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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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

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PLENARY SESSION

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

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M E E T I N G

(9:06 a.m.)

CAPT COLBURN: Okay, good morning. I'm going to ask for our facilitators to come forward. So for this morning we're going to continue in our breakout sessions. I spoke to each of the facilitators in the three rooms. So if you are here and you were in Alarms or in EMC yesterday and would like to continue in that, they're going to continue for a period of time this morning.

Once they have kind of completed their work, they may fold in, but at some point this morning we'll all be coming together to kind of do a brief overview of what we've been working on the last 2 days anyway, but we want to continue what we have discussed yesterday in this group for the -1.

And, Al, where has your partner in crime run to? We were looking for him. Usually he's not that hard to spot. Look for that little shiny dome, and I guess we'll say he's conspicuous by his absence. Yes.

I'm glad to hear that the audio is a little better today. It hopefully will carry over to those online as well.

For those online who are looking to go to one of the breakout sessions, just please go to the main workshop website where the agenda is, and you will see the breakout Adobe and/or WebEx connections for the rooms that you may want to join, or you can stay here and work through the -1 discussion. And then this room will -- this connection will maintain itself throughout the rest of the day as we go more into the plenary sessions later.

So with that, we'll continue on in this group.

Jen Chow (ph.), you had a housekeeping?

(Off microphone response.)

CAPT COLBURN: Advance some -- so this is the breakout session stuff. One more

slide. All right. I'm going to keep this one up for a minute so that way those who are trying to click on a link or look at a link can. Okay. There's the partner in crime. Okay .

One of the things I do want to pass on for our audience, we really want to hear from you, especially too from those who are representing the manufacturers and the smaller labs as well. I want to keep reiterating that, you know, anyone's lab, whether it's a third-party outside lab or a manufacturer's own lab that works in this in an, you know, under an accredited environment in the standards that are going to be a part of the pilot is -- can -- would be able to apply for recognition.

And so we want to make sure we're hearing from all the different perspectives of those who are part of this as well. And I think that's valuable for people that are primarily labs as well, to see the different perspectives and how this all fits into this. And it will help us drive how the scheme itself will unfold, and then how we look at working with accreditation, accreditation bodies, setting up our own requirements and so forth.

And there was a lot of great discussion yesterday. I heard a lot of -- you know, we -- a lot of new work, clarifications, guidances, tools that we may need to develop, to help build the atmosphere a little bit more, specific requirement documents possibly, certain things. So I know we'll want to make sure we capture those, especially when we get into later this morning and this afternoon, to make sure those that are in the room that are in those businesses may have some, you know, questions they may want to ask, to get a better direction for that work. All right.

Pick up your mike, go to town, sir.

(Breakout sessions.)

CAPT COLBURN: We're going to go ahead and take a 15-minute break, and come back at quarter after, where we'll also be joined by the Biocompatibility group. And I'll ask each of the facilitators to, when we start at 11:15, to be up at the table. I'm kind of wanting

to just overview what were the main areas that each group were able to discuss, some areas of clarity, areas that were very challenging that you do not yet have answers for, and to see if other groups had a chance to kind of tackle that, because I did see, throughout the last day, different topics being discussed in different ways, with potential solutions that might be applicable to the other groups. And that's kind of the goal here with ASCA, is not to develop four different schemes that are completely different from each other, but to try to converge into a singular scheme so we can have some level of predictability as to how we are operating as well.

So why don't we take 15 minutes. And we will come back to this room then at 11:15 for our breakout discussion summary. Thank you.

(Off the record at 11:00 a.m.)

(On the record at 11:22 a.m.)

CAPT COLBURN: Could you just grab our Biocompatibility folks and tell them to come on over? Shuliang and Jen Goode, Molly Ghosh. All right.

So when we were planning this workshop, Biocompatibility is like can we just have a few more hours, just a few more hours, please, because we know they would use it all and then some. They're probably saying couldn't we have had one more day? All right.

Ms. Shuliang? Okay. Come on up. Someone put a name tag for you, so I exceeded the fire marshal's request to put so many people on here. That's a separate standard.

Okay. Well, thank you everyone. So we are coming back together in plenary here. And for those who are online, we're also going to continue trying to monitor the chat room.

The goal here is to kind of, obviously, summarize what we have been doing over the past couple of days in our separate breakout rooms, to try to highlight some of the areas that you think are going to make this program work. What is it that you feel will be key for -- whether it's the Agency, what did you hear from the stakeholders that were involved in

your group as well? But this isn't a, you know, table talk discussion. We really want to still have this be open also for those who are in the audience.

I want to open this up, though, by reading a comment that we just received online, and I think it's just -- it's pertinent, I think, to a lot of the discussions that I heard in the separate rooms, and it might help us frame, do we agree with this statement in general. So I'm just going to read it word for word. It'll take about 30 seconds or so.

"I believe that compliance with standards is a valuable and critical benchmark in assuring a product's safety and efficacy. Key to this is the rigorous execution of the testing, clause by clause, with attention to detail and rigorous upfront planning. Risk management, essential performance definition, and clear pass/fail criteria are very important aspects.

"That said, training, mentoring, and policing are all essential to creating good output, training of both the manufacturers and the test labs. For ASCA, in addition to the regulatory formality of approving or auditing test labs, please embed into the program an equally important emphasis on training. Subject matter experts for the ASCA-covered standards will be the key, and training programs will be of critical importance. Knowledge and rigor at the test lab and manufacturer level are the key to ultimate success of the products in clinical use."

I thought that was an interesting comment, and I want to thank the individual who sent that in. I think that's a lot of what we were trying to get at as the underpinnings of building in the whole, you know, those -- filling in those gaps that we've discussed, whether the standards identify essential performance or whether some of the things we're trying to do in biocompatibility and understanding how tests are conducted so the end results are supporting the intended use and safety, all those things are important.

So, with that, and if we're in general agreement that we think that's kind of what we were here to try to do and that ASCA has a role in trying to improve this, if we are going to

collaborate with accreditation bodies and recognize testing labs, what should be our role in helping fill in those gaps, from a training, from filling in some of those technical expertise areas?

But I want to turn this over, and maybe we'll just kind of go through the -- down the chain here and have everyone introduce themselves. And then we'll start with the Biocompatibility group to give a quick summary on what they did, and then we'll turn over then to the 601 groups that broke out.

So we'll go ahead and do introductions.

DR. LI: Okay. My name is Shuliang Li. I'm from CDRH Standards and Conformity Assessment Program. I'm a Senior Standards Advisor.

MS. GOODE: My name is Jen Goode. I am the Biocompatibility Program Advisor for the Office of Device Evaluation.

DR. GHOSH: My name is Molly Ghosh. I'm currently the Acting Deputy Director for Division of Biology, Chemistry and Material Science in OSEL, CDRH.

MR. FITZGERALD: Brian Fitzgerald in the front office of OSEL, CDRH.

MR. TAYLOR: And Al Taylor, ditto, with OSEL being the Office of Science and Engineering Laboratories.

DR. BEARD: Brian Beard. I'm in the Center for Devices and Radiological Health, and I'm the Deputy Director for the Division of Biomedical Physics.

MR. SEIDMAN: Seth Seidman, Office of Science and Engineering Labs, and we're the MCA program advisors.

MR. FORREST: Shawn Forrest, Senior Lead Reviewer in Cardiac Diagnostic Devices Branch in Office of Device Evaluation.

CAPT COLBURN: Okay. Why don't we start with Biocompatibility? You guys, I kept hearing a lot of great discussions going on over there, but just from your perspective,

something that you think would be important that you -- came about in what your goals or your objectives were and things that you think maybe the other groups would, you know, should have an interest in, in considering maybe if that would help them in developing the scheme. And I'd ask each of the groups to kind of consider that as well.

I think Biocompatibility had a really unique plan when developing this workshop and in a way to develop a strong relationship with the testing labs in a very positive way that enhances the labs to continue doing the work that they do, to meet their customers' needs, and how ASCA can also leverage the important work that that does to help make us have confidence in how testing is being done.

So, with that, I'll turn it over to our Biocompatibility folks. I think there were --

(Off microphone comments.)

CAPT COLBURN: Thank you.

MS. GOODE: So we did have someone come up to us after our first session last night and say this is great, we love being able to talk to FDA about this so that we can do the testing that both our clients want and you want before it's done.

So we talked about certain particular biocomp tests and whether or not they would be appropriate for use in the pilot so we could learn from them, and pretty much everybody agreed with what we had proposed, suggested that we add a sample prep. And there were some recommendations for looking at some additional cytotoxicity assays and ocular irritation.

We talked a lot about what the different key stakeholders might do in our breakout session, so we encourage folks to look at those slides afterwards if you weren't in our session. There was some discussion -- the test labs, a lot of them use electronic records. They also agreed to talk about what might be substantial changes that could impact study results and the level of information that might be needed in documentation that they would

submit to us at the beginning of the program.

We also had one member of an accreditation body who spoke up. He pointed out that accreditation bodies, if we select more than one, might have challenges with being consistent unless we're very specific in what we write out in terms of the scheme requirements. And then the technical assessors themselves, anything that we can specify in detail would be helpful to them. The depth of assessment can impact cost, so like in yesterday morning's session, this gentleman pointed out that we do need to think about that.

We also talked a bit about using "no action indicated" and "voluntary action indicated" findings from our bioresearch monitoring to help us decide whether or not sites don't have issues and that could impact study results. But there was a note that sometimes inspectors are not consistent, so anything FDA can do to improve that would be helpful.

Then one of our topics had to do with very specific scheme issues that we were considering. We had proposed using only GLP studies for the pilot, and that was agreed to. Modifications to methods, they agreed to work together to come up with lists of things that they think would be substantial, that might require revalidation or qualification, partially or fully, and those that would be nonsubstantial so that we could agree that we wouldn't look at certain things if they decide to make changes.

We also talked a lot about proficiency testing. We were thinking that there might be specific numbers of animals or durations of experience that test labs might need. And we talked about the fact that we have pretty experienced test labs, but somebody new might come along. And they were -- the test lab participants were really helpful in terms of thinking about volume that a test lab has in terms of number of tests, could make it much longer for somebody to demonstrate proficiency, and that might not be fair. And so we're hoping to learn from folks participating in this, a great deal over the next months on that

topic.

We also proposed a high-level summary and gave two examples. And, in general, I think those who participated yesterday afternoon agreed that what summary information we identified made sense. There were some questions with how we had laid out the proposal that might need some clarification.

We also proposed to exclude, for the pilot only, hydrogels, absorbables, and animal materials or in situ polymerizing because we think there is not consistency in terms of how devices with those kinds of materials may be handled from a test article preparation perspective. And so, during the pilot, we are also hoping to continue to have dialogue on sample preparation for those types of products so that we can come to agreement on what might be a more appropriate, more standardized approach so that when the pilot's successful we can expand it to include those as well.

We may need to think about some training or white paper on how to use a form once we come up with a final approach, so that both industry, test labs, and FDA staff who would review it all have the same understanding.

And then there was a concept of signatures, a test lab signature that the summary represents what was in the actual detailed test report as well as a manufacturer's summary that they did a check and it was consistent. And who actually signs that, we had proposed certain people. And I think the general agreement was that the test lab manufacturers could decide. And there may be some issues with electronic systems and implementation of forms, and so we also would need to think about that.

Today we had 2 hours of very healthy discussion. We apologize for being late, but we were trying to write up our summary. We talked about each of the specific tests that we have proposed for use in the pilots and identified the critical elements that we think it might be important to understand from each test lab. And the panel participants and

audience members agreed that we had identified most of the critical elements. But they did point out that for in vivo studies, animal identification is important. For acute system toxicity, balanced calibration is key.

For irritation studies, the rabbit colony selection and maintenance issues that we need to be thinking about. Complement activation, while it uses a test kit, there's not a standard method that's necessarily used, and there can be variability that could impact results. And so through this process, we end up with a more standardized complement activation approach that could be helpful. Training and documentation, the technicians may move through that at different rates and may need different levels of training, and so that may be different across labs, and we're going to need to pay attention to that.

Proficiency assessments and requalifications are often needed, just routinely or if some type of retraining is needed. Some groups do this annually; others do it quarterly. It may be lab or test dependent, so we probably need to look at that pretty closely. There was a recommendation that more dialogue on some of these topics would be helpful. And so yesterday afternoon I spoke with Scott a little bit about the possibility of developing a community of practice so that we can work through some of these issues in more details and learn the kinds of things we need to learn.

And then, as I noted earlier, there is probably further work that needs to be done, either through this process or through standards development on sample preparation and extraction selection as consistent approaches may be helpful for some of the more complex devices.

So we wanted to thank everybody who participated in the panel and the very active audience participants. And just noting here that anybody who was online or in the room and had more questions, that's the contact information.

Thank you.

CAPT COLBURN: Thank you, Jen.

I think what we'll do is we're going to continue. I'm going to ask Shawn -- I understand you guys did a few slides, so we're going to move to Alarms, and then we'll go to EMC and then 601, if that would work all right. So --

MR. FORREST: Okay. So our session talked about initially what was seen as the benefits of the ASCA program. The things that were highlighted were improving consistency in the test methods, the transparency particular to the manufacturer in how those tests are done, and then a hope that we would be able to develop the standards more efficiently by having the collaboration between the different stakeholders involved.

We also asked about what problems to look out for, and there was -- one concern was that there's not a lot of test labs in the country that do 1-8 testing, so that might not be enough to pull from for the ASCA program. There's some uncertainty in how to handle labeling and risk management requirements, so interpretation by the test lab where that's necessary in some of the requirements, and then whether the testing and the report would be usable for a global marketing as opposed to just the U.S. market application.

And then talking about which -- so whether 1-8 is a good candidate for the pilot program, there are some parts of it that are not particularly well defined. And we highlight the sections on intelligent alarms and distribute alarm systems that would need some significant interpretation for whether -- while they meet the requirements of the standard, whether that would be -- they would give the information that's necessary to do a full FDA review of those features.

Overlap with particular standards was a positive, that there's -- the group wasn't aware of any particular standards that impact the alarm standard, and so not having those part of the ASCA program wouldn't necessarily be a problem for the alarm standard being part of ASCA.

And then it was identified there were some problems with the current amendment, that is the Amendment 1 version that's recognized right now, in discrepant descriptions of testing that have been addressed in a future revision for 2019 publication. But so there was a question of how we would handle that and whether the 2019 -- the Amendment 3 or 2.2, whatever that ends up being, would be the one that would be under ASCA or if we would manage some of those issues with the current amendment.

And then as far as criteria for competency for being part of ASCA, some of the things that were discussed were training requirements, what equipment requirements should there be, where you do the testing, as far as the physical set about the test facility and those procedures. There were some suggestions about standard, meeting the standard for those, but it wasn't -- some parts were not really clear what is actually necessary for an ASCA requirement.

But so, overall, I think the discussion was really helpful. I think the group was very enthusiastic about 1-8 being part of the program, and that overall, that testing could be -- you know, we could develop those requirements clear enough to work well in this program.

CAPT COLBURN: All right. Thank you very much.

We're just going to do a quick slide switch here before we go to our 1-2 folks. And just -- what we're going to put up is just the four main question objectives, Seth and Brian, just so I know that's what you guys worked from.

While they're doing that, I just, you know, I wanted to say thank you. I think this, what's unique about the 1-8 standard is this is the one to where I think manufacturers' laboratories might have an opportunity to be a part of the ASCA program a little bit more directly as well because it kind of gets into more of the device-specific areas and the environments that potentially can be more appropriately handled in that environment or through that tool, more clearly defined when they go to an external testing lab or a third-

party lab to be able to have that performance criteria built in. And ASCA, hopefully, can help bridge some of that. So thank you.

