot. And answer your questions about the ASCA Pilot.

Today, Angela DeMarco, (Shuliang Li) and (Eric Franka), all members of our ASCA team here in CDRH, will present an overview of the ASCA Pilot program. Following the presentation, we will open the line for your questions related to information provided during the presentation.

Participants can also submit questions via the Q&A function in the WebEx application used for today's webinar. Additionally, there are other (center) subject matter experts here with us today, to assist with the Q&A portion of our webinar. Now I give you Angela.

Angela DeMarco: Thank you, Irene, for the introduction. Today's webinar is designed to update participants on the ASCA Pilot and provide practical recommendations for how to apply for ASCA accreditation and how to effectively participate in the pilot. We will address four topics.

I'll start out by sharing the progress we've made on the ASCA Pilot so far, and then I will walk through how manufacturers should compile a device submission that includes testing from an ASCA accredited test lab. Then my colleague, (Suliyang Li) will provide an update on biocompatibility for ASCA, followed by (Eric Franka) doing the same with basic safety and essential performance. We'll close with a question-and-answer period.

So what exactly is the ASCA Pilot? To start, the ASCA Pilot is authorized under Section 514(d) of the federal Food, Drug and Cosmetic Act and is part of the Medical Device User Fee or MDUFA commitment of 2017. It is a voluntary pilot we developed with input from experts across the medical device manufacturing and conformity assessment community, to capitalize on

the existing use of voluntary consensus standards in a device development and review.

It leverages an already existing and well established international conformity assessment infrastructure and combines it with the regulatory needs of the FDA. Now that you know what it is, why should you use it? Well the pilot was designed with the intention of increasing FDA's confidence in the test methods and results contained within medical device submission.

That enhanced confidence means that manufacturers should see fewer requests for additional information regarding testing methods from an ASCA accredited test lab. This in turn helps lead to a review process that is more consistent, predictable and efficient, which supports CDRH's commitment to release (burdens) and approach.

Finally, at the end of the day, ASCA should help the patients we all serve, to have access to safe, effective and high quality medical devices. Now that we've talked about what it is and why you should use it, how does ASCA work? First, FDA grants ASCA recognition to accreditation bodies to meet pilot specification.

These accreditation bodies are the ones who accredit test labs to ISO/IEC 17025 and the additional specifications FDA has identified for the ASCA Pilot. Then the test labs may apply to the FDA for ASCA accreditation. Both independent and in house test labs may participate. Part of the accreditation process involves training sessions provided by internal FDA experts so that test labs are aware of FDA needs when putting together the ASCA Summary Test Report, which we will discuss in more detail later.

Once accredited the test lab's information, including the scope of accreditation, is posted on the FDA's Web site so that device manufacturers may select an ASCA accredited test lab and develop a test plan with that lab. The test plan should be within the scope of the ASCA accreditation.

Once a test plan is developed, the test lab conducts testing and sends both the complete test report and an ASCA Summary Test Report to the manufacturer. The manufacturer then compiles their premarket submission including both a declaration of conformity and the ASCA Summary Test Report. The ASCA Summary Test Report is provided to FDA as is. And finally, FDA conducts its review of the ASCA testing according to the ASCA pilot guidance. We'll dive into how all this works in just a moment.

But first, a little background on the guidance documents we've mentioned. Three guidance documents outline the parameters of the ASCA pilot. The first is a program guidance with general information about the pilot and how to participate. The other two are standard specific guidances that outline specifications for the two standards families included in the pilot - biocompatibility and basic safety and essential performance.

So how do we go about choosing which standards should be included in the ASCA pilot? Well we obtain feedback from internal experts, industry and conformity assessment experts. We wanted to include standards and test methods that were both cross cutting and product specific, and ones that revealed good insight into how a conformity assessment program should work.

The ASCA team is right on schedule in its implementation of the pilot. Per the terms of the MDUFA IV commitment letter, we published the draft guidance in 2019 followed by a final guidance document a year later. In

November of 2020 five accreditation bodies received ASCA recognition and could begin to evaluate test labs to ISO/IEC 17025.

As of now, 53 test labs have been granted ASCA accreditation and more are expected soon. The ASCA Pilot is in full swing now that test labs have been accredited and review staff have been trained, and we're hoping to see device submissions soon.

Now let's go over how to prepare a premarket submission that contains testing from an ASCA accredited test lab. The ASCA aspects of a premarket submission are straightforward and can be summarized in five basic steps - choose the standards you want to use, develop a test plan with the ASCA accredited test lab, plan the submission elements, obtain documentation from the test labs, and finally, prepare the submission.

Let's review each step in more detail. Step one is very straightforward. Identify the standard or the standards you want to use. The important thing about this step is that you should first check the list of standards eligible for the ASCA pilot and then go to FDA's recognized consensus standards database to access and review the supplementary information sheet for the standard. And we'll talk a bit more about this in a bit.

Be sure to check the extent of FDA recognition, whether it's partial or complete, as well as the addition. A quick but important reminder, the manufacturer maintains responsibility for the choice of standards and test methods, and their appropriate use and application in support of those device submissions.

Next up is to select an ASCA accredited test lab from the list posted on the FDA Web site and then work together with the test lab and agree on a test

plan. Just remember that even though it is collaborative, the manufacturer is ultimately responsible for the test plan that is developed. As you develop the test plan, please keep the following in mind.

Consult all relevant FDA guidance documents to ensure that the testing you are conducting is in line with FDA policy regarding that specific device or general scientific area, and do not rely solely on the ASCA pilot guidances. In addition, the standards you use must be the FDA recognized version of the standards. So be sure to check the extent of recognition in the recognized standards database.

You'll also want to confirm that the test plan you agreed to is not outside of the test lab scope of ASCA accreditation. Step three is to plan the submission elements. So what goes into an ASCA premarket submission? You will need three things - a cover letter, a declaration of conformity, and an ASCA Summary Test Report. We will go over each of these in greater detail in the next several slides.

