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BREAKOUT SESSION II 60601 BASIC SAFETY AND ESSENTIAL PERFORMANCE

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M E E T I N G

(1:03 p.m.)

CAPT COLBURN: So we're going to kick off into the opening session here for the afternoon. And really this is designed to kind of set the platform for the base discussion of how 60601 as a series, as a community of standards, operates.

And we have a bunch of different perspectives being brought into this, you know? How does FDA view basic safety and essential performance? How does that play into our thought process as a risk-based regulatory agency? How does the idea of working with an accreditation body to help develop competencies with the FDA, you know, criteria or perspectives build into this, play into the overall role that ASCA is for?

And so we have a series of experts here. And I'm actually, instead of introducing all of them, I'll ask each one of them to just introduce themselves before I have Dr. Zane Arp come up and give opening remarks.

DR. ARP: First, I'm apparently challenged by the microphone. I'm Dr. Zane Arp. I am the current Division Director for the Division of Biomedical Physics here at the FDA.

MR. FITZGERALD: My name is Brian Fitzgerald. I'm in the front office of the Office of Science and Engineering Labs.

MS. GWEN: I can't hear you, Brian.

CAPT COLBURN: Yeah.

MR. FITZGERALD: Can you hear me?

MS. GWEN: No, Brian.

CAPT COLBURN: I strategically turned his off. No, I'm just kidding.

(Laughter.)

MR. FITZGERALD: Can you hear me?

CAPT COLBURN: You have to bring it close.

MR. FITZGERALD: Can you hear me now?

MS. GWEN: Yes, Brian. Thank you.

MR. FITZGERALD: Okay. So I'm Brian Fitzgerald from the Office of Science and Engineering Labs at the front office.

MR. TAYLOR: And I'm Al Taylor. I work in the next office to Brian, and I am going to actually yield my time at the podium today to my esteemed colleagues from the state of chaos, but I'll be helping to moderate the session in here after the break.

MR. EISNER: I'm Leo Eisner. Do you hear me, Pam?

MS. GWEN: Yes, Leo. Thank you.

MR. EISNER: You're welcome. Product safety, regulatory-type person, and I'm a consultant. I've been dealing with 601 for 26 years or so.

MR. GROB: Good afternoon. My name is Alex Grob. I come from Medical Equipment Compliance Associates. We're a testing laboratory focusing on 601 in Wisconsin.

MS. LEAMAN: Good afternoon. I'm Dana Leaman. I'm the Chief of the National Voluntary Laboratory Accreditation Program.

CAPT COLBURN: And also a Packer fan, I see, as well, so -- there's a lot of Wisconsin -- I too am from Wisconsin, so this is great. I feel very much at home. We should all have some cheese.

(Laughter.)

CAPT COLBURN: All right. So before I have Dr. Arp come up, I just wanted to make sure -- so questions, we want lots of questions. We want discussions. We want thoughts and ideas. But what we want to do is try to get through all the different presentations here to kind of give you the big picture of what this group of people have been working together -- are bringing to the table. And so after the presentations are done, we'll have a lot of

opportunity to then open up questions. Unless you have something so burning, you know it's going to leave your mind, then try to get the attention. But we would ask to try to have questions towards the end, is my understanding.

And we will continue this, again, until we go to break this afternoon, and then we'll break out further. When we do break out further, if I don't have a chance to show you, the 60601-1-2 group, EMC group, will just go out and to the left, and it's Room 1504, I believe. And there's a classroom right there. The alarms group, for 1-8, you'll go down if you've been to the restrooms, that's where that room is, in 1406 -- 1408 -- I'm sorry. I tried doing that one. So and that's just way down there. So those are the two rooms for you for when those come up.

And then again, for those who are online that are interested in those specific groups, there are separate WebEx sessions that will be going on, and there'll also be the opportunity to ask questions and in the chatroom, and we'll try to bring those in as we see appropriate to help drive discussions. But, again, the expectation is that we're not going to be doing a question/answer for each question that pops up because we want to try to see if we maintain the discussion going in the room.

So, with that, I want to introduce Dr. Zane Arp. He's the Director in the Division of Biomedical Physics in OSEL.

DR. ARP: So let's see first if we have our slides. Which button is it? Nope. Nope. Do we have slides? Well, I guess I can start and do this chalk-talk style for the minute so that we can stay on time.

So I am the relatively new Division Director for Biomedical Physics here at the FDA. So having only been here 5 weeks, I'm really only the talking head for a whole -- a very large -- or a fairly large organization that's doing a lot of the real regulatory work here and who's participating in standards and ASCA and a variety of different activities.