So we're just trying to sort through the hundreds of slides that are in there to get that up. But why don't we go ahead and have Brian and Seth go ahead and start?

DR. BEARD: Okay. Good morning. We did 60601-1-2, the EMC standard, and we began by talking about incentives to participate in the program. And as should be fairly obvious, we feel that the -- and the group felt that the manufacturers needed to see decreased review time at minimal cost increase to testing.

We also established that communication is essential between the test labs and the FDA. It needs to be frequent, bidirectional, and documented.

We did not want the ASCA program to be limited to the particular standards but to -1-2 in general. We felt that limiting it to particular standards was, in fact, too limiting. There wouldn't be enough devices that it would be economical for the test labs to participate.

The scheme or a guidance should specify what the FDA wants in test reports for EMC, and the least cost way to do this is if the test labs can simply incorporate those elements that the FDA needs into their existing test report formats.

Also, if the test labs' current accrediting bodies will just have an extra checklist that they need to go through to accredit the lab for ASCA, that would also be the least cost way for them to get into the ASCA program.

And the test lab should be able to ask FDA general questions about how to interpret standards for ASCA use. And the example of the FCC online system was brought up, which provides anonymous but documented answers on the FCC's opinion on how to proceed.

We also decided that having the test labs address labeling issues is problematic. It might not be a good thing to include in the ASCA pilot, primarily because of the timing.

Labeling is almost always the last thing that's done by the manufacturer, and the tests may have been done up to a year before that. So it's just hard to put it in there.

And the test plan is the responsibility of the manufacturer. The test plan involves the risk-based elements, such as essential performance and pass/fail criteria that are frequent causes of deficiencies. Yet those elements, we will expect to see as part of the test report, even though they're not necessarily determined by the test lab.

MR. SEIDMAN: A couple of other notes that we had during our session, as Brian mentioned, cost was a big driver and making sure to minimize that. And so it was thought that there should be no such requirement to require like a full test report for ASCA. That way if a device came back and had a small change or needed just a part of it to be tested, that it would still be applicable under the ASCA certification.

When we got into determining the competency of the test labs, there wasn't a whole lot we thought was necessary based on a technical competence because these labs are already accredited to do these standards. But the competence would be more on knowledge of appropriate documents, including like FDA guidances, particular standards, you know, what's wanted in a test plan and how to develop quality test reports.

As Brian mentions, the group did discuss labeling quite a bit, and while we thought that -- it was the consensus of the group that we thought that the lab should be evaluating that, it was just very logistically difficult, so that's a hurdle that we'll need to figure out.

And there was a strong desire for the test labs -- the test labs wanted FDA to specify essential performance for specific devices.

And then finally, I think Brian mentioned it but it's worth repeating, just communication was really the biggest part of this. There was a big push also for training from potentially FDA to the test labs, to manufacturers. And, of course, this does add additional cost, but we thought that that would be beneficial.

CAPT COLBURN: Before we move to our -1 folks, one thing I heard, and you know, I was a reviewer for about 7 years myself, and one of the hardest things as a clinician, when doing reviews and finding something that, you know, we needed to do additional information, questions on, or something that was not quite addressed, or even say the performance wasn't quite meeting what we wanted, but then the labeling part came in.

Well, we could label this risk out in a way that might be considered appropriate, but you know, I'm a nurse, and a lot of times I don't always read the instructions for use or all the labeling. And this is an area, from a clinician standpoint, that I have -- you know, that's what I'm really trying to do in this program to improve it.

So how can we improve the expectations of what's necessary when developing the design controls of the device and taking the user or environment or patient's needs into account up front, and doing it in a more appropriate and correct way so that way when we do decide the elements that need to be tested and the labeling that would accompany the appropriate use of the device, would make more sense and reduce the need for additional information questions to add to the solution of, well, we could label this risk out so it's made sure that the user wouldn't accidentally use it?

And I think that's what we're trying to get to. And that's when we've had similar discussions about how the essential requirements plays a role in helping the design controls of a medical device. It allows a manufacturer to know, what are the expectations? What are the risks? What are the things that the regulators are hoping that you're doing to take into account the safety of the patient or the user? And we can build that into our design controls at the earliest stages to support a more complete file that hopefully will have minimal to no changes based upon additional information questions.

That's always, I think, the goal. And if we can do that at the earliest stages prior to submission to the FDA, then we have a more complete product that's designed and will act

safe in the environment when it goes into the market. So I just -- I appreciate Brian and Seth bringing that area up about training, and then the idea of, you know, labeling sometimes being in effect way after the testing and design of the device, but it actually is a key element, I think, in the design control process, when you consider all the use, users, and what the true product is for, at least from a clinician's standpoint.

So to our -1 folks, you got the big room for the day. What'd we discuss?

MR. TAYLOR: Thank you. Yes. We got the big room, not necessarily the most people. So Mr. Fitzgerald and I could talk about this topic all day and often do. And we worked really hard to throttle ourselves back in the sessions and have you do the talking.

We really pushed hard on this question of value and were met with a lot of passivity actually. On the other hand, I didn't perceive any body language in the room that said that we don't like this or we don't see the value. The consensus that seemed to emerge was, yes, there's potential value here, but it's going to be really hard to realize it.

We got lots of insights into issues and concerns, somewhat fewer suggestions for how to resolve them. But we heard extensively from representatives of several of the testing labs, at least two accreditation bodies, and a number of FDA reviewers, and I think that at times the conversation got pretty lively, so that sharing of perspectives will certainly be of value for those of us who were in the room and heard those different perspectives.

In terms of capturing that, those insights, rather than Brian or I trying to say here's what we heard that was most important -- that would be filtering through our biases -- I think the fact that the meeting was recorded and there will be a written transcript, we'll mine that written transcript for the many nuggets that I heard and not try to summarize them here.

There are just a couple of key things that I think were, you know, certainly from my perspective, very important. And one is, of course, that 60601 is a beast. Brian repeatedly

asked, is this a suitable candidate for the pilot? And almost every time he asked that question, there was silence in the room. But on the other hand, we didn't hear anyone saying no. And I think the sense of the folks in the room, from what I gather, is that all of us who work with that standard think it needs to be in the pilot. And, again, it's going to take a lot of work to gain the value that's -- the potential that's there.

Let me just ask Brian what you want to add to that.

MR. FITZGERALD: Just a couple of observations. It seems that the element -- the elephant in the room is risk management and how risk management can be, if you like, captured -- encoded is perhaps a word to think about it -- in evidence that's generated to show compliance. It seems as if the consensus is that the -- indeed, it's what the law and common sense says, that the manufacturer is the one that has to do the risk management. They have to somehow then build a portfolio of which only a part will be a test report form and that some additional evidence should form the residual element of that portfolio.

Perhaps we, in the Center, haven't taken the time to specify what it is that we need in sufficient detail, moving forward, in order to facilitate the existing industrial infrastructure to participate in a realistic scheme template, which can cause the types of problems that we're used to seeing to occur much, much earlier in the design cycle before they ever get to us.

A couple of other observations is that we heard mention that our slides, our discussions talk about test labs, and it was mentioned that maybe we should be considering conformity assessment bodies writ large. That's because that maybe some of these functions may exceed the bounds of the marketplace currently occupied by test labs. Maybe there's space for a type of certification body in there.

Another interesting element that was passed on is that we don't see much of the basic safety and essential performance called out in Q-Subs. These are these preliminary

submission meetings that industry has with us. Tends to be somewhat of a stepchild frankly. We clearly need to do better, and we need to do better earlier in the design cycle. And the scheme, if it's to succeed, has to help us encode that in the regulatory portfolios.

CAPT COLBURN: All right, thank you.

I'll first just open it up to see if, based upon some of the comments you heard from the other rooms, because none of these people got to benefit from going from room to room, and so I just -- is there anything else you would want to add based upon what you heard?

MR. FITZGERALD: Yeah. I will say congratulations to the party on my right, the Biocompatibility folks, who seem to have gotten further down the road than our 601 community. I find that actually really rather surprising given that there's really a flourishing industry already present in the 601 world. I'm hoping that we can -- together we can pick up the pace in the 601 community to get these things ironed out so that we catch up to these folks.

CAPT COLBURN: It might be a game of the turtle and the hare. Who knows? We'll see, right? Okay.

One thing I do want to make sure is that this is an opportunity, too, to ask questions based upon what you heard and areas that maybe you thought that were identified in one group that might help discussions that were taking place in another. Remember, the goal of this is to develop a scheme, not a bunch of schemes, in the way that makes it very clear for us in how we operate internally as well, because if we have so many schemes, that makes it much more difficult for us to be a scheme owner.

I'd like to try to hear from the different categories of stakeholders here. So we have accreditation bodies, we have testing laboratories, we have manufacturers, and we have regulators here. I'd like to see what your thoughts are, and also from this, what do you see

as a valuable nugget? How is this possibly -- we'll use the marketing term -- marketable for you in your area to what you think would help improve from what we have existing today, to possibly have a system where testing can be done at a level where regulators are feeling that they have a much more level of confidence in making a determination on the first go around, or being able to even improve at the earliest stages how manufacturers are able to identify the appropriate safety and performance criteria?

So I just want to open it up for anyone. Maybe we could ask some of the staff from SMS to maybe help with any -- well, we have microphones. You can either come right to the microphones, or raise a hand, we'll bring a microphone to you. Any comments? I'm not going to release you for at least 5 to 10 more minutes, so you have to say something.

Thank you, Grant. Never short of words. I appreciate it.

MR. RAMALEY: I almost thought of asking Gordon here for his opinion on this, but Alford's --

(Off microphone comment.)

MR. RAMALEY: Yeah. I relate a lot with Alford's statements. I was talking with Fred. There's a lot of pensivity about the value to our industry. And but at the same time, you can create value. I really believe that. And I'm surprised we didn't hear more from NVLAP, because they're deep in accreditation. They know the standards. They're going to be heavily involved in this process.

To add value, it's got to be connected to some benefit where we're going to get this on there and regulators in all parts of the world are going to go, yeah, come on in, you can sell your product here. And right now we have something like that with the ILAC MRA. We get a little ILAC mark on our test reports, and it's our passport. Maybe there would be an ASCA mark.

But as a scheme owner, you could do that, but it has to be done through a process

where you're involving the entire, you know, group of accreditation bodies that are participating in ILAC. And that's my personal opinion. I would like to know what Gordon thinks about that.

MR. GILLERMAN: So just in response, you know, I think one of the things that does happen -- and Scott already participates in the international global regulatory forum. And certainly, if you use the European Union for an example, right, they have a whole different system, right. In many ways, they've already devolved the responsibility for individual device authority to the marketplace to private sector organizations.

We're not in the same regulatory construct in the United States, but I think there are possibilities to work together with our partners in other countries and find out how we can work together to reduce the barriers that medical device manufacturers -- to enter into the global marketplace. And I think steps like this are one step forward, right. We're looking at taking a step where work done in the private sector in conformity assessment will have a different role in FDA medical device approval. And, again, I think it's one step toward a global future where things may be more interoperable from a conformity assessment perspective.

DR. RAGHEB: Hi. My name's Tony Ragheb from Cook. I work for an internal CRO within the Cook organization, so I kind of represent both a testing lab and a manufacturer to some extent.

Some of the comments that were just made emphasized this thought in my mind. So I have a lab that's ISO 17025 accredited, and I was thinking about our scope of accreditation, and I checked it just to be sure. The standards listed on our scope of accreditation are not just ISO standards. So it got me thinking about -- if this has already been mentioned and I missed it, I apologize. Have you thought about the future vision, whether the methods that you would accredit to -- in fact, we have laboratory-developed

test methods that are on our scope of accreditation.

So have you thought about there are certain standards that FDA recognizes, partially recognizes, and not. What's your future vision? And I think that could impact the global applicability and the marketability for standards and methods that maybe are not currently FDA recognized.

CAPT COLBURN: So going back to how come we didn't pick the 1,200 standards we have in our program but, you know --

DR. RAGHEB: Well, not for the pilot program.

CAPT COLBURN: Yes.

DR. RAGHEB: But this pilot program --

CAPT COLBURN: Looking forward, yes.

DR. RAGHEB: -- leading to a future vision.

CAPT COLBURN: So the future vision of this is to, from our perspective, gain an appreciation and understanding of how -- what is the power of accreditation? What is its meaning? How does that fit into the overall part of what we look at from a risk-based regulatory agency? You have quality systems in your organization. From our -- from the discussions we had today, we would probably like to learn, is your accreditation to 17025, when looking at how it folds into the quality management standards that it's associated to based upon your certification to 1345, or is it based upon how it's done, written more in the base standard of 9001?

That was one of the discussions that came up yesterday. And that's where manufacturers' questions were lying in as well. So I think there's information from that that would help us again gain an appreciation and confidence of seeing how does this work in the piloted standards right now? And then from an outgrowth of that, how does that apply to the standards that we have seen as important for recognition? And what could

understanding or recognizing testing labs that are accredited to a variety of standards that may be outside of the ISO/IEC realm -- we didn't focus on those because they were ISO and IEC. They just happened to be and they made the most sense from a pilot start point.

But there are several standards across all the SDOs. And I think we're involved in over three dozen SDOs and have most of those represented in the recognition platform that could be candidates to this. But we also didn't want to select standards that didn't have a very large audience to start a pilot from.

But the idea is to try to see is there enough value in developing a scheme that could help push forward and fill in some of those gaps from a regulatory science concern, that would help promote the use of standards more appropriately, more consistently, both in how testing is conducted, how the appropriate types of test reports are brought to the Agency, and therefore also how we interpret how that meets the end result of what we're trying to do in making a regulatory determination?

That then helps us fill in what we're trying to do, and this is to Gordon's point, from an international regulatory forum. If I can understand how standards are developed, and we know they're very -- you know, they're built to try to adopt the innovation that's coming as well as to try to support the testing that needs to take place. But that's the big challenge we have as regulators is we don't see all the solutions baked into the standard.

If we can try to understand, through the development of the scheme, how to appropriately add those additional technical requirements to get the confidence we need and be able to share that in an international regulatory forum, then we can start building more trust across from one regulatory determination to another. In the development of our guidance, that's going to close on draft tomorrow, those are some of the areas those regulators brought into concern, though, is our friends from the north, and Health Canada go, God, we really wish all standards had endpoints. Well, every regulator would love to say

that, but we know that's not the case. So how do we build the confidence in? So this is one of the ways that we're hoping will build that out a little bit.

Dana, you were going to walk up. I want to make sure you get an opportunity too.

MS. LEAMAN: So Dana Leaman with NVLAP.

As an accrediting body, I just wanted to speak to -- I think you've got a lot of valuable information that's been communicated to you. And I alluded to that in my slides yesterday, that as an accrediting body, one of the things that we would look at in applying this program in our accreditation world is these additional specific program requirements. So I think you have a lot of valuable feedback in looking at some of what I call pain points that many people have brought forward in your current process. So I would encourage you to work with your stakeholders and include the accrediting bodies as we move forward to develop these specific program requirements in the ASCA program.

Thank you.

CAPT COLBURN: Thank you, Dana.

Alex.

MR. GROB: That'll be easier, I guess. Alex Grob from MECA.

I just -- two things I wanted to mention. The first one is when we talk about the value proposition, which we kind of beat on pretty heavy in this room, as a testing lab we see value in being able to provide a service if the service will get our customer where we think it will take them. But it's a secondary value because if our customers don't see value in it, then there's no sense in us offering that service, right.