Let's start with the premarket submission cover letter. Some of you may be familiar with the FDA Form 3514 also called the Submission Coversheet. This form contains the same information of the cover letter and typically can be used in lieu of a written cover letter.

However, with all submissions being received in electronic format such as a USB, we are asking that a hard copy cover letter be provided to identify what the submission is and what center it belongs to. That way we can route it correctly to be logged into our system.

For the ASCA pilot, we are asking that you include some ASCA specific information in this hard copy cover letter, to assist us in logging in the

submission. This is because the Form 3514 does not yet have a place to identify that the submission includes ASCA testing. The additional language for the cover letter is very simple. It should clearly state that the submission contains ASCA Summary Test Reports and is part of the ASCA Pilot.

It should reflect the ASCA accredited test lab's information including its name, location, and ASCA identification number. And it should list the specific ASCA standards and testing methods being cited. Next up is the Declaration of Conformity. Remember that the Declaration of Conformity is the manufacturer's responsibility to assemble.

For submissions that include ASCA testing from an ASCA accredited test lab, the Declaration of Conformity should reflect the test lab's ASCA accreditation status at the time of testing. In 2018 we have published the appropriate use of voluntary consensus standards in premarket submissions for medical devices, to lay out what a Declaration of Conformity should contain.

For ASCA, we then expanded upon this guidance and included example declarations of conformity in the standard specific ASCA guidances. (Shuliang) will speak in greater detail about Declarations of Conformity, but the next two slides outline the key elements of the Declaration of Conformity.

The appropriate use guidance stipulates the following elements for a Declaration of Conformity - the applicant's contact information; the device's identifying information; the actual statement of conformity to the standard; all the standards being cited; and the FDA recognition numbers.

Please note that a Declaration of Conformity cannot be provided for a non-FDA recognized standard. The other elements of the Declaration of Conformity are the date and place where the Declaration of Conformity was

issued, the signature of the responsible party and any limitations on the Declaration of Conformity's validity and finally, any supplemental documentation supporting the Declaration of Conformity, including the ASCA Summary Test Report.

So the third and final ASCA specific element for submission that contain ASCA testing is the ASCA Summary Test Report. This document is created by the test lab and provided to the manufacturer. You can find example Summary Test Reports in the standard specific guidances. There are nine provide compatibility and one for basic safety and essential performance.

The ASCA example Summary Test Reports were created in response to feedback to the draft ASCA guidance and they are generally expected to be the only supporting documentation needed when they accompany a Declaration of Conformity. Please note that the example Summary Test Reports are just that, examples. They are not templates or forms. They are simply advice on what to include.

That said, they were developed by FDA subject matter experts so they are designed to contain the information review staff needs to assess the testing performed. Test labs will likely have their own format for Summary Test Reports. And if a lab creates their own format, it is your responsibility as the manufacturer to ensure the summary contains the information FDA needs since you are responsible for its contents as they directly relate to your premarket submission.

You as a manufacturer, are not allowed to modify the ASCA Summary Test Report but you can work with a test lab to ensure all necessary information is present. Later in this webinar my colleagues will go into much greater detail

about the biocompatibility and basic safety and essential performance Summary Test Report.

Returning to our step wise approach to compiling a premarket submission that contains testing from an ASCA accredited test lab, step four is when the laboratory will conduct the testing according to the agreed upon plan and then send the manufacturer both the complete test report and the ASCA Summary Test Report. The complete test reports are sent to the manufacturer for their own record keeping.

Step five is where it all comes together. You prepare your (unintelligible) submission. You will include your cover letter with the ASCA specific information we discussed in step three, a Declaration of Conformity for each identified ASCA test, and the Summary Test Report for each test that is conducted by an ASCA accredited test lab.

As a reminder, manufacturers do not modify the ASCA Summary Test Report from what was provided by the test lab. They are submitted as part of the premarket submission in as is condition. That means we submit them in the same condition that they are received from the test lab.

And don't forget, the non-ASCA related components of the submission. The ASCA Pilot does not alter the statutory requirement for premarket submissions. You as the manufacturer, need to make sure you include all necessary components of your chosen submission (type) whether it be (510(k)), PMA, De Novo, or IDE.

Some of you may be familiar with the (ESTAR) pilot currently running. It is a voluntary pilot consisting of a billable PDF meant to walk you through compiling a premarket submission. The hope is that in the near future we will

incorporate questions specific to ASCA to aid in the assembly of a premarket submission that contains testing from ASCA accredited test labs.

Once we have the go ahead to incorporate these changes the ASCA selections will look like what is shown on this slide. For all tests eligible for ASCA, an option will be present in the drop down menu for which test was conducted. For example, in the image on the left, the ASCA options as added to the (unintelligible) (prior) toxicity test.

If selected the questions depicted in the image on the right, will appear. These are mainly administrative questions meant to collate information about the test lab, its accreditation status at the time of testing, and identified deviations from the scope of accreditation. The goal of this addition is going to get easier for both the manufacturer to include the information and for the (staff) to more easily find the appropriate information related to the testing performed by an ASCA accredited test lab.

Before turning the program over to (Shuliang Li), I'd like to recap what we've discussed so far. ASCA's advantages are potentially significant for both manufacturers and the FDA. It is designed to increase confidence in the testing conducted, and consistency and predictability in FDA's approach to assessing conformance which should reduce regulatory burden.

Most importantly, we expect that patients (unintelligible) will benefit from the ASCA Pilot as safe and effective devices are made available to them without unnecessary delays. We reviewed the five steps for preparing a submission with testing from an ASCA accredited test lab. They are identify the ASCA standards, agree on a test plan with the ASCA accredited test lab, plan the submission elements, obtain the complete test report, an ASCA Summary Test Report, and prepare the premarket submission.