If I had slides up here, which we'll talk about in a minute, I'd be introducing you right now to what DBP is. We are a fairly diverse organization as far as what we currently look at. In particular, we have people who look at regulatory submissions ranging all the way from MRI-RF to optical to x-ray to a variety of different other areas. Of course, today we were really wanting to focus on EMC wireless and electrical safety.

What's important about this is my organization is about 35 personnel total. Of that 35 personnel, or full-time personnel, we have a lot of research that's ongoing. Full organization size is really around 100 people when you add all our research scientists in the form of post-doc students and others.

So out of 35 people, I have about 11 people who are currently dedicated to the EMC wireless and electrical safety aspects of the review cycle. In that regard, those people are currently working on a variety of things, including standards development. They're highly specialized and trained in these particular areas, standards development. They do a ton of reviews. Again, if I had my slides, I had about a couple of graphs to show how the review cycle and the number of consults that we're asked to do a year has increased over time in these particular areas.

And at the current point in time, we currently handle about 500 consults a year with 11 people. And it doesn't take a rocket scientist to figure out that that's a lot of consults per person and probably a level of consults that is difficult to keep up with. Many of these consults actually -- so out of all these -- and let's see -- are we going to get them? Aha, now we're getting there.

Out of those 500 consults, and I don't have a metric on this, but talking to the experts in my organization, the mass majority of them are going to have a deficiency of some kind. Those deficiencies can range from major deficiencies to really minor stuff.

Aha, there we go. Let's see if I can cycle through these real quick. Wrong way, of

course. There we go.

(Audio issues begin.)

COURT REPORTER: Your mike -- his mike --

DR. ARP: -- a lot of people are -- a lot of different areas that we're focused on.

COURT REPORTER: Your mike, please?

DR. ARP: What's that?

COURT REPORTER: Your mike.

DR. ARP: There we go. Better? You'll see wireless and electrical safety is really what we're focusing on right now -- highly trained and recognized experts, significant activity in the standards development. They are engaged in a variety of research and development activities to help improve the regulatory process and -- provide consultations to the reviewers -- medical devices.

I want to really hone in on -- because it's probably one of the most important things -- ASCA program. As I was saying -- hire more people to do more consults, but that's really not the focus here because all that does is add a -- amount of resource, and quite honestly, deficiencies prevent good medical devices from getting to the patient as quickly as possible.

Just to give some perspectives and some examples of some deficiencies that we might see that really should have been handled if we were following the standards -- ASCA program in place. This is an example in which we have -- testing with a power adapter plugged into --

So what are our concerns with this? First off, it's not being tested in a manner that's really -- there is no medical device associated with the power adapter. The first step is, is why is there no medical device associated with this, which leads to the question, too, what is the value of that particular test if the medical device isn't there? You're not really

proving anything in this case.

And last but not least, what is the expected outcome with respect to this particular test -- medical device in place? How ASCA could -- in place -- quality of the testing and potentially of opening the communication between the FDA and test labs --

Just another quick example of a deficiency that might be seen in the organization or has been seen in the organization. This is an oxygen pressure monitor. Now, here are some of the key things that came up in this one. First off, there's oxygen inputs with potential for a fire/explosion hazard. But due to a difference in opinion of what testing was needed, no testing was completed with respect to that oxygen/fire/explosion hazard.

In this particular case, there are several design flaws with this particular system. It could have been mitigated had there been discussion early on with the FDA regarding this particular device, fire locks between the lithium ion battery and that oxygen input; testing should have been done ahead of time. And in this case, ASCA could have helped us by improving the quality design compliance with -- before the device was under FDA review to begin with, which would have saved everybody a lot of time and money.

Just some background for the breakout session: You know, why are we doing this? And at the end of the day, this is really about the patient, and we want to get devices to the patient as quickly and effectively as possible. Whenever we have these deficiencies, that just leads to time, money, and effort that goes into review cycles on our sides, manufacturers slowing down, and more review time -- our reviewers.

We all want to make this regulatory process more efficient, more transparent, and more consistent so that everybody in the game has faster times to get to these critical medical devices for patients.

21st Century Cures Act -- concept the least burdensome, so we want to relieve that burden overall for everybody involved. And last but not least, as I said earlier, I can hire

more people to go do reviews, but that doesn't -- good. The efficiencies just don't exist there. So we can compound the efficiencies by making sure that we address these problems effectively with something like an ASCA program, where we're having more efficient processes to begin with on the review -- before it gets to the review.

So just a quick background for the breakout session. Things that we want to achieve today: We don't want to spend any more time than necessary on standard testing that's done well. So in other words, we'd like to see testing -- have to go through everything by specialists in my organization. This allows us to actually focus on the more critical things, where there are no standard tests available, those cutting edge pieces of equipment that really do affect patients -- if they are affecting those -- happy to review more standardized testing. In this case, that would be things where data actually suggests that a deeper review is actually warranted as opposed to using standards and standardized tests.