So I think one of the key things to figure out is, from the manufacturer's point of view, what is the value to the program? Because they have to invest it for the test labs to invest in it. It's a chicken-and-an-egg scenario, right. A test lab won't do it if a manufacturer's not going to be interested, and a manufacturer won't do it if there's no test

labs.

The last thing that I wanted to say -- I just completely forgot. So maybe I'll remember in a few minutes, but that's it.

CAPT COLBURN: I thought you were ready to go karaoke on us when you grabbed that mike. I was kind of hoping there.

Anyone else, from a perspective? So I think you touched on an interesting point, and that's, you know, part of what we'll come back after lunch to discuss is, you know, what does success look like? What are the key performance indicators that we should be baking into this so we understand what we're looking for, what we're driving?

If we're not seeing success from a certain area or from a certain stakeholder, how can we make sure that it's being built in appropriately, if that's something that a testing lab was making sure they wanted to see in this so they would want to participate in the future or that an accreditation body wanted to make sure it added value to what they do already? It's just not another regulator stepping in and throwing a scheme in the bucket just because it says it has to do this in MDUFA.

What's the purpose to add the value, and then, you know, from the manufacturer's point of view, of course, as well, same thing. What does this bring value to you when you are building the relationships and the contracts that you 're developing with the testing labs and how you are pulling that all together into delivering that information to the regulator that you're working with?

And then from the regulators, what does this look like for us? What does success look like? And we will have them, someone from the regulatory community, after lunch discussing that from a high level as well.

And so what we'll do, unless there's any other comments before we break for lunch -- I busted that by saying before we break for lunch.

MR. TAYLOR: Maybe one more.

CAPT COLBURN: Yes, Al.

MR. TAYLOR: So I think one important thought that came out of our discussion is that this document that's going to be provided by these conformity assessment bodies that we often refer to as testing labs has to be more than a 17025 test report. It's clearly less than a declaration of conformity to the standard or a certification of conformity by the traditional meaning of that term. And the devil is in the details as to exactly how we characterize that document that is going to be provided by the conformity assessment bodies under the scheme.

And we did hear a lot of specific thoughts that will inform us as we work out those details.

CAPT COLBURN: Okay. Any other lunch crashers?

Okay. So when we come back, we'll have the session, the ASCA Pilot Performance Metrics. We will also have another opportunity for anyone to kind of give a short presentation or discussion. And then we'll do a wrap up, and that would call the end of the day.

So what we'll do is we'll break until 1 p.m. That gives us a little bit more than -- well, 54 minutes. And come back here at 1 o'clock, and we'll go into our next session. I'll ask those who are on the panel to just, at 1 o'clock, be up here, and we'll have a name tent for you. Thank you very much. And thank you to our facilitators for doing a great job the past 2 days.

(Applause.)

(Whereupon, at 12:06 p.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(1:00 p.m.)

CAPT COLBURN: Okay. So I'm going to welcome everyone back. I know we're going to have some tricklers in, but it is 1 o'clock, and I want us to be mindful of time and want us to utilize any time that we can as appropriate.

So this afternoon we're going to start off with, you know, a group of representatives who I think can kind of give us the different approaches and what we're looking at with those that were heavily involved both in helping think about this program and in the negotiations under MDUFA IV, and also in seeing from, you know, on the premarket side, what are areas that maybe could benefit from this, what are some of the areas that, you know, the senior leadership and the Agency's hoping to see that's where we can improve on the appropriate use of standards, how this plays into a larger picture that you heard being discussed in opening remarks yesterday.

We have a standard developing organization that has been interested in hearing what is ASCA and how does -- what does ASCA do from a standards development? We've discussed a lot over the last day and a half about the standard and where the standard may not have the nice baked-in ingredients. It tells you what your cake needs to look like, and guess, go take a guess on what type of flour and eggs and how many times to turn it sometimes because the standard might tell you -- not tell you all that. What can we do to improve that? What are some of the tools that each groups can have?

And then we have organizations, both from AdvaMed with Jamie and through Elisabeth George representing MITA here. And so I wanted to kind of kick this off and look at, you know, we have a slide above that are kind of the main areas, what we're looking at, but I've asked each participant here to kind of give a 5- or 10-minute overview on both what they're there representing and then how do they see this in a bigger picture. And then

we're going to kind of just open it up again. This has been a big, you know, sharing exercise, so this is an opportunity for you to be quiet for an hour and a half.

And I want everyone here to continue and open up discussions and ask questions to a different set of stakeholders that have not been up here yet, you know, to discuss some of these topics, so that way we can get those perspectives brought in.

So who wants to go first? Everyone always looks at the FDA person. All right.

Angie. And poor Angie, she was very ill 2 days ago, and I'm very thankful that she was able to come here and looks like she never was ill.

So thank you so much for making it.

DR. KRUEGER: Well, thanks. My voice is still a little raspy, so I hope you can hear and understand me. If not, let me know.

Thanks for that introduction, Scott. And I really appreciate being up here with these women. We've had a couple of calls, and it's nice to be able to put faces with names and collaborate in this space.

Closer? All right. And so is that better? Okay. Thanks.

And so I think, you know, as Scott mentioned, I'm here kind of providing the FDA perspective, you know, particularly in thinking about from a premarket review perspective and how we use standards now. And so I was trying to think about, you know, what's the current state, and what do we want the future state to look like? Because I think that helps us figure out what success is.

And, you know, and I have review experience myself, but I also understand how our staff do it these days. And, you know, I think a common scenario -- and you guys can attest to whether this is true or not -- you know, is that a sponsor submits their 510(k), for example, they submit a declaration of conformity to a specific standard. They may indicate some specific deviations, or they used, you know, had to select certain criteria or

methodology within the standard. And they outline those things. And we know that there is variability in the testing and how a standard is used.

And so with that paradigm, I think it's difficult for us to establish safety and performance. And the result of that is that the reviewer requests a lot of test reports. And So, you know, a whole slew of paper, in this electronic age PDFs, you know, come into the Agency, and our reviewers start weeding through them. And they're looking for, you know, an assessment based on the standard and whether they believe that information is valid and true and whether they can rely on it.

And what that usually entails, with all of those reams of paper, are buried somewhere in there, there is, you know, a question that our reviewers have. And so they reach out to the sponsor. And, you know, there goes kind of the interactive review or a set of questions. And all of that takes time. It's all resource-intensive, both for the Agency and for the company and, you know, we're -- you're submitting a lot of information to us. We're reviewing a lot of information.

And I think, in terms of the premarket review, what ASCA offers us, you know, is a different paradigm. And we can, you know, look from a policy perspective and tweak how we think about the use of standards and premarket review, but I think sometimes we recognize that we need a different approach. And I think that's what ASCA is offering us. And I think from a success perspective, you know, in thinking about premarket review, it's really a total different paradigm shift with, you know, the use of conformity assessment, which allows us to have confidence in that information. And instead of test report after test report after test report, we're seeing, you know, several pieces of paper that outline how that conformity was assessed and so that we have confidence in that.

And that may mean that we don't have to see detailed test results and all of the test methodology, and so we can go from volumes and volumes of data down to, you know, a

handful of pages. And that, I think, is where we see a lot of payoff from the premarket perspective, both in terms of resources for industry and FDA, but truthfully, from getting innovative products to market and making sure that patients have access to safe and effective products as quickly as they can.

MS. WOLSZON: Thank you, Angie. And thank you, Scott, for inviting us to be part of the Panel.

I'm Jamie Wolszon of AdvaMed. One of the privileges that I have at AdvaMed is to represent our standards working group. And we, along with MITA and MDMA, were involved in the negotiation of ASCA. And so I can sort of talk about what we were hoping to see from the program at the time.

And, Angie, you gave us sort of the perfect segue, which is that, you know, I think the bottom line is we're hoping for shorter review times, right, that at the end of the day what we're looking for is a shorter review time, you know, sort of questions on how do you necessarily measure that, right. Angie mentioned the questions, whether they be through the form of interactive review or through the more formal additional information requests.

You know, we are really hopeful that for this program to succeed, for those particular standards that are participating in the program with the particular testing laboratories, that that's something where there won't be those particular questions, right, that it can really sort of really be a reliance on what's coming in. And to that effect there -- you know, there's language in the commitment letter about that, right, about essentially that it won't -- there won't be re-review unless there's, you know, a periodic audit or there's a material question of safety, right, some reason that it really needs to be done.

So I mean, I think for us, really the bottom line is we are hopeful that it will allow FDA, as Angie was saying, to sort of, you know, free up their resources, free up our resources, result to faster review times.

I had someone ask me, you know, are you -- how many more hours or days -- or less hours or days would the reviews need to be for buy-in to the program? And I don't -- I mean, maybe your members have discussed this, but I mean, we didn't talk about that kind of granularity. It was, you know, the idea of tracking review times, the idea of looking and seeing how often questions were being asked about the standards that are participating in the program.

One other point I thought, in light of yesterday's discussion, was worth mentioning was again this idea in terms of value. Dr. Shuren mentioned, for biocompatibility, the possibility of having a review that's currently 11 hours go to a 15-minute review. And that, you know, is the kind of -- that is certainly I would believe to be value, right, that if that's the kind of thing that you can demonstrate, that that is something that would certainly be attractive to device manufacturers.

I think it's also worth mentioning that it is a voluntary program. Just because, you know, to the extent that there's concern about having to be part of this program, we always sought, and I don't think FDA has ever said anything different, that it is a voluntary, opt-in type of program. So I think those are my initial thoughts.

Elisabeth?

(Off microphone comment.)

MS. GEORGE: No. It works.

Hi. I'm Elisabeth George. Many of you have already heard me talk a couple of times over the past 2 days. I am here actually representing MITA, which is the imaging devices, so x-rays, CT machines, and the like.

And I have the fortune of actually sitting at the MDUFA negotiating table, and actually, this was one of the areas where industry really was very excited. We were excited for a couple of reasons because we could see the ultimate future of this. We know that it's

going to take a while. We know that we have to start with a pilot. I believe, if I remember correctly, that even in the negotiating, we had talked about only three standards needing to be in the pilot.

We wanted to keep it focused. We wanted to keep it broad, like we have been talking about the standards that we're talking about today, so that it touches many different products so that it would be open for engagement by many different manufacturers if they so were so interested.

It's interesting that we talked about this scheme or program being a voluntary. Just remember, standards are also voluntary. So, you know, it's nothing new here. You know, you don't have to follow the standard to claim compliance. It's a heck of a lot easier if you use a standard because it helps you with criteria and things like that, but you can always create your own ways.

I did want to mention a couple of things as what I myself and MITA and many others that I've spoken to have really felt are things that should be considered and values. One, it is important that we leverage existing schemes. We don't want to duplicate things. We heard Gordon mention earlier today about the regulatory schemes. Every country, in 140 countries, 140 ways of getting our products approved, anybody who's distributing products knows that. Some places, we get to self-certify, different risk classifications, all of that. But one of the things that is common is the standards that we can leverage. So if there's an opportunity to use existing methodologies, that should be the way that we follow.

If there's opportunity to improve those standards, the way to do that is, is participate in them. Be there. You know, we -- I was in the Alarms group. We talked about -- it was great. In that room we had representatives that are sitting on that standard that were actually talking about specifics of how they're improving things. So that was really valuable.

I like that Scott and his team identified more than the three standards because I think it will be valuable to get lots of insight and data. I like that we have some that are the beast, as Brian and Al spoke about, you know, that are going to be difficult to deal with.

I think it's going to be important, with the guidances that come out, that we understand that some of those guidances are going to start off as the guidance for the pilot, not necessarily the guidance of where will you go, because the only -- we need guidances to how to work in the pilot, and then we're going to learn from the pilot and create more guidances. And it will be slow at first, but I think we expect that.

The biggest gain, as has been already mentioned, is, you know, time to market. And sometimes one of the things during negotiations, and I know this may make people cringe, but if we can improve the time to market, sometimes we're okay with spending a little bit more money. I know that that may make some of the small manufacturers cringe to hear that, but you know, sometimes it's worthwhile to spend a little to get a lot. That should be part of the way forward.

Some of the mindset that I was thinking about that could go on during the pilot that would be ancillary support to actually support going forward, similar to the guidance process, the FDA has kind of their A and B list of how they handle guidances, it would be nice if we start pulling together an A and B list of standards that we want to work on. I know we've heard about home health. I know we've talked, in MITA, about the EPRC standards, about DICOM, about cybersecurity, which I know everybody's probably cringing on that one, but you know, opportunities for us to make things easier, to limit the amount of questions, limit the amount of data to be submitted up front.

I know that there's also been discussion that there had not been a lot of questions arisen in some of the areas, particularly in the 60601 area, and partly because in a lot of cases manufacturers are just submitting reams of paper already or submitting large test

reports already. And because we're submitting so much already, maybe that's why there aren't as many questions.

It would be nice if those could be handled more as a design history document review because, again, if you think about it, the standards test is not the only thing that proves that the device is safe and effective. So there's a lot of other -- you know, our design history files, like everybody in the room's, are probably for each device maybe as tall as I am or larger. So there's a lot there.

And then the one other thing that I was thinking about, associated with training, that I heard a number of people talk about training, I think that there's lots of opportunity for everybody in training. We've talked about, we've heard the risk management files are overly burdensome and difficult, so maybe there's some training that could be there. The quality of them is poor. The test reports are illegible. You know, there's lots of opportunities there.

But another training that I was thinking of, I know the FDA, in the pre-cert program, had a wonderful opportunity to actually spend a couple of days sitting with manufacturers, understanding their design controls process, understanding how they were developing their software and doing that. It might be a really awesome opportunity for the FDA to actually get to go to a test house, get to watch a test be performed, get to look at what the test plan looks like, get to look at what the deliverables that a test lab gets from a manufacturer to do that activity, because I'm sure that the only way to actually understand that process is to get to walk that process.

So I've got lots of other things, but I'm going to pass the -- pass it on to Jen, then.

MS. PADBERG: Hi. Jen Padberg here.

I first just want to echo the thoughts on the panel here and thank Scott and the FDA team for inviting me to come and participate in the session today. I've really enjoyed the

last day and a half and learning more about this process and the concerns of everyone.

To give you a little bit of a background on AAMI, we're a professional organization. We're focused on health technology. We're not a trade association. We don't do any advocacy. And we have about 7,500 members in the association. Our members are manufacturers, test laboratories, regulators, healthcare delivery organizations, engineers, clinicians, students, academics, researchers, consultants. It runs the gamut.

We've served as a standards development organization for well over 40 years, and we also carry out educational activities, certification, and other things. We're accredited by ANSI. And we're the secretariat for 11 ISO and IEC technical committees and subcommittees and 18 U.S. technical advisory groups. We administer more than 170 national committees and working groups that develop American national standards and technical information reports.

We've published about 280 standards, and we have more than 2,300 domestic and international participants in our standards development activities. We hold the secretariat, specifically for the IEC Subcommittee 62A, which oversees the 60601 series, and also the U.S. TAG for 62A.

We participate as a member of the ISO/TC 194, Biological and Clinical Evaluation of Medical Devices group, where the one -- where the 10993 series of standards is. And we also oversee the U.S. TAG for that group.

I think that there's a lot of challenges that the Panel has talked about. And I also think there's a lot of opportunities for how AAMI, in particular, can help with the ASCA program. AAMI, as a professional society, as a convener of stakeholders to develop standards, is very well suited to assist in this. What we can do is that as standards are developed and revised, we could be clear in terms of what compliance to requirement means and also what, if anything, can be included in standards that would help the

regulators in this goal. We just need some clarification about what those things might be from the regulators about what we can include in standards for that.