Make sure you include not only the ASCA specific submission elements, but all other elements necessary to meet the statutory requirements for the submission type you are preparing. And finally, we reviewed the three elements of an ASCA submission - the cover letter with ASCA specific information, the Declaration of Conformity, and the Summary Test Report.

Now I'll turn it over to (Shuliang Li) to discuss updates regarding biocompatibility in the ASCA Pilot.

(Shuliang Li): Thank you, Angela. Next slide please. This section of our webinar will focus on three topics - and update on ASCA biocompatibility testing followed by deeper dives into Declarations of Conformity, and ASCA Summary Test Reports for biocompatibility. Next slide please.

The biocompatibility scope in the ASCA Pilot includes the standards listed in the left column and the test methods in the right column. There are nine biocompatibility test methods and eight standards included in the ASCA Pilot. Be sure to check the ASCA biocompatibility standard specific guidance.

There is also a button on the ASCA Web page called “View ASCA Pilot” that will take you directly to a list of ASCA standards in our recognized consensus standards database. Next slide please. It is important to remember that just as with non-ASCA testing, manufacturers work with the ASCA accredited test labs to create a test plan.

In doing so, please consult the general FDA biocompatibility guidance entitled Use of ISO (10993) Biological Evaluation of Medical Devices, Part 1 Evaluation, and the Testing Within a Risk Management Project. This

guidance has invaluable information about what testing needs to be conducted as well as appropriate endpoints for biological evaluation.

You should also be aware that for all biocompatibility testing under ASCA, test labs should comply with 21 CFR 58, Good Laboratory Practice GLP Regulations. Next slide please. Before we move on, I want to point out that while most medical devices are eligible for the ASCA Pilot, a handful are excluded for biocompatibility.

These are devices requiring customized sample preparation and/or testing methodology. Absorbable devices, in situ polymerizing devices, liquid devices, creams, gels, hydrogel devices, and devices containing nano materials. Next slide please. Next, I'd like to share with you information about biocompatibility Declaration of Conformity under the ASCA Pilot. Next slide please.

As we will see with the ASCA Summary Test Reports, the ASCA biocompatibility guidance also offers an example Declaration of Conformity in Appendix A. In the next three slides, we will review the elements of this example Declaration of Conformity.

As a side note, most of this information will apply to the basic safety and essential performance Declaration of Conformity as well. So some of the information for those Declarations of Conformity might be different. Next slide please.

Angela mentioned earlier, the various elements of our Declaration of Conformity which you will see in this example Declaration of Conformity. The Declaration of Conformity is completed by the manufacturer. I'm going to walk us through the important part. Here is the first section. You can see

where to enter the responsible party's contact information, name and address next to the blue arrow.

By the red arrow the device information is entered. This includes both product specific information like device name and model number, as well as the FDA product code. Next section is the actual Statement of Conformity. The actual Attestation of Conformity goes into this section. It looks like a lot of information, but it's very straightforward.

The statement should include the title and FDA recognition number for each recognized standard cited. The recognition number can be obtained by searching the recognized consensus standards database. We will share that link with you at the end of the presentation.

Next to the green arrow is where you enter whether the standard has options. This is very important. For many biocompatibility standards there are options. For example, ISO (10993-10) has four test methods that are included in ASCA. The check box next to the green arrow is where you will check and indicate which clause or test method that you have selected from the standard.

For example, if you conduct a closed-patch sensitization test, i.e. Bueller test, you enter Clause 7.6 closed patch test, see ASCA Summary Test Report, closed- patch sensitization, in this box. And then you enter the test lab information including its name, ASCA ID number and the location. Next slide please. The Declaration section continues with a place to type in the date testing was conducted as well as to confirm the lab's ASCA accreditation status.

I want to draw your attention specifically to the next section, which is called supplemental Documentation. As you can see by the red arrow, this is where

you indicate the location of the supplemental documentation. If you as the manufacturer, use an ASCA accredited test lab and Summary Test Report, this is where you include the location of the Summary Test Report within your premarket submission.

By checking the box you also confirm that there are no differences regarding the data and the testing conditions between the complete test report and the Summary Test Report. Please note, it is important that you don't alter the ASCA Summary Test Report.

The test lab submits both the complete test reports and the Summary Test Report to you. It is the manufacturer's responsibility to make sure that there are no differences in terms of data and the protocols between the Summary Test Reports and the complete test report. Next slide please.

The last section is where you describe any limitations to the Declaration of Conformity that might exist. Next to the red arrow, this is where you as the manufacturer, include the information about the devices that are used for testing in comparison with the final finished device.

If you use the final finished form of the devices for testing, you can indicate here or enter the location where this information can be found in your summation. If the representative portion of the device is used for the biocompatibility testing you indicate here or where this information can be found. As indicated in the footnote, the general FDA biocompatibility guidance has more information regarding the use of the final finished device and the use of representative portion of the device for biocompatibility testing.

The light blue arrow indicates any concerns during the testing that was communicated between manufacturer and the test lab. By the green arrow this

is where you include information if there are any observations or degradations during the testing and how they were resolved during the testing.

Finally, the dark blue arrow, this is where you include a statement about the exclusions. As we mentioned earlier, devices that require customized sample preparation and/or testing methodology or if devices are absorbable, in situ polymerization device, liquid, cream, gel, hydrogel devices, and the devices containing nano materials, these devices are not included in the ASCA Pilot for biocompatibility. And of course, do not forget to sign and date the Declaration of Conformity. Next slide please.

As we discussed earlier, in addition to example Declaration of Conformity, the ASCA Pilot guidances share example of ASCA Summary Test Report, ten of them in fact. One for the basic safety and essential performance scope which my colleague, (Eric Franka), which Eric will outline shortly, and one for each of the nine biocompatibility test methods. Next slide please.

Before I go into detail, I'd like to point out some key aspects of the use of ASCA Summary Test Report. First, the test lab has the responsibility to send both the company's test report and the ASCA Summary Test Report to the manufacturer. When a Declaration of Conformity is accompanied by an ASCA Summary Test Report FDA does not generally need to review the complete test reports.