This workshop really helps us to define those tools that are routinely used and consistently used and, to a degree, discussing what is routine and consistent in that space; 60601-1-2 and 60601-1-8 are the two that are being currently kind of targeted as preliminary areas to look into. I think that there's debate around whether those are the right ones and what that could look like.

Then, last but not least, what does that framework look like that is beneficial to the patient, regulators, testing labs, and manufacturers? So I have my little diagram there. You know, we want this to be a beneficial, and this has to be a beneficial aspect for everybody involved, the device companies, FDA, testing labs, and most importantly, the patients that we're serving at the end of the day.

So, last but not least, key questions for this session, and this is really just a repeat of what's in your program already:

What are some of the major challenges that are facing manufacturers and testing

labs? It's important we have discussions around that to make sure that we all understand what the issues are.

What are some of the major challenges to improve manufacturers' and testing laboratories' collaborations, in particular, around 60601 -- standards and 1-1 -- or 1-2 and 1-8?

How do accreditation bodies, testing labs, and manufacturers manage the requirements and these standards?

And, last but not least, what are accreditation bodies' perspectives on this ASCA pilot, and how can we work with them to ensure that we get testing labs that are actually accredited and able to deliver on what we're trying to get through this program?

Last slide here, just some key contacts within my organization. Please feel free to reach out to anybody up there. I believe these slides may be available later. So you should have plenty of contacts today. If you have any questions, of course, you can always reach out to me as the Division Director.

And, last but not least, the U.S. FDA is really Food and Drug Administration and -- let's see -- come up -- and devices.

So, with that, I'm going to turn it over to Brian.

(Applause.)

MR. FITZGERALD: Good afternoon. I've got eight slides. I'm going to burn through them pretty quickly. What I want you to take away from these are that, number one, we don't know all the answers. We don't even know all the questions yet. So we're going to be very happy to engage in discussions over this next day and a half to find out what it is that we should be doing to meet your stakeholders' needs.

And that's one thing that I want to characterize that Captain Colburn has taken a great deal of effort in, and that is to identify the constituencies, the various stakeholders

that the ASCA scheme has to provide for winning -- every single member of that ring of stakeholders must get a win out of this somehow.

So some 601 series standards are candidates for the selection -- ASCA pilot. The question really goes to how many more of these and whether the ones that we've got are suitable for the beginning of -- this is really about whether during the course of this pilot we can get comfortable enough with the methods that we determine are suitable to expand this thing or just to wind it up. It's a pilot.

That's me, part of the ASCA core team. I'm from OSEL, the Office of Science and Engineering Labs. I have no disclosure except that I have a vested interest in this program winning, and if you want to email me, that's how you can do that.

So the problem: We have incomplete or inconsistent 601 test reports as part of our regulatory submissions. We have "unexplained" and "not applicables" in a lot of test reports, abstract reference to risk management file test reports, and little or no reference to essential performance characteristics identified, much less any verification of these.

And I want to also leave this thought that the patient stakeholder is underrepresented in this entire scenario. And that goes to other slides that I'll be moving through here soon that will show that essential performance is something that -- since 2005, as presented in the -- to us in the regulatory realm -- has not -- the patient representation that we have been looking for.

So it's -- we have to end up asking additional information to get that level of confidence in the submission, and it's as if the testing -- the status quo of these test reports. And I have to tell you, and I'm sure most of my -- agree with this that absolutely the worst possible time to have someone interrupt your engineering flow on your way to market right at the regulator desk. It's as if, if we could find a way to fully bake this cake before it ever got into the regulator's office, that we would all achieve a huge win from this.

So one solution, and it's the solution on the table at the moment -- it's not the only possible solution -- is to bring the 601 standards into ASCA. And one part of that is going to have to be when we embrace safety and essential performance as an indivisible tuple for medical devices. We have to work that all safety engineering problems are identified before the FDA submission catches them, allowing the manufacturer to plan and stage on their own clock the conformity assessment steps that need to go into that.

There's bound to be some iteration. There usually is anyway. It's very important that iteration happens before the end of the end of the design cycle and the beginning of the regulatory review.

In order to make that happen, I think, we've got to make some important improvements. We have to communicate our needs to the full constituency of stakeholders. Scott has talked about this, this morning, where for the first time we're beginning to contemplate having relationships, both official and less than official, sort of ad hoc, and informative with the full sweep of stakeholders and --

And all that will bring in education, it'll bring in partnership and risk sharing. Oh, yes, there will be third-party accreditation, alignment with domestic and international conformity assessment schemes, because that's where the value is going to be found, not in doing something different and something separate, but getting something aligned with what's already needed for many other conformity assessments and regulatory schemes out there.