Related to test report forms, we could also be developing those in parallel with standards as opposed to after the fact. I think that that would help things move along a lot easier. We definitely feel that that should be part of consensus process, and so going hand in hand with standards development, I think, seems to make some sense. Probably best to do that at the national level initially and then perhaps take it to the international level or to ISO.

AAMI is also well suited to assist in developing other tools for ASCA. We have a lot -- we're a long-time standards developer, as I mentioned. We have a proven track record for bringing together all the stakeholder groups. And we have a robust consensus process for standards development in medical device and technology space.

So just to sum up, you know, AAMI is sort of primed to help with the ASCA program in developing tools or handbooks that would help bridge standards with reports. Elisabeth and I had a quick chat about education, and she just mentioned it as well, how there's a lot of education that needs to be done, a lot of training. And AAMI is well suited for that as well. So we're more than happy to help with that.

But just to summarize, I think, you know -- AAMI, I think, is a supporter of ASCA. We feel that if we can get to a point where there is shorter times to market for these products, I think that's going to be a win for everyone. So, with that, I'll just turn it back over to Angie.

DR. KRUEGER: Now, I appreciate all of those perspectives, and I think, you know, a couple of things that I would echo. One would be the training and education. I think that's incredibly valuable for all stakeholders but particularly for FDA to, you know, learn how the companies think about these things, how they put all of the pieces together in terms of their manufacturing, the risk management pieces, you know, and then particularly as

Elisabeth mentioned, you know, the testing labs and thinking, you know, just learning how they approach things and how they build quality into the work that they do.

I think we have some opportunities through ELP and other approaches that the Agency has taken -- you know, precert was another example of where we took kind of an innovative approach to that. And so I think that's something that the FDA will really need to think about in terms of how we get that to the right place.

Then I think, you know, throughout the pilot, as we collaborate with our stakeholders, you know, we'll also need to develop training plans, you know, for our review staff. How do they incorporate this appropriately into premarket review and we do it consistently? And, you know, that we have transparency in the process.

So, you know, I completely agree with those things, and I think that's something that FDA, you know, is very committed to.

You know, the other theme, I think, that you brought up, you know, is kind of leveraging, and what can we learn from, you know, things that are already out there. And that's something that, you know, we always look to try to leverage as much as we can or rely on, you know, existing processes and information. And so figuring out how to best leverage that information to make the process efficient in the pilots is something that I also think FDA needs to take back and think about.

So I really appreciate all of your introductory comments. You know, I think they're, you know, consistent with how FDA wants to approach, you know, ASCA as well.

MS. WOLSZON: Thank you. There are -- I think there are a lot of interesting ideas that I heard there.

First of all, Elisabeth, you were reminding me that it's true, ASCA was one of the first things that we agreed on, that we were like able to get that one done and then kind of move on to some of the other areas because we had good alignment on that.

The point about leveraging that you both made, that's something we completely agree with, right, that there's already these existing, you know, existing efforts that we should certainly leverage on -- leverage as much as possible.

Angie, your point about ELP jogged something in my memory, which was I think FDA actually included at one point a request as part of ELP saying, you know, as part of the process, we are interested in one of the areas of interest. We are interested in going out to -- I can't remember if you asked for testing labs or what exactly you asked for. Did anybody take you up on that? I'd be interested on knowing what happened there.

CAPT COLBURN: Yes.

DR. KRUEGER: Yes. We had -- I think we've actually had several ELP trips to labs. And I don't know how many of our staff have participated, but I know, in the biocompatibility space, for example, we had a number of staff who were able to participate in ELP trips specifically to testing labs.

MS. WOLSZON: That's good to hear, but I think the point is taken that even, you know, additional --

CAPT COLBURN: Yeah.

MS. WOLSZON: -- maybe additional opportunities would be good as well.

DR. KRUEGER: Yeah. I agree. And I think, as we think about ASCA in the pilot, you know, those -- that type of training might take on a different role when we're trying to think about in the conformity assessment scheme.

MS. WOLSZON: One of the other points that I also found interesting, Elisabeth, was your idea of including sort of potential standards for inclusion in the ASCA program -- I think I understood that correctly -- in the A or B lists. So I just -- first of all, did I understand that correctly? And is that something, you know, like the A and -- are you thinking it would work, A and B list, you know, FDA proposes, you know, tells us what they're thinking of and

then we sort of react to that? Is that kind of what you had in mind?

MS. GEORGE: Yeah. I think -- you know, I know that everybody submitted very long lists. I know that, you know, MITA submitted a very long list. AdvaMed submitted a long list. MDMA, I know a few of the test labs submitted a long list, and IFIA did, and so there's a huge list. So, you know, maybe that's the starting point that the FDA could take that list and say, you know, we think these might be good ones as A and B, similar to the way they do guidances. Or maybe they could throw it back at all of us as industry to say, you know, pick your top two or your top three, and we put those as the next steps.

Obviously, we still have a lot of work with the ones that are on the list, you know, so that's kind of something maybe to say put on our action plan for a year from now or something to that. But, you know, the biggest thing that I know from my perspective is, is I'm excited that Scott and the team are ahead of schedule from what was identified and agreed to. I'd love to see that progression to continue.

I also like the fact that there's more standards than was originally, so that the more data -- you know, we have to get more people excited about it. You know, as I mentioned earlier, I'm a little embarrassed that there aren't more manufacturers physically in the room to be able to have had the discussions because I think that the discussions were equally as fruitful as the presentations were, so a lot of good -- a good banter back and forth, and then the hallway conversations were even better.

MS. WOLSZON: And the other thing I wanted to piggyback off of what you were saying in terms of -- I completely agree with all of those. And you're even ahead of schedule in terms of scheduling this workshop, right? You're even --

MS. GEORGE: Almost.

CAPT COLBURN: That's the part where we're at.

MS. WOLSZON: So, you know, but to this point about, you know, the other thing is

FDA, I think, has been really innovative in terms of the standards that it's thinking about. You did not pick easy ones, right. I think there's been a lot of discussion about that. And in our -- as Elisabeth mentioned, we put together a large list because -- you know, and sort of prioritized and -- because we wanted, you know, we want to be giving you a bunch to think about.

And you had said, well, one we're wondering about is -- I can't even remember which one it was, but you're like but this one's too easy. Right. Why is this one here? And we said to you, well, you know, we are trying to give you an easy way to show success. And you said, but I want value, right, I want this to really matter and to mean something. And I think that, yes, that's going to mean it's going to take longer and we've got more issues to work out, but I think in terms of the other side of value proposition, it does give us something.

CAPT COLBURN: Anyone else? All right.

MS. WOLSZON: I actually did have an additional one. I just wanted -- I just didn't want to hog it.

Jen, I wanted to hear more about your handbook, the one that you were mentioning. That sounded interesting.

MS. PADBERG: Well, thank you, Jamie, but we don't actually have a handbook yet. That was just a proposal for perhaps creating one that might help to do some sort of a crosswalk between the standard and what the test report might say, just to make sure the linkage is there and that there's an understanding of what the standard met versus -- what the standard meant versus what the test report form was saying.

CAPT COLBURN: There was an interesting discussion, though, on what other tools can be used to help assess. I'm going to ask Sharon to come over to the microphone, Sharon Lappalainen. She brought a nice example in the 1-2 yesterday about the TIR that

supports the use of ethylene oxide and how does one, you know, assess this. I mean she, being that this is her world, gave a nice, quick 1-minute description of it.

But if you could speak to that, I think that might help identify are those the type of additional tools that would be helpful in filling in some of these gaps to create that better relationship between the manufacturer and the testing laboratory to help improve the selection of appropriate tests or identifying the appropriate endpoints that aren't necessarily baked into a standard. So just if you could give an example of how that works in the ethylene oxide world.

MS. LAPPALAINEN: Yeah. So AAMI has a TIR for contract sterilization for ethylene oxide. And it lays out, you know, who has responsibility for what, when the product will be released from quarantine, you know, when -- you know, what, how far out are you going to grow your BIs, what kind of biological indicators are there, what kind of microbiological support is that laboratory going to do, if that's not done in-house, who does what, who does the endotoxin testing and when and things like that.

So AAMI has quite a nice TIR about how to select a contract sterilization service for those medical device manufacturers that don't have that in-house. So I thought of that TIR as being analogous for other types of testing where we haven't seen that kind of a TIR.

CAPT COLBURN: So there are certain types of tools to put into perspective that maybe we haven't thought about that before. Other thing I think I mentioned in the Alarms group was, you know, if we're looking at and we're doing a parallel adoption to a standard, are there additional things that we could place into the parallel adoption in the form of maybe a modification -- not a deviation but a modification to the standard, to add the value that would be appropriate for when that standard goes into its conformity assessment testing procedures that would help create those relationships through the format of that, and is that something that can also be assisted?

It may be, even if it's not through the parallel adoption, through another mechanism that may be through the recognition program, if we can try to leverage that type of information. The thing we try to stay away from when we talk about putting additional information into how we recognize a standard is we don't want to run into GGP land and start creating a guidance for everything because then that slows the process down drastically, and we want to utilize the tools that are nimble and quick to help feed the beast, so to speak, without creating a big blockade through a procedure that wouldn't be helpful.

MS. GEORGE: One of the things that I was also thinking of that could be very valuable, and again, I saw it very much in action in the Alarms meeting today, but I think if you really have all the stakeholders at the table when you're developing the standard, and if we help them to think about the whole concept of conformity assessment when you're developing the standard and really think about, you know, where is this going to be done and how does it mitigate risk and all of those things, make it a lot clearer in the standard itself.

And, you know, in the next 5 years, every standard should be touched, if not sooner. So, you know, there's lots of opportunity. So it's -- now is the time to not forget that because, you know, how often do we hear that, you know, wow, that standard's really cool but we can't test to it, or we don't know how to test to it, or there isn't a methodology, or there isn't an acceptance or rejection criteria; you know, it's something out there in the, you know, in the space that somebody is supposed to clairvoyantly interpret.

So maybe that's something, sooner rather than later, that as part of an ASCA pilot we should be thinking how to develop, because if we wait until 2020, when this is supposedly, the pilot -- or 2022 when the pilot report comes out, you know, all the standards will probably have already changed and we'll have missed a potential window.

CAPT COLBURN: Yeah. So when we did have that, I think, discussion looking at our Alarms folks a little bit about there's an amendment that's going through and what are some of the things we could do, that's an international standard, so, you know, sometimes leveraging change at that level at a later stage is hard, but this is where -- what can we do in the meantime -- you know, I always ask -- as a regulator, you know, we adopt lots of standards in the U.S.; what does that mean? You know, what does that -- what value does that mean to myself or to a testing house who's utilizing that? What is that TAG really supposed to mean?

And it should have value, or we should take advantage of what that value is really intended for, not that it just went through the ANS process and we made sure that we have balance on the committee that you may not see otherwise in the ISO process where there are balances done by country vote. So what does that mean? And how do we attribute value to utilizing either adoptions or the ANS process or even in an SDO's individual process when they're, you know, having a standard that's published, you know? How does it communicate to its stakeholders in development what this means, you know, for the stakeholders to use it appropriately?

So we've talked -- did you have a little bit more?

MS. GEORGE: Yeah. I just wanted to add one additional thing that I was thinking of is, is that one of the things that we need to also address sooner rather than later in that guidance will also be how the manufacturers deal with non-ASCA and ASCA standards that make up their solution because, you know, obviously there was the discussion about that the Part 2s are not there, so how we deal with that, and then how we deal with that, the overall complexity factor of standards, because obviously there's very, very few devices that have literally one standard applicable to it.

MS. WOLSZON: And, Elisabeth, I think that's a really, really good point. I think we

heard yesterday, and I can't remember who said it, that most submissions have or 510(k) submissions have something like seven standards in them. And I mean, the other thing too is, you know, a possibility of standards that are widely used by the medical device community that are not necessarily either -- they're either -- they're not part of the ASCA program or they might not even be FDA recognized. You know, how do you deal with all of those in the same submission?

MS. GEORGE: We just tell Scott we're using them.

CAPT COLBURN: And you do. And you do.

So we've talked a lot about standards development and potential standards use or where ASCA should consider an organic outgrowth of using standards, and we did -- and you just touched, in the last little bit, about what about the particulars within the 601 series. I know that was discussed a little bit in the -1 group and probably in the others of how do the, you know, the separate subclauses within each of those -2s call out the requirements for the -1-1-2 and -1-8.

That's one of the things we're looking at is, you know, is that a way for us to capture the types of devices that have further baked in those requirements to the areas to be more specific? And then I think I also heard some of the groups, what about the other device-specific standards that aren't in those series that do call out the normative requirements to -1-2, but that's as far as it really goes too. So then you're left to the base standard, with no requirements on how you would apply it. Those are two separate things.

But standards development is a process that to even see the improvement output of that will go -- well, the first output, if we started on that now, will happen after the pilot should be starting, or I will have to fill out my application and find jobs elsewhere. So what can we be doing now to be improving the testing? And I think that's the area we should be focusing on, to try to see what can we do now with the tools that we have or tools that can

be created in a very short term, say 14 months or 10 -- 12 months or less, to improve what we're trying to accomplish in ASCA.

And I want to say too that ASCA is not and I don't think ever should be thought of as taking on the entire recognition portfolio, simply because not all standards are attributed to being tested in the accreditation environment and may not need a scheme to develop that and further add cost and additional layers that could -- that aren't necessarily needed.

There are plenty of standards that are conducted today with a declaration of conformity and either a summary report or maybe even if it's baked enough that -- and no report is necessary, that are fine today. And that's partially why we didn't pick some of the standards that I think you were just being kind to us, saying why didn't you pick that real specific test method that had that endpoint? That'd be so easy.

It would be a little too easy, and I didn't want us to start adding complication to those standards because that doesn't add value to the regulatory review staff either, who are already accepting the use of those in many cases.

We also heard about, you know, how did we select the standards? We did do a utilization survey, and I touched on that real lightly yesterday, that did take into account not just what are the most frequently cited standards, but in those standards which ones were looked at from being tested in a third-party or accredited testing lab by the manufacturer, and where have we been asking more additional questions?

And those were really hard metrics to find, but we did kind of get a pretty good feeling that these were the areas that we thought we could start with that kind of would help us focus on them, where can we improve the relationship between how manufacturers and testing laboratories are trying to get to those end results. So that way, we're not seeing, from our perspective, an incomplete type testing done, and we are filling in more of those gaps by improving how we would like to see those being done.

MS. WOLSZON: Scott, just to clarify, I think it's to your credit that you picked the ones you did.

CAPT COLBURN: I didn't have as much gray hair before I picked them but --

So going back to what areas can be improved in testing, I think this is where we want to engage the audience more too. We had a lot of discussion before break as well. I wanted to see is there any questions from the audience or areas that we think, you know, that we could do to see what success can look like by improving, you know, areas between testing or the relationship between testing and the manufacturers, or where FDA can be improving -- create a relationship between the testing houses.

We will be working with accreditation bodies, which will hopefully have the perspective when they come in, what are some of the things that the testing houses would like to see from an AB's perspective when they're being accredited into the ASCA pilot that would be important to help improve the overall quality that we're trying to achieve here?

I'm looking at the audience.

MS. GEORGE: So while we're waiting for people to get up, I just wanted to mention one thing that came to mind. I heard it in the 10993, that community of practice concept. I think the devil's in the detail. I mean, again, I -- we sat in the Alarms meeting, and we were fortunate that there was like only 10 of us in the room. And we literally started to talk about some very specific line items.