That said, there are a few occasions in which a complete test report might be needed for the biocompatibility standards and methods. These are – when the “other” option is selected for test article , when there are deviations and/or amendments. When you observe changes in color, turbidity or particles in the test (article) and/or extract or there was swelling/ degradation of the test

(article). And finally, when the results (including controls), are outside the range as specified in the ASCA biocompatibility guidance.

For more information, please review the footnotes in the example ASCA Summary Test Report, Appendix B through J in the ASCA biocompatibility guidance. Next slide please. This excerpt is from the ASCA biocompatibility guidance. Example Summary Test Report for cytotoxicity MEM elution test.

The test lab will complete the ASCA Summary Test Report. It's pretty self-explanatory but please note the important footnotes outlined here in the red box. They indicate a few instances when a complete test report may be needed. For each test method included in ASCA Pilot for biocompatibility, the guidance provides an example of the ASCA Summary Test Report.

Please pay attention to the footnotes where it indicates when a company test report may be needed for each test method. Next slide please. In summary, I'd like to reiterate a few key points. Please consult the FDA's general biocompatibility guidance to determine appropriate endpoints.

FDA recommends that manufacturers and ASCA accredited test labs work together to develop the test plan. Biocompatibility test labs should comply with 21 CFR 58 GLP regulation. And finally, submit the Declaration of Conformity accompanied by the ASCA Summary Test Report. But be aware when a complete test report might be needed. Next slide please.

It is my pleasure to introduce our next speaker, (Eric Franca), who is my counterpart test lab lead for the basic safety and the essential performance scope.

(Eric Franka): Thanks, (Shuliang). We can go ahead and move onto the next slide. So for this final section of today's webinar I'd like to emphasize three topics. First, I'll share with you some important recommendations for test labs who want to apply for ASCA accreditation.

Then we'll go in depth about the collaborative approach manufacturers and test labs should take in developing a test plan. And I'll conclude with a general overview of the basic (unintelligible) performance example Summary Test Report. Next slide.

Before we get started let's start - kick off with some background knowledge. Here are the two families of basic safety and essential performance standards included in the ASCA pilot. That's (unintelligible) specific for 1-1 including many of the collaterals and particulars and the logistics of one family of standard and IEC (1010-1).

Check the ASCA page for the link to the full current list of what standards are currently included in the ASCA Pilot. Next slide. Let's talk about how test labs can ensure they submit a complete ASCA accreditation application. Next slide. We'll start with what to do. Firstly, let's be sure to consult the relevant FDA guidances - not just the ASCA guidance document, but also device specific guidances and the appropriate use guidance as well.

We'll come to this topic a little later again in the presentation. So as a side note, I'd also like to strongly recommend that test labs and manufacturers review an (AMSCR) 500 which is an excellent introduction to the 60601 series and includes immensely helpful insights into essential performance, as well as regulatory context and perspective.

Okay. Before sending in your application ensure that your application is complete. Please. Include the administrative information about the test labs as well as a final scope of accreditation from an ASCA recognized accreditation body that shows your lab has been evaluated to ISO/IEC 17025 and the ASCA Pilot specifications.

Please note, we won't accept interim assessment reports which maybe demonstrate that there are no nonconformances remaining or any other interim report regarding your potential ASCA scope. We need the final scope of accreditation from your accreditation (body).

And then lastly, don't forget the signed agreement so you can copy this down and sign it digitally or otherwise in your application. Please avoid simply referencing the appendix in the FDA guidance document and signing your application that way. This way if the guidance changes in structure or with an update in the future, you won't need to update your lab's signed agreement.

So ultimately in the end, the ASCA Pilot program guidance document is your go to guidance for what to include in your application. Next slide. We appreciate that - please appreciate that we will review test lab applications as they're received. So we expect to complete our review within 60 days.

And if ASCA accreditation is granted we will add the lab to our public list of ASCA accredited test labs. We also want to emphasize that your scope of ASCA accreditation must match the scope from your accrediting body. If clauses and methods are excluded on the scope of accreditation from your accreditation body it will also be excluded on your scope of ASCA accreditation. Next slide.

Okay. We've covered what you should do. Now let's talk about what you shouldn't do. First, please don't send in an incomplete application. Check the ASCA Pilot program guidance and be certain you've included all the elements and be sure that your accreditation body scope matches your proposed ASCA accreditation scope.

Remember that the ASCA pilot doesn't include all of FDA's recognized standards. Check that you're not seeking ASCA accreditation to non-ASCA standards. Likewise, don't propose including standards which you have not received accreditation from your accreditation body for.

A good way to avoid this misstep is to simply refer to the scope of accreditation from your accrediting body in your application, since this is ultimately what will define your potential scope of the ASCA accreditation. And finally, if your test lab has satellite sites please don't submit individual applications for each satellite.

Rather identify those lab locations for us in your application, just for our information. Ultimately, the satellite lab is included as part of the main lab and should be noted as such on the scope of accreditation from your accrediting body. Next slide.

So if ASCA accreditation is granted - as we mentioned earlier, if your lab is granted ASCA accreditation look for your information to be posted on our Web page. We'll let you know once this is about to occur or is occurring. A quick note, we do require a point of contact in your application in case we have questions during our review.

But if you would like the public facing information meaning the contact information on our ASCA Web page to feature a generic contact for your lab,

please let us know in your application. The scope for your lab on our Web site, it won't show the versions or additions of the standards for which you've received ASCA accreditation, but you should remember to only test to those to which you've been accredited, (using) any of the exclusions in the scope of accreditation you received from your accrediting body. Next slide.

So you've heard from both Angela and (Shuliang), how important test plan development is to the ASCA Pilot. So let's switch gears a little and talk more about this key element. Next slide. Who is responsible for the test plan? This is a question we've heard several times now, and ultimately the answer to this question has not changed.