We want to avoid unnecessary overlap and unnecessary duplication. I'd like to think of conformity assessment schemes where they're well -- that is to say that you can add conformity assessments -- in order to achieve new levels of compliance in new areas without having to redo it, without having to replace it.

And that reusability is something that's very important. The way that international

regulators are beginning to coordinate now or, as well, for the future, that when a conformity assessment activity that meets one regulator's needs is put together and it's shaking out some of the kinks, it's likely that other regulators might pick that up as well.

We also need to make sure that the requirements that are found in the standards are identified and that they're verifiable, in other words, in producing that conformity assessment into the standards development process, that they're actually necessary and complete and that the regulators and other customers, let's just say, customers of regulatory requirements, are able and willing to recognize them as meeting their needs. And that's actually a human issue as much as it is a technical one.

We have to ensure that consensus standards and conformity assessment to these consensus standards is reasonably attainable. It can't be enormously expensive for it to be successful. It has to be an incremental, composable approach, where existing base layer conformity assessment can be built upon to achieve new levels of compliance.

Last but not least, this solution that we're proposing, one solution, is that it include -- of feedback, feedback to the labs, feedback to the accreditors, also -- in collaboration with labs and accreditors in order to establish it to kick it off, to give it the momentum need to move forward.

So one big thing that we're going to find here is that we need to characterize essential performance before we go too much further. 2005, first edition of the 3rd Edition, 3.0, as it's sometimes called, had this notion of essential performance. And you know we've already known for almost a century that basic safety is composed out of fire, shock, and casualty. And if you go back many, many decades now, you will remember that UL 544 and 187 were the first to introduce a patient constituency into this because of the transitive nature of many of the --

But later on we began to find out that only extending basic safety -- patient

constituency wasn't enough, that in -- in an electronic and programmable system, in a world of cyber security, many of these newer -- exist in that area of the essential performance -- so the traditional basic safety testing paradigm, which is a compliance paradigm, needs to shift. It needs to mutate towards a risk management-based paradigm, which that 601 attempted to set off in 2005.

I have a couple of references in these slides, and you'll be able to look at these references, but we've built our regulatory models in FDA around risk management and essential performance since 1976. We've always been asking these questions. And we were glad that in 2005 that there was going to be now finally an element of essential performance called out, identified, and verified in 601. And by the way, 14971 itself now calls -- that essential performance needed to be reviewed.

So we always assumed that this thing would get better, and it hasn't gotten better, however. It's remained almost the same. And perhaps there's some blame here that we haven't required it with the fervor that we actually have internally. And since 14971 has itself required, you know, these elements of risk -- essential performance be reviewed as part of a risk management report, we hesitate to imagine how manufacturers can fully assert compliance with 14971 if they don't know how yet to define essential performance.

So something has to be done -- one solution here -- we know that -- risk -- the total product life cycle of medical devices yields up much better, can be used by manufacturers and improving their results and would form part of, along with all the stuff that they advertise their devices for, the essential performance.

So by exclusion here, I want to leave you with this sort of notion. The remaining equipment specifications whose failure to be achieved during the intended use -- remember, the intended use of a medical device specifically, and which failure may result in a patient risk, will usually be essential performance.

So -- my friend who's not here with us -- said, well, how can failure to boil water in a kettle be essential performance? It can't. Kettle is not a medical device -- and the lack of that essential performance does not harm a patient. It's not essential performance. Look to what the patient risks are that are introduced when the device does not perform according to a specification. You could think of metrological stability, a whole host of different things that are not looked for normally in basic safety testing.

So the incorporation of risk management: Our healthcare sector is risk-based. It's not a compliance model, where a lot of other industrial sectors are. So we permit and in many cases we do foster deviation from standards when innovative technologies that benefit the patient are proffered. In other words, a 100% compliance model -- in the standards is something that is alien to us and is impractical in real life. It doesn't happen very often, but when it does happen, it's usually for a very good reason. In reality, it's --

14971 gives a beautiful template for manufacturers to incorporate risk management into the design of their products and to evaluate those residual risks. And remember, the FDA is looking at the evaluation of residual risk, taking into account that the disease condition could very well be worse than any residual risks that are left in the device. This is not a compliance model.

I mentioned that deciding what's applicable and what's not applicable. Well, you know -- it's obviously applicable. Actually, I'm sorry. It's not always obvious why something is not applicable. That's probably one of the reasons why we get the most additional information requests from our reviewers, because they simply don't have the context that a test lab or a -- lab with the device in front of them. And we need to share that information with our reviewers in an open and transparent way. And in -- assessment scheme, sharing of that information can provide an expedited vision of what constitutes a level of compliance with the standard or a suitable compliance with the standard.