And I think that the devil is in the detail on each of these. It might be valuable to get some sort of a smaller core team, not the, you know, cast of thousands to start literally going through some of those and ask those questions; look at line by line in the standard and start to think about, you know, ASCA test lab, what do you really do for this, ASCA manufacturer, what do you really do for this, to start thinking in that concept.

And maybe also the other aspect to that would be to engage some of those subject

matter experts that presently participate in those standards because they are the expert, because I can tell you a number of times, even in what they thought was a simple standard, I have to say I'm very fortunate that many of these standards, we have people in our company that are there that we've walked over and go, WTF, what did you mean by this? Like I don't know what you are talking about because it doesn't -- it's not clear.

And they were surprised that it was unclear because they were like, wow, we spent hundreds of hours on that one paragraph. How could you not understand it?

CAPT COLBURN: Checked compliance by inspection of the risk management file, that was one that always scratches the head of the regulators.

FEMALE SPEAKER: Yeah. I just have two suggestions from the perspective of a reviewer of 6061 -- 60601. You know, I think, for the sake of increasing confidence in the risk -- in the testing report and also consistency review, I think it would be very helpful, I think, if the testing report format -- I think maybe they have information already but just not communicating yet. Maybe has a commentary column, just to justify maybe giving explanation or justifying those NA and NE, not applicable or not evaluated. You know, give kind of some explanation so that the reviewer really have a better understanding of the results. I think that's very practical and I think maybe easy to really fix.

The second is confusion about essential performance definition. I mean, if there's some kind of clarification in the guidance, just clarifying what the unacceptable risk mean in terms of maybe state-of-the-art safety benchmark in the market or in terms of risk management and request, that would be very helpful too. You know, otherwise a lot of them will be no, no essential performance, but actually maybe there will be confusion, and there may be disagreements on that.

So that's two suggestions.

CAPT COLBURN: Yes. All right. A new voice.

MS. KRINGSTAD: Hi, everyone. This is not a new a voice. I was in the Biocompatibility.

CAPT COLBURN: Please introduce yourself as well, too, for those who are on the phone and doing dictation.

MS. KRINGSTAD: I am Jean Kringstad from WuXi AppTec, here for all your biocompatibility testing needs.

(Laughter.)

MS. KRINGSTAD: So as a biocompatibility testing lab, what we want from the FDA is more communication. And I understand that you guys can't -- we have to deal with you through our clients and through the AIs. Any direct communication that we can get, whether it's a working group, whether you post something on your website so we all are available to it, we are very reactive to your needs and your wants. And we want to be proactive and have a voice in the conversation essentially.

CAPT COLBURN: So that is one of the primary advantages we're trying to create in ASCA is to open a door to a pathway where before we could only get to you through the manufacturer, as well as you to us through the manufacturer. And sometimes the manufacturer might have been just a regulatory affairs consultant and not even part of the manufacturer because they're from China or from another country.

So I think this is the area, and I know the biocompatibility platform that went on opened up some areas for this as well. And this was also where we encouraged, how can we -- so what is it you want to hear, you know, and what is it that we need to be thinking about is even just as important. How do we know what good looks like or where quality is? What's the right mixture of ingredients to help us, you know, accept a declaration of conformity in the end, based upon the testing that was done, the determinations that you made, so a manufacturer then can come forth with the right amount of information to

satisfy what we're hoping is the appropriate burden of proof to support the intended use of the product.

That's what this is for. So where could we improve this? I think a lot of discussion went into how we would recognize a testing lab from a biocompatibility point of view. I know there was some discussion about having with -- after the accreditation is done and your plan for recognition, the opportunity to share the types of protocols that you would be using and then also how to communicate where protocols might need to be modified based upon types of technologies.

We did bring that into the 601 discussion. I don't think the plan that has been worked on has been baked as yet. Amy has been -- Amy's message to our 601 folks, guys, is we're going to get to work on 17025 a lot harder following tomorrow, so be ready. She's ready for you, so --

But that will be some of the criteria for the testing labs and manufacturers in the room using the 601 that we're looking at. Those are the standards, as what are those types of things that would make sense to that area? Because in the IEC there are test report forms that are there. There are schemes that are developed, which is a little bit different than in ISO where you don't see that same type of thing coming out of the CASCO toolboxes and stuff.

What can we do on the IEC side to leverage knowledge that's happening already, gain confidence from that? What's the types of information that we would need to see then from the manufacturer to help support all the determinations that were made in an already existing test report form? Or do we need to add some information? I think the example you gave is an appropriate information of how to make a little bit more -- make it a little bit more clear to the reader, how you made the determinations of not evaluated or not applicable. That's very important for -- especially from regulator point of view when

you're -- you know, when we hear that it's like what do you mean?

You know, especially -- you know, no essential performance? I mean, really? I had a 510(k) once that the whole section on performance was just left blank. And it was an electrically operated medical device, no performance. Sort of like the equivalent device.

So, again, clarity on what's expected and what's needed obviously wasn't there. Their need to show that they needed to do testing maybe wasn't apparent, but we don't get that through sometimes understanding the manufacturer as well, and so working that relationship is very important. I don't know if -- maybe from a manufacturer's perspective as well, you know, they're saying they want to hear from us.

What would be valuable to you in working with a laboratory that -- you know, what would be the things you would hope they would understand, in our perspective, when you are shopping around for the right labs to work with?

MS. GEORGE: Well, I know we actually, again, have had -- I have the opportunity of spending a lot of time with a lot of the lab guys, so I get to hear a lot. But that's one of the things I think that, in general, most manufacturers, when and if they engage with an external lab, it's a supplier-management process. It's probably not the people that are in the standards development side that are helping to write that. It's, you know, some purchasing guy in your company that's writing that PO that interacts with the test lab.

And then some R&D guy or some clinical person comes in to help set it up and test the product. And then the report magically pops out and magically arrives at the manufacturer so that, you know, the manufacturer that engages with the test lab doesn't necessarily even -- is probably not necessarily the expert in the standard.

So I think one of the things, maybe as manufacturers, we need to do better is better understand who and how we are engaging with those test labs, because yesterday I think one of the comments that was made was is 9 out of 10 times the way we make our decision

is who's the closest guy to the office that's designing the product because, you know, we don't want to ship the product because it'll cost a lot to ship. We don't want to ship the bodies that have to support it, so we go to the guy that's down the street.

And they hopefully are capable of doing the testing. Most of the time they are, but they may or may not be the optimal person to do it always either. So I think that's something that manufacturers maybe need to have a better understanding of what our obligations are in general. You know, maybe I understand them, but I don't know that all of my colleagues in the company necessarily do.

MS. WOLSZON: I completely agree with what Elisabeth said. And I would just add, first of all, that one of the nice things about the ASCA program is I've been getting to meet some of the individuals within the laboratory community. That's been a nice part about this. And I would also add that as an extension of what Elisabeth said is that I do think selection of a good, you know, a good laboratory cannot be understated.

And I think some -- we've been talking about, you know, companies that are newer to the game. It might not be quite as obvious, you know, sort of -- if you've dealt with a lab for a long time, you have a sense of, you know, who you can, you know, who you really feel comfortable with. But if you're new to the game, you might be doing it through trial and error.

MALE SPEAKER: So I wanted to bring awareness to one -- I'm from FDA, and as a reviewer, one thing I've noticed from test reports is that -- I brought this up in the -1-2 break session, but as an observation, I will see that they will, the test house will write, you know, device had problems, passed. And that's all I see from my end. So there should be some kind of awareness saying that what does that problem mean? What was the issue that was recognized by the test house? So if that could get communicated to us reviewers, whether it's from the test house or from the manufacturer, that would be great from our

end.

MS. WOLSZON: And that's an -- that reminded me even of another thing which is, of course, you know, when that manufacturer is getting that particular test report that's identifying a problem, it behooves them to then go to the testing laboratory and discuss it and -- right, so by the time you get a submission, it says something like, here was the issue, here is how we, you know, here is how we resolved it or here is why it's not particularly applicable in this place, so you're not left as a reviewer with this basic -- you're just seeing a flag that says there's a problem and you don't know how to resolve it.

MALE SPEAKER: That would be great, but usually a few times, maybe 3 out of 10 times, I would not see that. So as a reviewer, we struggle, and that would be, you know, asking AI questions, delaying the time line when the submission comes through and total time decision and everything along those lines. So -- just an awareness.

MS. WOLSZON: I think you bring up the important part of, you know, we talk about faster reviews, but there is, of course -- it's, you know, a dual side street and, you know, but I think what you're talking about, where if you're a manufacturer and you see a flag like that, to talk to your testing lab and to -- I mean, that's got part of good submission practices.

MS. GEORGE: Well, and I would hope -- I'm not going to say it's a guarantee, but I would hope that, number one, the person who received that test report actually looked at it and had that discussion. Number two, worst case, I would hope that the regulatory specialist who put that 510(k) together and stuck that report in there actually looked at it and so that, hopefully, somewhere in their quality system, they have a QAPA or something. So maybe shame on them that they didn't supply the response as to why it was a non-issue, but hopefully there should have been at least two checkpoints within the company -- maybe it's the same individual but -- that should have caught that. But I'm tripping over my tongue

because I'm -- and all fingers and toes are crossed that that's reality, but that should be the reality.

MS. WOLSZON: And I would just -- also I -- you mentioned interactive review which, you know, we are big fans of, you know, so to the extent that you can pick up the phone and say I saw this in your test report, this doesn't -- you know, they've identified an issue and I don't understand why it's going on, that's -- you know, we like interactive review.

CAPT COLBURN: But I think that's a key performance indicator that we should strive for to improve is when test reports, you know, have the opportunity to just say that, that's an area of improvement right there, that how do we -- and I think that goes to the point earlier from our other reviewer, how do we justify those non-applicables, not evaluated, skipped overs, whatever it may be that wasn't -- you know, we don't even know if wasn't intentionally not evaluated. Hypothetical failures? Yeah. So --

Our gentleman from Cook, Tony.

DR. RAGHEB: You know, the discussion about interaction between the sponsor and the test lab and the regulator stimulated a memory of a deficiency that we received from FDA that said -- and I mentioned that we're something of an internal CRO. And it said, "In the future, please make sure that the test lab is not connected with the sponsor in any way."

Now, I know sometimes there are challenges with writing, and I think probably what the person meant to write is could you please explain what are your measures for managing the potential for bias or conflict of interest. But that's not what it read. And, in fact, I thought to myself, there's a textbook on contracting with CROs for non-clinical studies. And the theme of the textbook is that the manufacturer or the sponsor needs to establish an in-depth relationship with the test lab and have that understanding.

So, you know, there are lots of challenges in this, but that way of thinking and the

challenge with writing, you know, the words, "any" and "all" often catch my attention when I see them in writing because usually they're an unnecessary form of primacy of some sort.

But, anyway, it's refreshing to hear that need for more interaction. And it'd be good to have that thinking permeate more because sometimes it's not there, per that example.

MS. GEORGE: My company similarly has our own internal test labs, and so I think one of the things that I know that we talked about also is, is there's that line of testing versus consultation that is a fine line. And I think that's part of one of the things that, particularly with an internal lab, that you have to be very cautious of is those inner -- iterative tweaking in the middle of a test or modifications while the test is going on and how much of it is consulting, how much of it is a new version, and do they have to start over, and all of those things, things that are a lot less likely to happen at a third-party that might happen internally.

So that relationship, I think that has to be clear. And it's harder when there isn't that formal contract like you have with a purchase order.

MS. WOLSZON: And I'm very glad -- actually I was thinking about when you talked earlier, when you were talking about your, you know, your in-house capabilities, that one of the things that was important to us be included as the commitment -- in the commitment letter, and is in the commitment letter is a statement that to the extent that an in-house testing laboratory meets all the other, you know, whatever other requirements are for an external, that they can equally participate. So that is in there in the letter.

CAPT COLBURN: So and it is -- and it was placed in there because, you know, in the standard of 17025, that area is specifically addressed. And so we are, in the development of our scheme, looking at that and seeing, is it addressed in a manner that makes sense from a medical device manufacturer and medical device regulator's interpretation of that? Or do we need to clarify the verbiage of it in a way to make sure that we're seeing it clearly

enough so those types of questions are apparent in what is an accredited lab, especially under the ASCA scheme? But we're also trying to see, in terms of how that is addressed right now, what does that mean and does that meet our specific requirements, where we wouldn't have to say, then there's these FDA additional requirements on that area.

So those are the things we're doing throughout the entire standard of 17025 is reading it line by line or even comparing it to other regulatory jurisdictions like OSHA in the U.S. and how they've applied similar approaches to assessing their program to 17025, and where they determined maybe an additional requirement was necessary for their program, and trying to compare that to make sure we're not doing something that is very different but also that still makes sense and meets our requirements.

And that's one of the things that we're being shepherded down the yellow brick road with AAMI and all of our groups, that we've been doing. And I think that has been very helpful for us in understanding and appreciating the level of rigor and the level of -- levels, even say the level of excellence that goes into what an accreditation is about, or utilizing that standard as part of that, you know, management structure and the management system of whether it's the company's own lab or the third-party labs and how this world works.

A couple of years ago, this really wasn't our -- it wasn't -- that wasn't anything in our verbiage when we talked about standards and recognizing standards and declarations of conformity and what that meant. This is where we're excited in going so we can build that relationship into the system and have a better appreciation for what's taking place, but then add the criteria or clarifications for our own internal purposes as well as the stakeholders who need to use those internal things.

Sir Gordon.

MR. GILLERMAN: Thank you. Gordon Gillerman, NIST.

So I think, again, this --

CAPT COLBURN: A little more.

MR. GILLERMAN: Yeah. This is --

CAPT COLBURN: There you go.

MR. GILLERMAN: So I think this, again, speaks to that communication factor that's going to be so important in the success of this, because just like good communication between the agencies, the manufacturers, the accreditation and monitoring laboratories, it's going to be necessary to bring some level-setting to the expectations in how tests are conducted and how reports are report -- or I'm sorry, how results are reported.

You're also going to find that dealing with the management of impartiality, which is kind of the magic phrase inside of the current international standards for conformity assessment to deal with this issue that traditionally had been called things like independence, is very, very important.

And as we look at a program that allows for manufacturers' own laboratories to become accredited and be in the ASCA pilot, there may be some need to discuss and work with the community on what are reasonable measures for the management of impartiality for a first-party laboratory. And many of those expectations may need to be documented in some of this ASCA document and be part of the conversations between the Agency and the accreditation bodies and the laboratories that participate so everybody understands this the same way.

And I think one of the things I've seen from my attendance today is there's this theme of communication. That seems to be perhaps one of the greatest benefits to this program is going to be -- is there will be a venue for all these stakeholders to come together and work together on what's reasonable, what's expected, and how do we demonstrate it in a meaningful and normal way?

Thank you.

CAPT COLBURN: Thank you, Gordon.

Elisabeth.

MS. GEORGE: Scott, two things that came to mind for me with that, one on the communication. One of the things that maybe we should consider with this program is some place on the FDA website of having like frequently asked questions or regular updates on what's going on in the program, you know, where we are with different things and different activities so that you can keep the masses well informed, because I think that, you know, out of sight, out of mind. If we're not constantly throwing stuff into people's vision, they may forget about it, especially with it being a pilot. So I think that that would be very important.

Something else, though, that was actually interesting that came into my mind with this added, potential added activity of accreditation, interestingly enough, our in-house customer test lab, we actually were able to convince the Chinese FDA to accept our test reports without any additional work. Shock, shock, shock.