The responsibility for the test plan and appropriate selection and use of standards lies with the manufacturer. That said, ASCA accredited test labs have expertise and experience that should be tasked when developing the test plan. The aim of the ASCA Pilot is to enable test labs to be more involved in the development of the test plan. The goal is a collaborative effort between manufacturers and test labs. Next slide.

Earlier Angela mentioned the importance of reviewing a standard supplementary information sheet or SIS. We can't emphasize enough the value of reviewing the information in our recognized standards database. You'll find the standards extent of recognition, more on that in a second and the relevant references and non-ASCA FDA guidances that should be consulted in the development of the test plan.

Here are a few examples of basic safety and essential performance related guidance. There's the electromagnetic compatibility EMC guidance. There's also a draft guidance entitled EMCF medical devices that we hope to have finalized in the near future after considering all of the comments we received

during the draft guidance comment period. So look out for that at some point in the near future.

The home use device guidance, laser products guidance which discusses specific standards related to the devices, and the pulse oximeter guidance (offering). These are often listed in SIS for standards included in the ASCA Pilot. This leads us to an example where learning more about the extent of recognition of the standard is critical for test (client) development process. Next slide.

This is a screen shot of the top part of the SIS or ISO 80601-2-61. That's a particular requirement for pulse oximeter equipment. Here's where you'll find the standards recognition number, a notation if it is included in the ASCA Pilot. And hey this one is. It's next to the red arrow. And general information about its scope. Next slide.

So scrolling down the page the next part of the SIS is very important for ASCA purposes. The extent of recognition, next to the blue arrow here, up on top. Please pay careful attention to the section as not all standards are recognized in their entirety.

In this case, a specific clause as the standard, is excluded from recognition. Meaning this standard is only partially recognized. In these cases where a standard is only partially recognized, we will provide the rationale for this. So you can see next to the red arrow here.

In this case, the excluded clause conflicts with an existing FDA guidance, the pulse oximeter guidance I mentioned a couple of slides back. And that leads us down to the green arrow, highlighting the relevant guidance and other

documents that should be considered when using a standard, including in the development of a test plan.

In this case again, it provides the specific guidance document I mentioned, referenced in the rationale as well, and also (AMSCR) 500. And I'll happily reiterate that we would really encourage everyone to review the content of (AMSCR) 500. And if you have any questions about an SIS standard, the extent of recognition, feel free to contact the technical contacts listed on the SIS page and the ASCA program for when the question has something to do with ASCA Pilot. Next slide. Next slide. Sorry.

Okay. No, no, sorry Angela. Go back one. I got disconnected a second ago. Thank you. So while the manufacturer and the test lab are expected to agree upon a test plan and its implementation, we recognize there may be disagreements. If an ASCA accredited test lab has concerns with the plan, they should be comfortable exercising their independent engineering judgments and should communicate those concerns to the manufacturer early on.

If for some reason, reconciliation is not possible in the development of the test plan, the lab should provide details regarding their concerns in the summary test report that it submits to the manufacturer and that we will ultimately review. Next slide. So while the biocompatibility scope has multiple test reports, basic safety and (central) performance just has one. And we're going to go through a quick overview of its content page by page. Next slide.

As a reminder, the example ASCA Summary Test Reports that you'll find in our guidance documents and the one we're looking at here, they're not templates or forms. They're simply recommendations on how to structure things and what to include. So each lab may have their own formatting or

flavor of test reports and we don't expect that to change for these ASCA Summary Test Reports.

And while the manufacturer is not allowed to change anything on the Summary Test Reports they receive from the test lab, the manufacturer is responsible for its content. So please be sure to check that they contain all of the information that FDA expects. If anything appears to be missing, please discuss this with your ASCA test lab.

So moving onto this example Summary Test Report, the first part addresses three elements - the administrative information next to the blue arrow, provides details about the testing and the labs. It includes a reminder in number 5 here, that the lab should - that the lab should have that testing or method in its scope of ASCA accreditation. And this is simply an administrative (test).

The red arrow indicates the device's essential performance characteristic section. So it should reflect the essential performances that the manufacturer has (defined). If there's any confusion over what the essential performance is for a device, test labs should be comfortable discussing this with the manufacturers without the test plan adequately covers the essential performances for a given device.

This section should also indicate if there are any differences between the essential performances identified in the standard, if any, and those essential performance characteristics which were considered during the test. I would also like to say at this point, if manufacturers are unsure of what FDA would expect to see regarding essential performances of a specific device, please submit a pre-submission to the relevant review office to ensure that your testing will adequately address FDA's expectations.

So in the next section with the green arrow, this describes use environment, reflecting where the device is intended to be used, including any relevant detail. Next slide. So in the clauses test section next to the blue arrow here, we should have details about how and what was and was not tested.

The test lab will also want to indicate if any modifications were made to the test methods or the acceptance criteria highlighted there by the red arrow. Some standards, detail options are allowed for modifications and this is where that information should be covered.

And Summary Test Reports should also include details about any additional testing that was performed, such as testing to address a hazardous situation that isn't addressed by the standards. See the green arrow here. And at the bottom of this page, next to the yellow arrow, you can see that we would want to understand how the device was configured, including its mode of operation during all of the testing. Next slide.

The test lab is expected to be very clear about any observations and degradations during the testing as you can see next to the blue arrow here. If such observations were noted, only the unexpected ones should really be described in detail.

In the next section the red arrow indicates whether the test lab made any modifications to the device. They then can describe any identified concerns which is next to the green arrow here, which would have been - should have been clearly communicated to the manufacturer. This could be an area where the test lab goes into detail about unresolved concerns regarding the test (client), confusion over essential performances or anything else that should be described.

This is a critical section for the ASCA Pilot. We need to know when these concerns exist and how it relates to the testing that was performed. And finally, the yellow arrow down here points to where the test lab signs to confirm that the document is accurate and summarizes all original and any retest data.