So we also remember 14971 needs to know and needs to report on and to evaluate the models of risk acceptability for residual risks. And the levels of non-applicability, therefore, need to be communicated not merely to FDA but also to the manufacturer so the manufacturer is able to ask questions, as Scott mentioned. What happens if we ask about why a particular box has been labeled as not applicable for a manufacturer -- asks why a test lab -- not applicable. And then you start a 3-month cycle of other problems of missed deadlines. All of the sudden, what could have been caught early on in the process has been allowed to impinge upon the whole regulatory process, and the time to market is now in a place where it shouldn't be.

So 60601-1 is FDA-recognize standard. That's the AAMI notion, AAMI ES60601. It has a national deviation. Another one of the biggest problems we see is failure to -- national deviation -- it does embody the risk management paradigm of the 21st century medical devices and -- that device residual risks might be more acceptable than the existing disease risks. So we have no compunction about trading off perfection with the ability to get it to patients quickly here in the U.S.

It embodies the assumptions that medical device regulators have worldwide and have always had, that is, that evasion from the risk is not normally considered possible, that no consent to a risk may be possible even if I tried -- be able to sign a disclaimer for that medical device. And the failure of essential performance is a patient risk. And that's by definition. You know, if the basic safety is okay and there's a problem with the essential performance, it is a patient risk. Otherwise, it wouldn't be essential performance.

And we know in the basic safety world that "single point safe in normal condition" gives us an excellent level of confidence. And that's why that is such an important precept, but it doesn't work that way for -- this essential performance, you know, needs to be identified and it needs to be -- as being present somehow. It needs some verification, some

validation.

60601 and its stakeholder community, you know, may not be the perfect candidate for the ASCA. I happen to think that we can up our game and make it so that it is. We simply have to begin to bring essential performance into the mainstream. In order to do that, we're going to have to build a community of experts, of accreditors, of test labs, of manufacturers who are willing to wear this scheme as a -- for long enough to identify the problems and knock the rough edges off where we can so that we can finally make it something that everybody gets a benefit out of. The benefit for -- this is a journey -- the benefit is that we get three additional long-term, strategic benefits here. We show how we can properly include and verify essential performance in a third-party verification.

If this pilot is successful, we'll all know how to do it at the end of the pilot. We pave the way for other standards to be included like -- and there are a ton of other device-related standards that may or may not in the body of the standard have called out specific essential performance characteristics. But we will know by the end of the pilot; if we're lucky, we will know how to do that in an ad hoc, real-time manner.

And the third thing is that the aspects covered by standards of regulated products that come to FDA will come into FDA "fully baked" as part of the regulatory submission. But if there is that level of confidence that they're not going to get turned back and that they are complete, I can scarcely imagine how we couldn't reasonably say that we've made a little progress.

Now, can we directly correlate that with improved review times? I don't think so. Scott mentioned that earlier today. We're not in a position to do that. But we probably are in a position to hold out the hope that as we include more and more standards and more and more devices get essential performance characteristics identified, that the promise of an easier review cycle, managed on the clock of the manufacturer, performed in large

measure by the test labs and the community out there, and then reviewed as -- onto the next one, you -- that promise if this pilot is successful.

So, with that, I'm going to pass you over to Leo Eisner who will talk to you from a different perspective and from a different stakeholder point of view.

(Applause.)

MR. EISNER: Thank you. So I'm going to take it from the manufacturer's perspective primarily. I'm a consultant, but I've been helping manufacturers for 20 years now get through product safety, testing, some regulatory perspective.

Here's quick background. I'm not going to get into it. There's way too much in there. I'm also involved in standards development around 601.

So today, like I said, I'm going to take it from the manufacturer's perspective primarily, not fully but primarily. So the first thing I'm going to do is talk about what currently are some concerns for selecting a lab, because that's going to be a backdrop for what are some of the concerns from the ASCA program.

Then I'm going to look a little bit at the cost-benefit. And some of these things have been mentioned already, but I'm going to remind us about. And I'm also bringing in a lot of questions that we're going to hopefully discuss later in the workshop.

And the last two bullets are more from the FDA perspective. Essential performance and how there's inconsistencies, and verification of that is a big question, and then justifications for "not applicables."

So from a manufacturer's perspective, how do you select a lab? These are just a couple considerations. It's not fully. Geographical location for test lab, especially EMC, seems to be more critical, from what I've dealt with over 20 years now, because most manufacturers want an engineer at the testing for EMC. It's a week or two test program where safety tends to be a much longer test program, 6 weeks or more depending on the

product, complexity, and a lot of other things. Some manufacturers still want that local, maybe because it's a very big device or whatever other reasons, and a lot -- maybe 50% are more flexible about it, maybe a little more.