MS. WOLSZON: Wow. That says something.

MS. GEORGE: One of our test labs. But it was a lot of communication. We spent a lot of time with them. We spent education time with them, showed them how we did things, showed them how we -- so that, again, it -- communication breeds comfort. You know, if you can have an open communication, bidirectional, there's comfort level. So that's an opportunity.

CAPT COLBURN: Yeah, thank you. And thank you, Gordon.

I think the communication thing is the key success element for this to carry forward. One of the reasons why we were, you know, deciding, you know, do we run this program as the owner and so the accreditor versus using the accreditation body, and ultimately looked

at, you know, working with accreditation bodies might bring extra value, from a pilot perspective, is to try to get as much involvement as possible by first appreciating what does the accreditation body do? How are they meeting what would see the requirements, both from a management side and the technical side? Where are some of the gaps? Because we had heard that sometimes the technical requirements, at least from a testing lab's perspective, aren't quite meeting what they were hoping to truly be assessed to. And maybe that's their improvement.

But the purpose of going with the ABs is because they're not just dealing with one lab, and they can deal with dozens or hundreds of labs and also work through different venues to help improve the breadth of sharing knowledge, from a perspective of the regulator, and then creating the system that opens the door for those testing labs to speak about, you know, I have an interesting case here.

We'll collect some of those, and just like in our third-party program, if we see enough of those in an area, we'll create an education platform for all the stakeholders involved with ASCA, internally and externally, to help improve the scope of accreditation to the methods that are inside the program.

That's one of the, I think, the gifts that the program brings to all the stakeholders is improving that, and that helps standards development, that helps regulatory review platforms and formats for the smart templates that we use for reviewers. That helps the e-submission platforms and how a manufacturer would clearly identify standards. And that's where we're really trying to go with this. You know, it's not to just create another regulatory program that looks neat and has a four-letter acronym that asks a lot of questions. This is -- really the idea is to improve those relationships, so I appreciate those comments a lot. Thank you.

MS. WOLSZON: By the way, Scott, we fully support your decision to not be an

accreditor yourself but rather rely on the existing capabilities of accrediting organizations. I think that fits very nicely within our theme of leverage existing opportunities and resources. And as you say, you know, if they see multiple ones, it can help inform their experience.

CAPT COLBURN: Yeah. Not everyone could hear her? Well, she was just saying that she appreciated that FDA did not go down the road of being the accreditor. And full disclosure, I brought the idea to our MDUFA IV management council and tried to see if --

MS. GEORGE: He said no.

CAPT COLBURN: -- and tried to see, what do you think? And these are all the, you know, the senior leadership and stuff in the management council, and we tried to even sell it by saying, you know, option one, you get to be in control, you're -- it's all, you know, all these things. Option two is, you know, you have to work a little bit more with this but, you know, they immediately saw the advantage too of trying to not operate this in a way -- because the first thing to say is you've got very limited resources here. And it's going to take a lot more resources to manage that aspect of the program when you're really trying to dig in deeper into the actual testing relationships and building those building blocks.

Let the accreditation process work. Use your resources to build into those, you know, that are here today with the testing labs and stuff. So the ABs will have a very important role. The testing labs will have an extraordinarily important role with us as well. And I think we'll improve the relationships through all this.

We talked about, you know, other -- you know, this workshop isn't the end of our collaboration with you. We've heard about communities of practice, to be discussed. I think these are areas where maybe there needs to be one or more communities of practice for ASCA to build more of these types of ideas in a smaller setting, more specific, so we can get into this a little bit deeper, and even, you know, thinking about the future outgrowth or how this supports other programs, to make Angie's life a lot easier in her roles in the senior

management.

Speaking on -- I want to shift gears a little bit to regulatory science platforms. We did mention a little bit about -- and, Angie, maybe you want to even speak to this. You know, if we're trying to improve the appropriate use of standards, and that's where we have a draft guidance that hopefully will come out in the next few months -- everyone who's heard me talk about our guidance knows why I have to knock on wood and laugh because I've now jinxed it for a few more months. That's the beast we have.

But the appropriate use of standards guidance is designed to try to get people to think more about, you know, a declaration of conformity and its format, and how do we use the ISO 17050 series to appropriately communicate the, you know, the current state of how we use standards in the recognition program.

Now we're bringing in ASCA, and we're talking about, you know, how that communicates more clearly, based upon the methods that are part of an accredited lab's procedures, and how that -- what does that mean towards information that would support a manufacturer's declaration of conformity. How do we then track some of that in a more appropriate way?

What are some of the things that you think might be of helpful -- internally that you think that, you know, we could get some input from manufacturers as well, and how they can ease and more so identify their appropriate use of standards, whether it's through the ASCA program or through the general use of standards, that would help us gain the metrics of success to help see how things are going, where do we need to improve standards, where do we need to improve certain methods that are in the ASCA program, etc.?

DR. KRUEGER: Those are great questions. I think, you know, a couple of things come to mind and, you know, I think Jamie and Elisabeth brought this challenge up before, which is, you know, not everything that gets submitted in a premarket application -- it's likely not

just one standard. And in the future, even in the course of the pilot or beyond the pilot, it's unlikely to be something where ASCA covers everything.

And so you're going to need this menu of options that you have to put together in terms of, you know, I have this piece of the puzzle and that might be, you know, something from the ASCA pilot, and I have this declaration of conformity, you know, but I -- you know, this particular standard didn't have test methodology, so I have to provide you some information about, you know, the method. And I think we have to be able to look at all of those options and think about, in the context of review, what do we really need to see for any specific, you know, issue or option in the way that the standard is used, to be able to build off of that.

And so what I think would be great, you know, from our review paradigm, particularly as we head into ASCA, is to think about how all those pieces fit together so that we can be really clear for our stakeholders and for our reviewers to say, you know, if this information was provided to you, you know, manufacturer, here's what -- you know, if you use this, you know, here's what you need to provide; reviewer, if you see this, here's what you need to do; so that it's very transparent to everybody if you're using ASCA, if you're using a declaration of conformity but you have some type of variation, or you don't need all the requirements of the standard, for example, you know, what information do you need to provide and what information should be reviewed, so that we're not, you know, in these situations where, you know, thousands of pages of test reports are submitted and a lot of questions are asked or -- rather that we're really focused on the right areas, depending on how that information's submitted and what you used the standard for.

MS. WOLSZON: Angie, a lot of good points there. And it also brought to mind something I've heard Scott say in some of his educational messages is that just because -- oh, sorry.

It just brings to mind something I've heard Scott mention, which is I think sometimes there's a misperception that if a standard is not FDA recognized, then you can't use it in a submission. Well, that, as Angie's pointing out, that's not the case. It has different implications if it's recognized and if it's not recognized in terms of the information that FDA's going to want to see. So those are the types of things to be thinking about as we go forward.

MS. GEORGE: I think, as you said, I like that menu of options concept. I think that that is a reality. I mean, that's a reality today. You know, if I think of 2 years ago, we didn't have the cybersecurity guidance. Now we have a premarket cybersecurity guidance so we know what to submit. So there, in theory, should be far less questions asked because it's a clear template. You know, and it's an iterative process, and some of that iteration is due to technology changes, due to clinical changes, due to current interpretations, learning, etc.

So I think that whatever is put together, I guess part of me wants to caution not to have it necessarily as a black and white released guidance, almost as some sort of a -- something that is less burdensome. And I -- not to say that guidances are burdensome, but we all know how expeditiously they go through the process.

So if we're going to have iterative changes happening and it is going to be a menu of options, it would be nice if there was a mechanism to be able to almost have like a webpage where you click on the things and magically it pops out, this is what you have to do, or something like that, you know, an artificially intelligent tool, you know.

MS. WOLSZON: Also, Elisabeth, I didn't follow up on your point about an FAQ. I think that's a good idea. And also I heard earlier, just since I'm not as familiar with FCC, this wasn't something I was familiar with, but the idea that there's like an anonymous portal where you can ask questions and there's a response, you know, generated and published, that was interesting to me too. I just hadn't heard of that.

MS. GEORGE: People shouldn't be afraid to ask the FDA, though. They're really not that bad.

CAPT COLBURN: Steve. Hi, Steve.

MR. MARGIS: Hi. Steve Margis. Just as we talk about these subjects, one thing I haven't heard come up yet in the last 2 days is while we're looking forward to the development of this program, one word that I haven't heard yet is governance of the program. And I think this is a good area of subject for that topic.

At the core of this, our technical specifications, in those technical specifications are standards as well as scheme-related rules. I will tell you that as an individual organization, as an organization who participates in regional schemes, I'll caution you to some challenges that we deal with.

One is when we talk about these FAQs and information like that, there needs to be a governance model to determine what it is that you're interpreting and how you're going to take those interpretations in some closed-loop system. Some cases, you'll have a situation where there's a requirement that's not clear, and you need to have a clarity until it can be put into a standard, and it will be -- have to be harbored somewhere, wherever that is, so decision and interpretation.

If it sits there and it's not in a closed-loop process that will go back into the standards process, you will have challenges sooner than later. So one thing to be aware of as you develop whatever process you develop to capture these ideas, those ideas have to be able to be nurtured through the process.

In some cases, it may be fastest to move it through the national standards process, then to the international standards process. And in some cases where you have requirements as the regulator that just will not meet the needs of those standards communities, you may have to have your own standalone requirements. But as long as

there's clarity and transparency on those items, as long as there's easy access to those items, and there's a governance to manage those items so it doesn't turn into a paper tiger, you'll put yourself in a really good position moving forward.

The second comment that I just wanted to make is that we also -- in our daily work as conformity assessment bodies, one challenge that we have, and you almost alluded to it a little bit is, there's kind of a fine line between trying to create menus and options and stifling innovation.

CAPT COLBURN: Yeah. That's --

MR. MARGIS: So as we're looking at putting clarity on these requirements, we also have to make sure that we recognize that the standards were built to have some flexibility to them, to enable innovation, while at the same time managing the level of risk that's associated. So I would just caution us on those two sides.

MS. GEORGE: I think those are great cautions, and I guess one comment I would just add is, is my thought on the FAQ was during the pilot, not as the long term, because I think that the pilot is where we're supposed to be learning and should be -- have a lot of that iterative. And then the ultimate process should really define that closed loop because I agree with you what that -- you know, the last thing you want to have is some paper that's hanging out there for 10 years and it totally doesn't map back to the standard. So that's great.

MS. WOLSZON: And I would just add that the constant conflict between the desire for clarity as a manufacturer and the desire for flexibility is something we deal with all the time because they are twin goals but they -- or you know, there's things we both want very much. We both want -- we want flexibility and clarity, and it's hard to have both at the same time.

So depending on the issue --

(Off microphone comment.)

MS. WOLSZON: Right. Right. But you -- it's a very good point.

CAPT COLBURN: So, Steve, I'm going actually ask you a question, to see if we can help.

So you mentioned, you know, where maybe standards, either at the national or international level, still might not necessarily meet the clarity, and then so the government may, you know, need to add some specific requirements.

One of the things that we're trying to do, and this was discussed, I think, from a number of different perspectives, is not try to veer way off from how this program could support either existing national programs, say like OSHA and stuff, but also be able to work in the international realm. And that's always the difficult thing when -- and it's actually now in our mandate, which is nice that we can say we're thinking -- we really have to be thinking about this in a very positive way. How does this reflect, you know, how other countries are doing that?

Oddly enough, we are not the best suited organization for that, as a regulator. But our manufacturers, our testing labs, our accreditation bodies tend to know the requirements internationally a little bit more. Last week -- or was it last week? Or the week before, we were -- 2 weeks before, we were downtown with the -- speaking with the IECEE group, with USNC, and you know, these are the organizations, you know, that in the U.S., working through the USNC or through the ANSI ISO Council or through the number of different tools and, you know, the NISTs, ICSP, to talk at a national-international level.

But is there ways that we could -- as regulators, where we traditionally have not been at the table to discuss these are some of the gaps that we see, how do the community of experts that are present at these types of organizations help bring these needs to those stakeholders to try to see what would be in the best interests to support conformity

assessment by reducing burden to all stakeholders, so we're not increasing costs unnecessarily, making it difficult for small laboratories to participate, small manufacturers to utilize these tools in a way that we're still getting what we absolutely need from a strong, you know, ASCA program? I was just wondering if you could provide some further thoughts on that.

MR. MARGIS: Yeah. That's a big one.

CAPT COLBURN: Yeah.

MR. MARGIS: I guess, for those that don't know, I'm Steve Margis from UL, but one of the roles that I play is I'm the U.S. alternate on the Conformity Assessment Board at the IEC, and I'm the Vice Chair for the U.S. National Committee to the IEC, so that's the context.

As far as how we can get into these areas, I will say that it's very challenging. And I think that everybody in their little role doesn't always see the context of the related stakeholders. Fortunately, we brought this issue forward. Actually, Elisabeth is going to be giving a presentation at the Management Committee about IMDRF and how there are forums that are outside the IEC, outside our own national systems, where a lot of these issues are being discussed. And maybe, just maybe sometimes it's not about trying to draw you into every little circle, but maybe coming to you in the circles that you represent.

So I think that's one thing that will be eye-opening in the IEC spectrum, at least, of better understanding IMDRF as a case study of how maybe going to someone else's forum will allow that conversation.

Within our environments that we have, we have NIST representing the voice of government at the USNC, and as well as representing sometimes, even in some cases, the FDA as a partial voice when we're having USNC/IECEE committees, etc. I would suggest that we have a lot of stakeholders around the table that are part of your stakeholder group, your process, be it industry, be it myself in conformity assessment. And I think we should all kind

of carry the badge with us as we go into these different forums, because for international acceptance to truly occur, we have to bring these ideas forward.

So while on the surface, the first answer is, well, we should have you at all of these forums and you could bring your voice forward, where that's not practical and we are at the table -- one of the reasons I brought up that 360 view is if an interpretation gets put on the table and clearly documented, it's a lot easier for us to bring that up into a national standards committee, such as the AAMI committee. Or it's easy for us to go to the TC at the IEC or to bring that to our group that's called the Community of Testing Laboratories.

So I'm not really sure there's a definitive answer, but I think the answer is that it's the wisdom of the crowd. And when we start trying to recognize that we are part of this crowd, and we wear these different hats, and if we could bring these messages forward, we can start making them come closer together. And in those cases where we don't have full agreement, you know, keep those on the docket and make those available for people to see, and we'll keep working at them.

So I'm not sure that's a definitive answer, but at least some insight. I welcome others to contribute.

CAPT COLBURN: Yeah. Well, thank you, Steve.

I bring it up because, you know, a couple of years ago, we -- before ASCA was even really a thought, a glimmer in our eye, as mother would say, we would -- we actually inquired about joining one of the IECEE groups that was discussing how to more appropriately add a test report form to incorporate the risk management principles of 60601-1. And our answer was, well, you're not a testing house. You really shouldn't -- you don't need to be there.

You know, and yet that's the major block that we have in accepting or understanding the acceptance, because from our perspective, a test report and a declaration of conformity

to 60601-1 includes all of those aspects that are baked into the standard. Yet the test report forms have not quite yet caught up at this time. And, in fact, that specific group had not been able to be successful enough to complete its work. And those are the areas that we're trying to figure out what if? What if we could have maybe brought a perspective, send, you know, Hamed down there to the group or something to provide some perspective. Would that have helped? And we would be able to do this in those types of systems.