As we mentioned earlier, individual test labs may have different styles or formats of their ASCA Summary Test Report. However, those reports really should reflect all the expected content described here and also in our guidance documents. Next slide.

So as a quick summary, test labs who wish to receive ASCA accreditation should remember to review all ASCA Pilot guidances and any relevant FDA guidances. Be sure to check that the application contents are complete before sending it to us, please.

Please don't include ASCA standards, non-ASCA standards in your requested scope. As mentioned, you can also simply refer to the ASCA section of the scope of accreditation from your accrediting body as the proposed scope for simplicity.

Please don't submit a scope of accreditation from an accrediting body with only accreditation to ISO/IEC 17025. The scope really needs to include accreditation to the ASCA specifications which can be found in our guidance document, in addition to ISO/IEC 17025.

Please also remember to only test standards in your scope of ASCA accreditation once you receive accreditation from us. So pay attention to any exclusions that are listed in the scope of accreditation from your accrediting body. Next slide.

And though the manufacturer has the final responsibility for the test plan, test labs should feel free to apply their expertise as well as assist in the development of the test plan. When working together on the test plan, manufacturers in test labs should pay special attention to the standard supplementary information sheet for information about relevant guidance and other resources as well as details about the (extent) of recognition.

And again, if any concern - any unresolved concerns from the test labs remain, there should be - they should be detailed in the asset summary test report. And finally, the ASCA Summary Test Reports are a key element of the ASCA Pilot device submissions. We encourage you to consult the example reports in the two ASCA standard specific guidances that we have.

If you don't use the example formatting please be sure to include all of the content from those examples. And next slide. I believe that brings us to the Q&A section of our webinar.

Irene Aihie: Thank you, (Eric). This is Irene Aihie. Before we open the line for questions we do have a few questions in the chat box here. And while my colleagues get those organized I do have one question that we would like to pose to the group. The first question is why are there no biocompatibility labs on the list of ASCA accredited test labs?

(Shuliang Li): This is (Shuliang Li). Thank you, Irene, for the question. Due to the complex nature of biocompatibility standards and the test methods, additional review time and interaction with the applicant labs are needed. We are working diligently with several labs who are making good progress. And we hope to grant ASCA accreditation to them in the near future. They will be published on the list as they receive ASCA accreditation.

Irene Aihie: Thank you. I have another question here. Is it okay for a manufacturer to submit a premarket submission with a combination of results from ASCA and non-ASCA test laboratories?

(Shuliang Li): The short answer is yes. A manufacturer should clearly identify which test was done from an ASCA accredited test lab and which one not.

Irene Aihie: Awesome. All right. We're going to go to some questions that are in the chat box here. One second. There are quite a few questions here. There's a question here that says (ER5000) doesn't really cover essential performance in detail compared to interpretation sheet one issued recently. Is that something that we can answer on the call today?

(Eric Franka): Sure. So I think the unique aspect of the CR500 is, unless I'm getting the number wrong there, is that it does provide FDA or regulator context to the essential performance question. So while it - interpretation sheet one does have some valuable information in there, we do like what it crafted in CR500. (Brian), I don't know if you have anything additional to add to that.

(Brian): No. I think that's exactly right, (Eric). I would point out that CR500 is a consensus document published by (AMI). And we have to be very careful about providing what is possible to interpret as guidance when it hasn't gone through the GGP principles. So we have to study and see what we can do in regard to interpretation sheets and the like.

There are certain things that we are not completely at liberty to do and other things that we may be able to contribute to the community's vision of what is a good system. That's really what I want to add.

Irene Aihie: Thank you so much. I have another question here. Are manufacturer labs required to be accredited if data will be used for design controls, regulatory approval documentation purposes?

(Eric Franka): I'm sorry. Can you say that question one more time? I'm not sure I heard the whole thing.

Irene Aihie: Sure thing. Are manufacturers' labs required to be accredited if data will be used for design controls or regulatory approval documentation purposes?

(Eric Franka): I think for participation in the ASCA program, meaning the ability to use the Summary Test Reports, using an ASCA accredited lab in support of a premarket submission then they would need to be ASCA accredited as listed on our Web site. Otherwise it's business as usual for submitting premarket documentation or submissions.

I'm not sure if that answers the question, but I think that's what we're getting at here.

Irene Aihie: Thank you. Operator, do we have any questions on the line?

Coordinator: Thank you for asking. At this time we do not, but as a reminder, if you would like to ask a question over the telephone please press star 1. You will be announced by name. Thank you. Star 1.

Irene Aihie: Okay. And while we wait for that I have a - I think a few more questions. There's a question here that says for the bio-com testing like NEM, we can choose the ASCA lab to protect things in the future. Can't choose - are we not allowed to choose non-ASCA labs? I'm not sure - that person may want to

reform their question. I don't know if you all were able to understand that question.

(Shuliang Li): I'll try to answer this question. This is (Shuliang Li).

Irene Aihie: Thank you.

(Shuliang Li): ASCA is voluntary. So for biocompatibility testing use the example here, MEM elution cytotoxicity ( that you can choose ASCA test labs or non-ASCA test labs. If you choose an ASCA test lab you can use ASCA Summary Test Reports with the Declaration of Conformity. And if you choose a non-ASCA test lab that you will do the traditional way that provide the complete test report.

And anybody else from the ASCA team or on the panel can chime in.

(Scott): Yes, (Shuliang), this is (Scott) and I'll just kind of reiterate what you said that, you know, and I think (Eric) mentioned this before that, you know, the ASCA program is voluntary. And even in the current testing paradigm nothing has changed. So no one is required to use an ASCA accredited testing laboratory.

That said, if you choose to use, you know, a lab that is not participating in the pilot you would just need to follow what you've been doing in the past in terms of how you submit the information to support your use of the standard, whether it's towards a Declaration of Conformity or towards general use.