Quality of test reports and documentation with respect to regulatory bodies -- and I'm a notified body auditor, so I have perspective of reviewing reports based on that. And sometimes it's easy to review reports that I get, and other times it's incredibly hard to go through. So part of the comments about not applicable and essential performance, a CB scheme test report, which is what you tend to see from 601, some of that is straightforward and easy to review, and other parts are not. And Brian alluded to that.

What about the expertise in the standards and also the appropriate test equipment? As you get into particular standards, there's more and more expertise that you need, and it's also a business decision on the lab's part what areas they're going to get into. Some particulars are more costly to get test equipment for and also collateral standards like the EMC and home use.

What about the cost and schedule, testing, and getting reports for the manufacturer? Some manufacturers, especially small ones that I've worked with, startups, will go and hop around, where others have established relationships and there's lots of other issues.

So looking at the pilot and maybe the rollout after the pilot, initially, we're looking at a limited set of labs. Are we going to have enough local locations for manufacturers to meet their needs? That's a good question. And you'll see there's lots of question marks on this slide. Also, manufacturers, some of them, have existing relationships. They're not going to want to switch to another lab unless there's a really good reason because it's hard to transition between one lab and another, just like transitioning from a notified body to another or an accreditor.

Will there be enough EMC labs? I'll talk about that in a later slide.

The 1-8, the alarm standard, from what I hear from Alex is that there's maybe about a dozen test labs for that area, and is that enough because are all of them going to come in, one or two, or none?

International labs versus U.S./North American. So that's an accreditor function. Whatever accreditor comes into the program, are they going to be able to deal with the international load, because you get a lot of submissions internationally, not just U.S./North America.

And this was a question I was asked put in specifically when we were talking last week. Can a non-accredited ASCA lab, local lab, key word local, be a subcontractor to an ASCA lab that's certified through the program? And that's going to be an accreditation question at a minimum.

So what are some of the costs of the program? Well, the accreditation of the test labs, they're going to have -- they're spending money right now. Alex is here. They spent money to come here. They're going to spend money to get accredited. How is that going to get passed on to the manufacturer, who's the consumer in this case?

Is there going to be additional time for testing? My hope is not, but I don't know that for a fact. Will there be additional paperwork? Very likely there will be some. FDA made it really clear last week to me they want to keep it as low as possible to make the program as attractive as possible.

So two of the benefits that we talked about -- and some of this has already been brought up, so I'm not going to get into too much -- hopefully improve the time cycle for the premarket review process like the 510(k). So reducing additional information requests or interactive review time, shortening it, and hopefully having much less non-substantial equivalence, but we don't know that for a fact yet.

The other thing, which Scott is involved in to some extent, is the standards side for IMDRF, is looking at and making the test reports transportable to different regulatory agencies through the IMDRF potentially and putting -- making it more international.

So other things to look at. This was one I sort of came up with is if you have -- your product has been tested by a lab and it's gone through FDA, can you -- what happens when you change the product in the future? How much retesting is needed? How are you determining what retesting is needed? Does the FDA and the test labs have the same perspective how to look at new testing? I don't know that that's identical. I don't know if there's major differences, though, either, because I haven't analyzed it. So I thought we should bring that up into the discussion.

Will there be a higher burden of proof for test reports through the ASCA program? And that can be manufacturer and test lab. I think test lab, you're going to have some additional paperwork, and you're also going to have the accreditation stuff, so there's going to be some additional burden of proof. On the manufacturer's side, I don't know.

Consistency in testing, test reports, etc. This has been an issue forever with test labs, even within a test lab. So I don't know if that's going to be much different with the ASCA program or not. Something to consider.

So a question that's more faced to the FDA: Will the program allow manufacturers to use their own test labs? And will the accreditation be the same process, or will it be different from a test lab that's already accredited? Or manufacturers may be accredited, too, under various programs.

So now let's skip over to essential performance. So premarket submissions, FDA in the last couple years especially I've seen this. I've helped multiple clients on this issue. They get a test report. FDA says it says no essential performance. Test lab said no essential performance. And FDA goes, well, give me your analysis showing there's no essential

performance.

So I've done a couple projects in the last couple of years, and both clients said, guess what, there's essential performance. So FDA was right to ask the question obviously. There's a bunch of guidances. There's four here listed. There may be others that I'm not aware of, but these are the primary ones that I've been familiar with for a while that identify essential performance in the guidance document, including EMC.