And that's where I'm trying -- you know, I said, a couple of years ago we didn't really even know about the IECEE, right. So where can we build that from? And that's one of the things I'm trying to promote as well, as well as through the IMDRF, and I think that's what Melissa's -- or not Melissa, Elisabeth. Sorry. We all see each other too much.

(Off microphone comment.)

CAPT COLBURN: Yes. And that's one of the roles. And why we are comfortable with, you know, a manufacturer talking about IMDRF is because in a lot of these areas, those are the organizations that are contributing in these formats as well. And so it's great, to your point, that we have other people carrying that badge. And that's one of the things we want to do in these, you know, community as a practice, maybe ideas too, is how can we have the badges be carried so we can improve the ecosystem to try to meet all of the regulatory requirements.

Thank you.

MS. GEORGE: I think that goes back to what I mentioned earlier about trying to help educate all the people that do sit on those standards. I think if we can start to educate people about what's going on in this room -- because there's a lot people that are on those standards committees that are not here. If that process can -- we can keep it iterative -- I know, as Steve mentioned, you know, it wasn't that long ago that medical on the USNC was

really only represented by the AAMI organization. And then, you know, gradually we got manufacturers involved. And then we, you know, we got the FDA so that they're sitting at the table. We have NIST sitting at the table.

And it's amazing the leverage that we, as a medical community, can get from all the other communities from, you know, industrial automation, from explosives. I mean, it's -- I sit in those meetings and -- you think this has been techie detailed, start listening to those explosive guys. And, you know, all of a sudden, I have ideas and I'm sending messages to people on my team going, did we check this out, did we check that?

So those -- you know, the more often that -- when we, any of us as industry, sit in a meeting, if there isn't an FDA person there and we think that there is an FDA value in it, figure out how to get that info back to him. He'll listen. Or reach out to, you know, the AAMI organization to say, hey, there wasn't an FDA person there, but I think there should have been because I agree. I think we need to play nice together to do that, and always think about the testing stuff. And if there isn't a test lab person there, you know, ask why not. You know, because you can't have the stakeholder group be effective if you don't have all the stakeholders at the table.

MS. WOLSZON: The other thing this discussion is making me think of, you're talking about, you know, talking about IMDRF. IMDRF is also trying to have closer relationships with ISO and IEC.

CAPT COLBURN: Yes. And we talked a little bit about that yesterday. And I think I've gotten 45 emails from ISO today on this Category A liaison role that we're trying to build. So a lot of those things are happening, and we're working with, you know, Frans Vreeswijk and Katharine Fraga from IEC to establish these roles as well, and actually trying to do it beyond just the standards development side of a Category A liaison but also working into the policy structure.

Both organizations and all the SDOs, including, you know, every -- the whole 250 organizations accredited under ANSI and many of the other international standards groups in the U.S., have been increasingly trying to extend that portfolio of regulatory relationships across all the different regulations. I think NIST has seen a bunch of new organizations continue improving the roles there as well, each of the separate departments or agencies.

So it has been something that's been very positive. And we're trying to really carry it, as a medical device regulator, at the national and international level.

If there aren't any other pressing questions, I do have one more question for the audience, and whether it's to our panelists but also to the testing houses, this is to try to make sure when we go back to work tomorrow, that we're thinking about how do we add these additional requirements into ISO/IEC 17025, when we're developing these additional requirements and, you know, to work on, you know, extending our next first big steps once we've figured out what it is we think we're looking at from a technical requirements standpoint, based upon some of the input here and our continuance of operating.

What are some of those things that you as testing labs or you as accreditation bodies would hope that you would be thinking that we would be doing in developing the scheme? So that way we don't -- you know, we're not missing the mark, but also trying to help improve the relationship. So this is really a question to there.

We heard a lot about test report forms, the TRFs and stuff, but we do know that this is also defined in ISO/IEC 17025. And that's the framework that Amy is really trying to push us to think about when we speak the term "test report form," that we're not just looking at the IECEE test report form. That's a different tool than what is in the accreditation of a testing lab and what test report formats and what those mean.

But from the standards that you saw us thinking about, and those or may not be the standards that end up coming in the pilot, but how in the format of 17025, to which you

guys are the experts on, not I -- half the time I give it a different number when I talk about it. How should we be thinking about any requirements that you feel would be important, from these types of standards, that would help create a higher quality program to achieve some of the gaps that we're trying to fill in?

I'm not seeing anyone jump up to the mikes.

Thanks for saving me. Did you get your tire fixed?

MR. GROB: I did. Quick tire change at lunch, and I got to eat my lunch --

CAPT COLBURN: Poor guy had a flat tire, rental car.

MR. GROB: So to answer your question, I think what would be most useful for a testing lab is really two things, and I was going to mention this earlier. The first is getting feedback on reports that you've seen from us.

I don't need feedback on other test labs' reports. But if there was some way for the FDA to give us feedback on reports they saw, even if it was just a question, because if it's something that we can easily fix and do better the next time, even if it didn't lead to a deficiency -- generally we only find out about something if it leads to a deficiency or an NSE decision. That's the only time our customers come back to us. And we're certainly not under the impression that our reports are always perfect.

So it would be useful if there was some way that we could set up a mechanism -- and I think actually it doesn't really need to be part of ASCA, which is a pilot which may end in a couple of years. But this would be useful even if the ASCA program doesn't lead to something else in the future, to have some way for that feedback to get back to the testing laboratory.

But more specific to your question on what we would like to see as requirements, I think a clear understanding of the expectations for a test report would be very useful. So when we operate under an accreditation scheme -- and the IECEE CB scheme is going to be

probably the easiest one to talk about because there they define you have to use this test report. You may have one or two versions of that test report that are available for you to use, depending on the version of the standard that's being applied, but we know the expectation. You have to fill out this form.

They also have operational documents, what we lovingly refer to as the ODs, that tell us the expectations for how we fill out that form. It explains in some level of detail the expectation for a testing laboratory on what you have to include, what you don't include, in some ways even how to fill out different sections if you're saying this requirement was not applied.

And maybe those ODs are useful in this context, but maybe there's something different that the FDA is looking for. I'm focused on the CB scheme TRFs because we use those in 100 percent of the tests that we do. That's our output, if we're doing testing.

And so if that's not useful, or if there is something that maybe is better, if that could be communicated. Maybe there's a list of the top 10 things that the FDA needs to see in a test report. These are the things that we have to have. Or maybe it's a list of the top 10 things that we see are incorrect or we know trigger additional information requests. And if the testing labs are able to know those things, maybe it's something that we could actually address going forward immediately, to start improving the quality of test reports.

MS. GEORGE: Scott, when he just said the top 10 things, what came to mind was when we were talking in MDUFA, not this last one but the one before, one of the things that was a big pushback for us to actually implement the RTA -- I had to think about what it's called -- was what are the top 10 issues that the FDA is seeing in the submissions. So maybe this is an opportunity for somehow -- and I know it'll be a pain in the butt to do, but to be able to look at some sample or to query the people who are doing it, what are some of the issues they are seeing, and you guys could quantify some of that. Because that was one of

the biggest ah-ha moments because, you know, when we were first told, you know, 80% of the submissions you guys are making are horrible -- that's, you know, how it was communicated.

We're like, well, we don't seem to know that. We're not hearing about it. You know, it doesn't -- we don't have that data. All of a sudden, when we got the data that said, you know, 72% are missing this and 32% of the submissions are missing that and, you know, we're looking for test reports -- that was one of the things in there is there were test reports, a section for it, but there was nothing in the section.

You know, it's like people were planning on -- that was the, what was that, promissory note element. You know, oh, we're going to submit the 510(k) because we can get it started to be reviewed; we'll send the test data later. You know, that was obviously an issue, so that's what got added to the RTA process. I don't know if that's an opportunity to help all of us, both the test labs and manufacturers.

CAPT COLBURN: Angie, you're scribbling notes. RTA, by the way, is refuse to accept. I know some people didn't know all the acronyms, so I wanted to make sure I helped someone in the audience. I didn't know. I saw you scribbling there, so I figured you might have something to say.

DR. KRUEGER: Oh, no. I'm taking copious notes. I think this is great.

No, I think that's really helpful on the -- you know, I think we always want to be able to communicate back to manufacturers or to test labs, you know, things that we're seeing, even if it's something that isn't bringing up a specific deficiency or it's a minor issue. And, you know, I think that all helps us work more efficiently together. You know, so I think that's something we can definitely take back and look into.

I think that we already have groups, you know, of folks, you know, centered around, you know, biocompatibility, for example, who have looked at some of those things. And I

think we have in other spaces as well. So we might be able to capitalize on that and communicate, you know, those things that we're seeing as the biggest disconnects.

CAPT COLBURN: Gordon.

MR. GILLERMAN: So at NIST we have the luxury of working with a lot of the federal agencies across a lot of different sectors, and one of the things we've seen, actually from the law enforcement community -- who doesn't really have their own conformity assessment programs, they're not regulatory bodies, but they buy a lot of stuff, and they like high-tech gadgets.

So we've been helping the Department of Justice write performance standards for some of these high-tech gadgets, things like optical license plate recognition systems, interview room video equipment, in-car video equipment, eventually body cameras. And one of the things we've found is the procurement process there is the driving force, but of course, procurement officials are buying everything for the law enforcement agencies. They're buying cars. They can't be technical experts in everything.

So one of the things we've done is in a lot of these standards, many of which are being written right now in ASTM and NFPA organizations, we have put in informational annexes as summary test reports to be part of the standard. And that way, in their procurement exercise, the law enforcement agency says I want a product, I want it to have these minimum performance parameters, and I want the information given to me in the form of the informational annex of the standard.

This really kind of brings it all together. And in standards where we don't have the mechanism of the IECEE CB scheme to create the TRF for us, this may be something actually this program brings back into standards development to improve the development of the standard and the way the information about conformity with the standard is communicated.

CAPT COLBURN: Thank you, Gordon.

So we're at 2:35. I already got one of those marks in the back, so I wanted to do a quick check. Is everyone okay if we take a 10-minute break right now, and then we come back? I'd like to see if anyone has any opening public remarks. I know you -- if you maybe didn't register or something but something you might want to say before we go into closing.

But why don't we take 10 minutes, come back at quarter of 3? No one leave. And we'll continue through on the last part of the workshop.

Thank you very much to our panelists. This was very helpful. Thank you.

(Off the record at 2:35 p.m.)

(On the record at 2:45 p.m.)

CAPT COLBURN: Go ahead and get started again. Someone wave out those people that are outside. It looks like most of you came. I forgot to use my coined phrase on the last, you know, break before everyone leaves during break that, you know, I usually say. If you come back, you'll get all the secrets to the world of how to get through the first time. Usually people come back, but that works only once.

So this -- I wanted to make sure we provided an opportunity to anyone who's here to provide any open public comments. You know, we traditionally ask for people to register and stuff, and we had a few people do that, and we gave them the opportunity to speak earlier, but there's been a lot of information, a lot of sharing, a lot of new ideas. And people have been very open. I really appreciate the openness and just people providing input to us. And continue to do so.

We are working towards -- another one of these things we keep laughing at, when's the last 49 coming out, when's your next guidance coming out. We're even trying to get an ASCA helpdesk type email, where we continue to get information and input from our stakeholders as we walk through this.

But I want to make sure we offer the opportunity for anyone who would like to give some just -- you know, any other public comments, to kind of help us. You know, we are transcribing this. This is all information and input that will be helpful for us to take into consideration as we do develop the scheme.

So anything you do say is going to be listened to, going to be discussed in our subgroups, whether it's specific to a standard or just to the general administrative requirements that we're building to the program, or how we build a relationship with the ABs, how we're going to open communities of, you know, of practice potentially or relationships to the testing labs, and how we're going to build the confidence in all this so everyone benefits from this.

So if there's anyone who would like to open up with any comments, whether you're from the Agency or from any of the other stakeholders, please feel free to do so. If not, then I have to hit "next slide."

So did you have some? Great.

By the way, I'm very happy we've had someone giving us so many great review perspectives, so I do really appreciate it. Take it away.

FEMALE SPEAKER: Thank you. Even after talking to Alex from the -- I think I got the name right, Alex, right? Yes. Talking -- and from testing lab, I think, come to realize this more and more, I think this is a good opportunity to really gather feedback from the FDA reviewers of some of the associated standards concerned in this pilot program, just to really collect the expectations of the testing report form.

I think maybe we can make this form really communicative and very clear and beneficial to both the industry, FDA, and the testing lab. For example, adding some of the -- just to gather the quick elements to really improve on the testing form, testing report form, and then will be really beneficial to the industry and then all the parties. For example, the

NA and the NE, not applicable and not evaluated sections, maybe just a commentary column citing the referenced standard requirements, and justifying why they are not applicable or not evaluated. I think that's very helpful for the reviewer and for the testing lab as well.

And maybe inviting the testing lab as a participant in the conversation, just to develop this very, I think, better scheme and format for reporting the test results.

CAPT COLBURN: Yes. Thank you. Yes. Thank you very much.

Yeah. I think the discussions on test report forms, outside of the existing, you know, formats that we have, but getting further clarifications on when determinations are being made, that might be -- been made based upon how the particular standard communicated to the requirements and how that reflects our recognition of the standard.

I'll be honest with you. In how we do regulatory review of standards that are recognized and say a particular standard calls out the certain requirements in -1 or -2, do those clearly communicate why you would or would not do certain tests, why you would say not applicable or not evaluated? Is that clear in there? Could we draw better maps to that that would help inform us? Because we sometimes will be only looking at the base standard when it's communicating how -1 was done, but yet it might have been further interpreted in -2. Those are things I think we can work on.

But in the test report forms too, where that's been a part of the risk management process in communicating the essential performance or basic safety of a device, how can that be better communicated in the test report format so it's understood from that if it's not specifically called out in the particular standards that are identifying that? I think that's a really clear and objective way of trying to get to that next level of helping understand the test report forms.

Any other thoughts on that, or any open comments someone would like to bring to

the table?

(Off microphone comment.)

CAPT COLBURN: There's an online question. All right. I was wondering if it was working. I hadn't seen one in a while.

"How can we work with you as an accreditation body to assist the formation of the program? Will there be future meetings with different stakeholders such as accreditation bodies?"

So we're working on that, and I don't know where my NIST boss is, as I call Amy. But so we're trying to figure out where is that next step. And we're actually even working with our policy folks; at what point can we go out officially into our community to start beginning building those relationships as necessary? We put, you know, on day 1 kind of what our objective goals are from the commitment letter, when we want to start the pilot, when we have the draft guidance and all that. But, you know, developing a draft guidance, getting it out for publication to the point we were done drafting it isn't a 2-week process or even a 2-month process.

So, but for us to go through that entire process, we need to start building that relationship prior to an initial draft publication, to start that relationship building, because if we can't set our requirements in working with the ABs of what we want to do at the earlier stage, then getting that pilot to start is going to be a really hard challenge for us.

So what can the accreditation bodies do and what are we looking to be doing? That, to be honest, it's still yet to be determined. We may need to do another type of workshop meeting or find other formats that we can do to build this. That's why we are leveraging those who do this for a living to help guide us, what's the right time to do this, what's the right process to do this. And I'm seeing Gordon smiling in the corner of my eye.

But this is one of the roles that we're looking for. We are still defining what our

requirements are and what are the characteristics that we want to have built into the type of ABs we're working on. We have heard a lot of discussions yesterday about some of the things that we would want to see from a manufacturer's perspective or a testing laboratory's perspective on what the accreditation would achieve, both at a national or international level, because that is one of our roles is to try to make sure we are facilitating the manufacturers' needs as well. And many of them are multinational distributors of their products into other jurisdictions. So we shouldn't be creating a process that couldn't help in that format. So we are trying to build all that.