In the area of biocompatibility we have guidance documents and other information that helps drive the type of content that is important to utilize. So if you're using an ASCA accrediting testing laboratory we have - our guidance documents in that area, specify exactly what is the minimum amount of

information that you need to support the use of that test that's included in the pilot.

Irene Aihie: Thank you so much. We're going to go ahead and take some questions from the phone. Operator, can you get those participants online?

Coordinator: Thank you. We do have a few. So our first question is from (Yaching Lu). Ma'am, your line is now open.

(Yaching Lu): Okay, thank you. This is (Yaching Lu) from (unintelligible). I have a first question, which is regard to partial recognize the standard. For example, that 80601-2-61, the clause 201.12.1.101.1 which is for accuracy of (unintelligible) equipment. So in our summary report do we have to specify this part is not recognized by ASCA programs?

(Eric Franka): You can - when FDA is reviewing the test report they will know that we would be looking for additional tests or whatever is covered in that specific guidance document. I would suggest including that in the Summary Test Report under clauses not tested. If it was tested then you can state no, it - it's not recognized by FDA and then that would be fine to just cover, to be comprehensive in the test report.

(Yaching Lu): Okay. Because this one I - yes, okay. Thank you. The second question is if the device isn't modified - so before the modification device didn't pass the test, but after the manufacturer modified the device it passed the test. Do we have to record this in our summary report?

(Eric Franka): Yes. So we would want to know about when the device is modified and when retesting was needed. There was a section of the example report which went into this. If you look at our guidances, and in the slides I think it's in one of

those slides. But in the boxes where, you know, we would expect information to be put if you were using our (unintelligible), there are examples or more information about what we expect to be covered in each of those sections.

So when a device is modified it then needs to go through retesting. We'd want to know how much retesting. Did we retest all of the tests after the modification, etc., or any justification for skipping industry tests. We would also want to know that as well.

(Yaching Lu): Okay. Okay, thank you.

(Eric Franka): Sure. Thank you.

Irene Aihie: Thank you. Operator, we'll take our next question.

Coordinator: On the phone our next is from (Tammy McRiff). And your line is open, ma'am.

(Tammy McRiff): Yes. I think (Eric) has actually answered my question. It was related to manufacturers and the requirement to be accredited - for their labs to be accredited. But I think he's already addressed that. So thank you so much. I appreciate the opportunity.

(Eric Franka): Sure thing. Thanks.

Coordinator: At this time I have no further questions over the telephone.

Irene Aihie: Thank you. We have a few more questions in the chat box. One second.

(Eric Franka): And Irene, as you're looking for the next question I'll just kind of reiterate, or continue from the last commenter to try and emphasize that yes, the manufacturers' own in house testing lab can participate in the ASCA Pilot so long that they become accredited to the program specifications to a standard included in the pilot.

And that that accreditation comes from one of our ASCA recognized accreditation bodies.

Irene Aihie: Thank you so much. Our next question here in the chat function, is are there content requirements for full test reports from labs to manufacturers?

(Eric Franka): For the ASCA program the kind of - one of the novelties of it is the Summary Test Report. So there shouldn't, and correct me anyone, if I'm wrong, but there aren't any additional or new requirements or suggestions for what to include in full test reports.

Man: And I'll add onto what (Eric) said that there are cases because of the complex nature of the standards and it's outlined in the guidance as well, that - where there may need to be certain types of modifications made or something is just a little bit outside of what's expected, that the Summary Test Report guides you to where you may need to provide additional information or a complete test report for that part of the standard.

And that is dependent upon which method, same biocompatibility versus, you know, which standard is being used or how it's being applied in the basic safety essential performance. But this is where it's very important to read the guidance documents and look at the Summary Test Report examples that are in the appendices.

Irene Aihie: Thank you. I have a question here from (Jeff Klinger). Slide 58 summary does not include standards outside the requested scope. Is this on the application or the accredited test scope?

(Eric Franka): So sorry, this - I was just answering this in the chat. So meaning don't - in the application don't propose standards which aren't included in your scope of accreditation from your accrediting body, or standards which aren't in the ASCA Pilot. And you might be surprised, some of the applications we received did have standards that. Usually it's like a different version or edition that isn't currently included in the ASCA pilot that were included in the proposed scope.

So those are not able to be included in the ASCA Pilot at this time. So I hope that clarifies that question.

Irene Aihie: Thank you. Next question here, a bit (limpy). (If) one of the suites of biocompatibility tests were not performed per the ISO 10993 standards. Can I still claim ASCA Declaration of Conformity? For example, the thermal by - the thrombogenicity test was performed in the in vitro study instead of the (K9) study model per ISO 10993-4. Can we still claim conformity?

(Shuliang Li): This is (Shuliang Li). I just want to clarify, the thrombogenicity testing is not within the scope for ASCA for biocompatibility.

Irene Aihie: Okay. Thank you so much, (Shuliang). We have a question over the phone. Operator, can we take that question?

Coordinator: (Yaching Lu), your line is open again. You may ask your follow up.

(Yaching Lu): Sorry. I forgot one more question. So if the product involves several standards do we have to write one summary report for each standard or we can just have a one summary report for all the standards?

(Eric Franka): I think there's a little bit of flexibility here. As long as a lot of the content of what we expect to see in a Summary Test Report is covered in kind of a relatively straightforward way for each of the standards that were evaluated. And I could see it being compiled on one kind of large Summary Test Report.

However, there's nothing to say that you couldn't do an individual Summary Test Report for each one. I think at least for the basic safety essential performance side of things.

(Yaching Lu): Thank you.

Irene Aihie: Thank you. We'll go back to the chat box here. We have a question from (Kathleen Mills). You mentioned that labs should follow 21 CFR Part 58. Should the ASCA AB be reviewing/auditing a lab to the CFR requirements? And should the FDA choose to visit a testing lab, would they review a lab not only to the ASCA approved standard but also to the CFR?