So the series of standards is a pretty complex series of interactions. There's the basic standard, 60601-1. There's the collaterals, which are the -1-xx's. So 1-11 is home use; 1-12 is emergency medical services. And then we have a whole slew of I don't know, about 50-ish particular standards, the -2s.

So the general standard says, you know, in title of all these standards other than the -4s, which are guidance documents, they all say basic safety and essential performance. So you would think essential performance is part of each of those standards in one way or another. The general standard has essential performance defined in 3.27, and in 4.3, which is the clause I reference up top, that's the process we're analyzing except -- essential performance.

But the standard doesn't say you have to have essential performance. It says it's up to the manufacturer to go through the risk analysis or risk management to come out with is there essential performance or not for the product, could be one or multiple essential performance. There are a couple tests in 601-1 that ask to confirm or verify compliance to essential performance, if you've identified it. 1-11 and -12 are the ones I'm referencing for collaterals that have essential performance, and I think there's one or two others that may.

Most particular standards have essential performance defined in clause 201.4.3 or 201.4.3.xx, depending on how they wrote the standard. There are a few particular standards, and I'm a convener of one of them, that does not have essential performance

defined.

So one issue is that how is FDA going to expect those standards that don't have essential performance defined -- is that going to be sufficient or not? My suspicion in some cases is it's not. I don't know about each one.

So one thing I think on the standards side, developer's side, that we're low proficient on is that we're not consistent how we write the whole series of standards for essential performance. And on one ring, if maybe we need to write a guidance document to help the standards developers and also manufacturers understand about essential performance. And there's a lot of ways to look at it. There's not one right answer.

So there is a wide variance for essential performance analysis by the manufacturers and also sometimes from the test labs. Verification of the essential performance is critical, and every manufacturer is going to come up with a different solution how to verify because their product may be different from another one, even if it's similar. And how is it documented in a test report, because that's what FDA is looking at, at this point.

So how are we going to come to a common understanding for essential performance? One concern I have is on EMC labs, some EMC labs know medical really well, and there are others that don't know the 60601-1-2 standard. They know the standard underneath it or set of series, the 61000 series. And so they don't know, especially 4th Edition of 1-2, that the manufacturer needs to do a risk management, provide the essential performance, and put together the EMC test plan, which is also in the FDA guidance about EMC.

Safety in EMC labs: They have variance within them, in between labs, which I've mentioned already.

So we need to come together as a community, and I'm looking at more constituents than most because I am a consultant for some reason, to preen and collect information,

come together and agree on how we're going to look at this. And it may be different how we look at it for different standards within the -- too.

So TRFs, for test report forms, which have been mentioned once or twice before: From what I've seen as a consultant for 20 years now, the majority of safety labs use the CB scheme test report form, or TRF, based on the 601 series. And there's, I don't know, maybe 50 of them, give or take. Not every single standard in the series has a TRF. Most EMC test labs don't, but from what I understand, there's an exclusion in the CB scheme that you don't have to use the TRF, and the EMC TRF, from what I've heard from other associates, is not the best TRF in the world.

So Brian mentioned not applicables and having trouble with them. So the CB scheme test reports are not meant for regulators currently, at least not that I know about. What it's meant for is bringing the test report over to another test lab to issue a safety warning, which the medical industry typically doesn't use in that sense; they use it more for regulatory submissions. So if the CB lab is writing it for another CB lab, they're not always going to explain every single NA. So one thing we talked about is maybe having summary reports that are above the document instead of changing the CB report so that we can address some of the regulator concerns through a summary report, maybe 1, 2, or 3 pages long.

And this is just a reminder of what we talked about. And if you need to get ahold of me, I have lots of different ways.

Thank you.

(Applause.)

MR. GROB: Hello, again. Alex Grob. I got one answer. All right. So there's one person that's awake out there after lunch. It's always the best time to give a presentation.

So this is me. I think this is only important because whenever someone is standing in

front of you telling you something, you should understand their background, and you can decide whether or not you want to listen to them but also what biases they may have in the information that they're sharing to you.

So I'm from a testing laboratory, so I have some bias in my presentation. And what I'd like to talk about is some of the difficulties or things that cause tension, discussion, debates, etc., between manufacturers and testing laboratories. My side of this discussion is generally as the testing laboratory. My career has been split into three sections. Two of those three sections were with testing labs, one with a manufacturer. So 33% as a manufacturer, 66% as a testing lab.

But if I could boil down these items, the five what I'll call key items, really, for the most part, it comes down to communication. So when we're standing here at the moment ready to move forward and do something new, I think it's important to understand the things that we're doing now that maybe creates some issues and figure out how to solve those issues as we move forward into this new accreditation scheme that we're talking about.

So the biggest thing that we have to make sure we get right is figuring out the scope. When a manufacturer and a testing lab have come together and decided that a report is going to be issued, we need to understand what it is that we're going to issue as a report. And there's a couple facets with that.