Once that's been established, then we will open up our doors in a way that would be appropriate, from a federal government point of view, of working that. And that's where our colleagues who have been helping us shepherd through this will do --

From all the other aspects of where the role of the AB and the testing labs -- and I don't see this as the end of a -- you know, we'll see you when the pilot starts. It is just no way. I told you in day 1, I and would think most of the people here at the Agency would say are not the experts of your world. And we want to make sure we understand your world a lot more and have a much better appreciation of it, and from there, see where does that build our confidence level up already, and then build those little extra gaps in or fill in those little extra gaps so that we can have a process that goes from there.

If we just develop our scheme and say now we're going to start a pilot and haven't had a chance to work with you and visit labs and work with the ABs and appreciate how this whole system works, then you're going to see a scheme that's not going to be beneficial, and no one's going to want to use it. And we really need to not go down that road.

So anything else in there? Oh boy. We've kicked off the international -- here. Let's see.

"How will FDA and other stakeholders prioritize the standards to add to the

program? Frequency of appearance and regulatory submissions, is that one?"

So we did talk a little bit about why did we kind of pick the ones that we discussed in the breakout sessions today, and I think we're going to continue to look at those, both from an appropriateness standpoint -- again, I mentioned I didn't want to pick a standard that is baked in and can be tested in, you know, the basement or garage type laboratory at an appropriate level and give us a declaration of conformity that we're satisfied with. That wouldn't be something that brings extra value to anyone here in the room.

So we picked some challenging ones right now. The program is not looking at the infinite number of standards that can be included into it but to gather the perspective of what does quality look like, what does acceptance look like, for us to build a foundation for where is it appropriate to engage in a third-party or accredited laboratory environment for the testing procedures? We don't need to have all standards go to a third-party or accredited lab of a manufacturers. Those aren't the expectations of the program.

Many of our standards would -- I would say 85% to 90% of our standards probably wouldn't fit into ASCA right now. Maybe more, I don't know. But we're working on that. So some of the metrics we are looking at -- and we'll probably go back to our old utilization survey. We're also trying to find ways in how -- this kind of goes into the guidances that we're working on today, to identify which standards are being tested in these environments today.

In those environments, where are we seeing additional information questions or areas of clarification or the testing reports not necessarily meeting what we feel is necessary for us to do our job? Those are the areas that we feel are good for ASCA. That's why we kind of picked some of the standards that we are looking at right now. Unfortunately, they weren't the easy ones, but it kind of goes with the game, right.

So we'll take that hard work challenge. We'll open up the doors in openness, to try

to get the feedback. And you ask us, what is it that you need? We'll ask you, this is what we think we need, and we'll try to build a program around that for success.

Any more, sir? All right.

Any in the room? Thank you.

FEMALE SPEAKER: So I'm going to preface this with I'm not saying this just because an inspection is imminent in our facility, but we do sincerely want to thank you guys for opening up this level of communication. There's always been the disconnect between the FDA and the testing labs, and by allowing us to come in here and give our opinion and give our expertise directly to the people that need to hear it, is phenomenal, and we sincerely thank you.

CAPT COLBURN: Thank you. Appreciate it.

Going back to, you know, we discussed, you know, visiting labs, and we had a few opportunities with the ELP program. And I think we had four or five specific to the ASCA. Biocompatibility also had a number of visits that operated from that. We are working to try to continue that. That's also a separate funded mechanism, but where those opportunities exist, we want to continue to leverage that.

Last year it was leveraged more to try to serve the engine to build an ASCA program, so a lot of the people in the room participated in that. The ELP really has been designed for people outside of those experts to benefit from working in the laboratory, so the reviewers, for example, that aren't a part of the ASCA team or the compliance officers or the postmarket people. And those are the ones that you want to be seeing and appreciating that as well.

However, we built into some of the funding and the negotiations to ensure that we can still gain experience as those who would be participating in the program, especially if we are going to have a role in working with the accreditation body, whether it's from being

a, you know, somewhere a technical expert or an observational member or just learning the whole process, so the members of that are involved, not just in the core team of the program but those who would be involved as the subject matter experts, helping us design the scheme.

So you will see us looking to come and work with these, you know, in this environment, the stakeholders here in the room, and that includes the manufacturer's own testing lab. And that always puts in the -- oh, but you know, and so there were some manufacturers that originally were very interested, but there were some challenges when they went and tried to get that approval because the big bad FDA would come in.

But we do want to make sure that, to our manufacturers in the room, that we are trying to come in to learn the accreditation process. If you are operating under 17025 and utilizing your quality management system through 13485 to support that -- we just, Dana Leaman discussed, and Warren Merkel, how there's different options that you can clearly delineate what's your quality management system that would support your laboratory's operation under this. Those are very valuable tools for us to consider in developing this ASCA program so that way manufacturers' own accredited testing labs can participate.

The same goes for certain testing -- third-party labs that might be specific to only medical device manufacturers that might be operated under that same management system. The more we can learn from that, the better we will be set up to develop a scheme that allows maximum participation and allows us to communicate to different bodies having jurisdiction, whether it's a national or international level of how our scheme operates in the system.

And I think that's real important, even at the standards development level, when -- I've been involved in a number of different standards activities. And one of the standards that we developed was a design standard -- God help me -- and we had to do verification

validation testing. And the experts in the room were trying to learn more about, okay, well is your lab accredited. And a lot of people were saying, yes, well, we have a certification of 13485 as a manufacturer.

But then the laboratorians were like no, no, no. We're talking about laboratory accreditation. And so that terminology, even at that level and in the standards development, wasn't clear. And I think those were one of the issues that came out of IMDRF in understanding, when standards are developed, and if they go through a verification validation process, to what level was that done? Was that done from the 5 p.m. to 9 a.m. shift of wine drinking, or was that done in an accredited lab?

Both happen, and we know that. But so that helps bring out a lot of elements that brings us to test report forms, how laboratories can interpret or make significant interpretations to the standards, etc., etc.

Jamie.

MS. WOLSZON: Scott, it's Jamie Wolszon of AdvaMed again. I just wanted to reinforce what you were saying. You mentioned the ELP and that some people might be afraid of having FDA come in. I just wanted to say that several of our manufacturers have participated in ELP programs, not necessarily related to ASCA but in general, and it's just always, always come back that it's been a really good experience, both for the manufacturer and for FDA. It's not supposed to have a compliance aspect to it whatsoever. And it's just, you know, it's -- everyone says it's a really good opportunity. So don't be afraid of it.

CAPT COLBURN: Be afraid.

So we have one more question here online. In the -- and this kind of goes a little bit about what I ended up with discussing on my last comment.

"In the efforts of global regulatory harmonization, has FDA considered or engaged other regulatory jurisdictions, such as the EU, for their perspective on the ASCA program?"

At a very high level, yes, we've informed and we've been working with our colleagues, both in IMDRF as well as just trying to through our communications. I'm looking to see if Ken Cavanaugh is still here. And we just came from a meeting that I was discussing -- where we were discussing the essential principles, which is, you know, the update that's being built from the old GHTF document that also developed the ISO 16142.

And so we touch on it. Now, this is where -- and I went back to, you know, Steve's question is how can you help us as well, because understanding how standards are being utilized at this level is something that a lot of the regulators, when we come to these regulatory forums, don't necessarily have that expertise and knowledge of as well, present company included.

So we are trying to find new ways to gain that experience and bring that to the table, to help then educate the other regulators so that way they know how to go get that information and gain that experience. From the meeting we were in 2 weeks ago, not everyone who was there, in the five different regulatory bodies, had that type of level of experience. And so you can only take it so far.

But there is a general interest in trying to see how can we gain value in acceptance of these types of new tests? Every country has a little different platform. I can't say any country is willing to change their regulations because of ASCA, and ASCA or FDA, because of the MDR or whatever may be happening. But there is a huge interest in trying to leverage how can we make this work more at an international level?

So I hope that helps answer the question online. Any other comments in the room? You're like, no, Scott, we've heard you talk way too long. Let me just do a double-check here. There was something else that came in. So I think that -- just double-checking.

So I think that, you know, that's all the questions. Is there any other --

Sharon. Go ahead.

MS. LAPPALAINEN: I pulled out my data. You know me.

CAPT COLBURN: All right.

MS. LAPPALAINEN: Little Miss Data.

So there were some questions earlier today about how many times FDA asks about test reports in 510(k)s. And in our survey, out of the 870 submissions that we surveyed, 315 or 36% had requests related to standards; 85 out of those 315, or 27%, were requesting test reports; 116 out of the 315, or 37%, had a question about the test report that was submitted; and 12 out of 315, or 4%, had questions related to the standard being modified or used in a different way. So that was some of the information we got from our 2014 survey.

CAPT COLBURN: Yeah. Thank you.

And that was part of what created this. We could probably do a little bit better by helping our staff, you know, who are doing this understand how standards should be interpreted into the submissions. You know, we're not saying you have to use a standard that's recognized by FDA; you have to use it the way it's recognized, but we need to understand how it's being used so that way we can do a better job of determining its appropriateness for use before writing the additional information question of you deviated from the standard, I need to see more information because it just -- that gap wasn't filled in.

So that kicked off a lot of updates that went into this guidance that we've discussed a few times and I've jinxed the output of. But maybe it'll publish tomorrow, then. But -- and then it kicked off the idea, and when we were talking with some of our experts who have been involved in conformity assessment of what else could we do? And this is that platform. And that's really where we came to today.

So thank you, Sharon, for bringing that up.

So we're trying to carve back on some of those additional information questions that weren't -- I mean, you would say, from the list that she gave, a lot of those probably aren't necessary if we had an appreciation for how testing was conducted. A lot more of them can be erased if we understood the non-applicables and not evaluateds. Many more would be addressed if we understood that the test report format that was used is something that's accepted in many other accredited formats and has meaning.

And so that's where ASCA will build those relationships. Again, we just -- a lot of times we didn't quite know it at that level. If you read our guidances, what you see is what we have for understanding the use of standards in the Agency. And while I think we do a wonderful job, I think these areas are going to be what's going to help improve us and get us to be able to get devices quicker to market, you know, first in the world as Jeff says, right, to help -- of global health importance.

Any other comments? All right. Well, yeah. I should look. Hey, Jianchao, I stole the reader. Nothing new.

MR SILBERBERG: Scott.

CAPT COLBURN: Yes, hey, Jeff.

MR. SILBERBERG: So -- yeah. I appreciate all the interest in the activity, and I know that you want to make it successful. I do think you've picked some challenging standards, in particular 60601-1-2. And ASCA, from what I read about the ASCA program, it's ideal when there are definite pass/fail criteria. And the pass/fail criteria in 60601-1-2, number one, is based on essential -- basic safety and essential performance. I think we have a lot of challenges as far as essential performance goes, manufacturers understanding it, different manufacturers of the same product coming up with different essential performance, FDA not agreeing with manufacturers about what their essential performance is and is not.

And then in -1-2, the standard in 4th Edition requires that for each product, specific

pass/fail criteria be identified. And so that's individual per the device or the product. So I think we have quite significant challenges ahead, doing this program with this standard.

CAPT COLBURN: Don't run away yet, Jeff. So to a two-part question is, one, do you feel this would probably be a job just for that area and all the devices that are relating into it that's too big for FDA by itself and, you know, to make the right and correct determinations in the development of a scheme?

And if that part is yes, probably a little too big for one stakeholder, should we consider a community of practice type approach where we can build and get the information using the experts that are involved in this and try to have those discussions and build the tools to help support the next genesis of how we can, as regulators, use standards to make our determinations? It's another --

MR SILBERBERG: I think a lot more -- and I've heard this from other people here today, today and yesterday also, that a lot more needs to be done regarding what is essential performance and how is it identified and how to help manufacturers and particularly small manufacturers identify their essential performance in a way that we agree with.

CAPT COLBURN: Okay. Thank you.

All right. Any other comments? Nothing. All right.

So I'm not going to go through a huge summary. I think, you know, if everyone really wants the full summary, there's a 16-hour recording that will be made available for you to listen to.

But we did, I think, go through a lot of different levels of trying to describe what is it that FDA's trying to do. I don't think what FDA is trying to do was what everyone thought when we first heard FDA's going to develop a third-party accreditation program. In fact, we explicitly try not internally use the words "third party" because that didn't always go well

with how regulators heard that word. And, externally, they are like, too, trying to figure that out.

So I think we understand what we're trying to do here, and this is to improve the whole genesis of how standards in general and the testing that goes into this, and working, you know, new relationships. There was a few new faces in a meeting, for a change, that we're talking about standards that we always don't get at. So I'm glad to see some new faces in here. And I'm looking forward to continuing to get to know all the different areas.

Next steps are a little bit undefined still. I think there's a lot of work still on our end to collect our thoughts and hear and listen to the 16-hour summary a few times to make sure we're capturing the key elements.

In the development of an accreditation program that it -- we're going to be following the lead of the guidance from what we've seen in many other regulatory programs that have been established. We're, you know, going to, you know, build our approach and make sure we understand what it is that we're looking for, make sure it meets the needs of not just those involved in the ASCA program but also the senior leadership, and also helps support what I envision ASCA being, which is kind of the bedrock of how the Center or even Agency, to that effect, should be thinking about conformity assessment and working with those stakeholders as appropriate.

So whether it's dealing with the UDI programs or MDSAP programs or third-party programs or even the food safety programs and what's going on with e-cigarettes or establishments, trying to build that community in, because by and large there are areas that, even across the Agency, that have better experience, and then there's others that are saying, jeez, we need to learn more about this.

And they've heard about us working with our relationships inside the government to help build a program that makes sense and has been shown to be successful. So that's

where we're going with that.

From there, we will try to be putting out regular updates before our draft guidance goes out to say what is it that we're doing? Where are we going to be making discussions on topics and presentation on this as we continue to go and receive feedback? And that's really as far as I can get into the details of next steps because those steps have not been built. I would fall right off the staircase if I kept talking because we don't really know that yet.

But I want to really just again say thank you from the bottom of my heart to everyone who came in attendance. I really want to, also for the conference planning group, this was a beautiful facility. Really worked out very nice. I do apologize, for those who were online yesterday, we did have some audio challenges that went agency-wide with Adobe Connect. So there was some drop-offs, and that created some heartache yesterday. It seems like it worked better today.

For everyone on the ASCA team and those who've been involved with helping the subgroups and working with us, thank you so much for making this, I think, a very successful workshop. I think we've learned a lot. Amy has said, get ready to work. Now it's time. The gloves have come off, and it's time to go.

We have a lot of work ahead of us if we're going to meet our objectives. In the same time, we're going to find out, where can we open up these dialogues with the appropriate groups and get the information we need. See, she's pointing. She's pointing. She's saying, it's ready.

And, again, for all the people that helped facilitate the rooms, presenters and speakers, both from FDA and from all of our stakeholders, and again, to just all the participants, thank you very much. And I look forward to seeing you all again very soon because this is, as they say in the standards world, is just the family, and we will see you

again in the next soccer game or wherever we'll meet.

If there aren't any other comments, and I'll pause -- wave your hand if you wanted to say something that -- oh god, I better say this before he closes.

Thank you very much, and enjoy your afternoon.

(Applause.)

(Whereupon, at 3:13 p.m., the meeting was adjourned.)

C E R T I F I C A T E

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

PUBLIC WORKSHOP -

ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA) PILOT

PLENARY SESSION

May 23, 2018

Silver Spring, Maryland

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health.

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SHAYLAH LYNN BURRILL

Official Reporter