(Shuliang Li): For the accreditation body assessment for the ASCA biocompatibility test labs (21) CFR 58 is part of the ASCA specifications and accreditation body will assess the compliance with the (21) CFR 58. And we do have communication with accreditation bodies and asking them to what extent they need to assess the (GLP) compliance. And what's the second part of the question?

Irene Aihie: Do you need me to repeat the second part of the question?

(Shuliang Li): Yes.

Irene Aihie: Okay. Let me find that question. And should the FDA choose to visit a testing lab will they review a lab not only to the ASCA approved standard, but also to the CFR?

(Shuliang Li): That's - visiting the lab, meaning from the ASCA perspective, that is not part of the plan. And Scott, do you have anything to chime in regarding this part?

(Eric Franka): (Shuliang), could you repeat that last part? I'm sorry. It broke up for me...

(Shuliang Li): Yes.

(Eric Franka): ...on my end.

(Shuliang Li): It's the question will FDA visit the test lab for GLP purpose, for the ASCA?

((Crosstalk))

Irene Aihie: Oh. I'm sorry. I was going to repeat it if you needed me to.

(Scott Colburn): Oh. Go ahead and repeat it. That way I make sure I do. Thank you.

Irene Aihie: Should the FDA choose to visit a testing lab, will they review a lab not only to the ASCA approved standards but also to the CFR?

(Eric Franka): (Unintelligible) requirements that should the FDA choose - I just want to make sure. So the ASCA accreditation body is taking certain responsibilities and making sure that the processes or oversight are - exist. But as a part of the application that information also needs to be clearly (outlined) in how they are

meeting those requirements or those program specifications in the guidance, in their application.

And I would recommend to any laboratory who's interested in applying to the ASCA Pilot, to contact us and we will walk through exactly where you can get that information. And also we'll provide you with more detailed information on how you, you know, it'll make it easier for you in putting together your application.

So I would strongly recommend that you contact us for any biocompatibility lab.

Irene Aihie: Thank you. Operator?

(Eric Franka): Actually Irene, I wouldn't mind - oh, I was going to say if possible, I wouldn't mind asking Ms. (Jen Goode), one of our biocompatibility experts, to kind of chime in on that question.

Irene Aihie: Sure. Absolutely.

(Jen Good): Hi. This is (Jen). Can you hear me?

(Eric Franka): Yes.

Irene Aihie: Yes. We can hear you, Jen.

(Jen Good): So in response to (Kathleen)'s question, the clarification I wanted to provide is that when test labs apply to us we are not going and looking at the labs. But there is in the ASCA program, the potential for us to audit a lab. And

depending on the reason for the audit we might look at specifics related to a standard or we might look at specifics related to GLP or both.

And so we have outlined in the main ASCA guidance when we would audit a test lab that is working with us in the ASCA program. And so I think there is an it depends answer to your question as well, (Kathleen).

Irene Aihie: Thank you, (Jen). I believe the operator had an announcement.

Coordinator: I would like to remind our guests, if you'd like to ask a question over the telephone, please press tsar 1. Star 1. Thank you very much.

Irene Aihie: Thank you. I think our next question in the chat, I'm not sure if it's already been answered but I'll ask it - are there content requirements for full test reports from labs to manufacturers?

(Eric Franka): I'm sorry. Can you read that one, one more time? My apologies.

Irene Aihie: No worries. Are there content requirements for full test reports from labs to manufacturers?

(Eric Franka): I think we might have answered - touched on this a little bit earlier. It hasn't changed with the ASCA program so full test reports should still include everything that was included in the full test report prior to the ASCA program's existence.

Just when using the ASCA program there's the new summary test report which has, you know, more specific content that we'd like to see in summary, of the results that would be fully covered in the full test report.

Man: And I'll just add onto that that the summary test report is what the manufacturer will use to append to their Declaration of Conformity as the supporting documentation for their Declaration of Conformity to the standard included in the ASCA Pilot.

And the reason why the manufacturer needs to have the complete test report is for a variety of reasons. But if there was any question to information that is contained in the summary test report, then it would be easier to have that discussion with the manufacturer during the (unintelligible) review. So it would be our, you know, under - and I think it's just good practice under quality systems, to make sure you have a complete test report of (custom) to your product.

But for the purposes of the 510(k) we're looking for the Summary Test Report.

Irene Aihie: Thank you. I do not see any other questions that have not been answered in the chat, if the team can correct me on that. I do have one last question here. Are third party review submissions eligible for ASCA?

Angela DeMarco: Hi Irene, this is Angela. I'll take that one. So for the purposes of the pilot, third party 510(k) submissions are not included. That doesn't mean to say that we won't include them in the future. But for the purposes of assessing the pilot we are not including third party 510(k) submissions.

Irene Aihie: Thank you so much, Angela. And Operator, do we have any other questions in the queue, on the phone?

Coordinator: Thank you so much. No, we do not.

Irene Aihie: Okay. Well I think we have reached the end of our webinar. Before I close out, to our presenters, do you have any closing remarks for the participants today?

(Eric Franka): This is (Eric). Thanks everybody for joining. If you do have any questions, feel free to email the ASCA email address. There should be a link in the slides that we presented. Or, you know, Ping us and ask any questions you have. We're happy to answer them.

Irene Aihie: Thank you so much, (Eric). Again, thank you everyone. 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](http://www.FDA.gov/Training/CDRHLearn), by Friday, May 28.

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 today's webinar, please complete a short, 13 question survey about your FDA CDRH webinar experience.

The survey can be found at [www.FDA.gov/CDRHWebinar](http://www.FDA.gov/CDRHWebinar), immediately following the conclusion of today's live webinar. Again, thank you for participating. And this concludes today's webinar.

Coordinator: As today's event is concluded, guests please go ahead and disconnect. Thank you very much.

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