So this is right from 17025. In fact, under 17025, as a testing laboratory, I'm required to know what I'm doing and be assured that I have the capability to do it before I accept your money or purchase order to complete that order. So I can't go and provide a quotation for services for something that I can't offer. That's a violation of my 17025 accreditation.

So the first question is what standards am I applying? So we're talking about 601.

The laboratory that I work for, this is the space that we operate in. We need to know -- usually we know the general standard is going to be applied. Are we applying any collateral standards or particular standards?

Just as a quick bit of information, if you're not aware, so collateral standards generally add additional requirements to the general standard, so the general standard being IEC 60601-1. Collateral standards for the most part -- there's always exceptions to every rule in the standards world, so keep that in mind -- for the most part, they added new requirements that don't exist in the general standard.

Particular standards are intended to modify the requirements either by adding, subtracting, or changing the requirements of the general standard for particular or specific devices or types of devices.

Are we going to be applying any of the support standards that are called out in the 601 series? Some examples of that are ISO 14971, which we sort of know we always have to apply; 62304, which is for software development. We may or may not have to apply that. And there's others that are called out specifically in IEC 60601 as things that your device may or may not have to do --

It was already mentioned about national differences. Are we applying national differences? If we are, which ones? How are we going to test that? How are we going to document it?

The other important thing to understand is what accreditation am I using to issue this test report? So as a testing lab, I have a choice of no accreditation at all. So we have the standards that we might look at and say, yeah, we can do that, but they're not covered in the scope of any accreditations that we hold. And perhaps that's okay with a manufacturer because they get what we would refer to as a non-accredited test report.

We have a 17025 accreditation, so our registrar is A2LA, so we can issue you an

A2LA-accredited test report. There are some rules that go along with using that accreditation. So we have to be in agreement that if I'm using that accreditation, these are the rules that are going to apply as I work on a testing document and a testing --

Maybe we're going to issue a CS scheme. So we've talked about the IECEE, the CB scheme report. Are we going for a U.S. NRTL, nationally recognized testing laboratory, which is accredited through OSHA? Or in the future, would this be a report that's under the ASCA accreditation that we would hope to obtain?

All of these things are important because each of those accreditation schemes may change what I can and cannot do as part of that testing activity. One example of that, and this was mentioned earlier today, if you ask for a CB report, I have to include the evaluation of usability against IEC 60601-1-6 and 62366. That's a rule of the CB scheme. I cannot issue a test report without including that evaluation. So if you say I want a CB report but you don't want me to look at your usability, we have a problem that we have to resolve.

Once we've figured out what the standards are -- that's usually the easier part, actually, is figuring out what standards were going to be applied for this evaluation -- then we start talking about cost and time, which are everyone's two favorite things to figure out with the testing laboratory. The more things we include, the more it costs and the longer it takes; the less things we include, possibly the less useful your test report is at the end.

So as a testing lab, again, following any of those accreditations or no accreditations at all, I can give you a test report for whatever it is that you want me to give you a test report for. You can come to me and say test one clause of this one standard and give me a report. I can do that. It may not be very useful to you. These are things, again, that we should all figure out before that were to go to the FDA and someone from the FDA says, well, there's 72 other requirements that weren't applied; why not?

Are there any limitations or exclusions to the work that I can do? The lab that I work

for, we don't do anything with biocompatibility. So we exclude in the 601 series our requirements for biocompatibility. We exclude those because we have no expertise in that area. So we will write a test report that says we didn't look at the biocompatibility. We leave that, then, to some other documentation that the manufacturer would have for the purpose of their regulatory submission of their overall goal that they have with the test report.

Same thing with the clinical data. We don't operate a clinical laboratory. If the standard requires testing of human subjects, which some of the 601 series do, we do not do that testing. It's not something that our lab is set up to do.

So these are things, again, that we need to communicate and make sure that everyone is on the same page so that you know what you're getting from us, we know what we're getting from you, and there's no surprises at the end. Certainly, it doesn't benefit the testing lab if their test report is questioned or rejected by the FDA because that puts everyone in a situation where nobody is happy, and usually those are not pleasant discussions on either side, I would imagine, for the test lab or the manufacturer.

Then, the final piece is figuring out what it is that's going to be provided for testing. And this is important because under 17025 -- this was referenced earlier today -- our test report is essentially a snapshot in time. It's not a certification report. There's no ongoing verification of compliance as part of 17025. It is a document that stands on its own and can only cover the things that were submitted for the testing. That doesn't mean everything has to be tested, but we certainly need to do some sort of analysis and have a discussion about what accessories are we testing.

Are there multiple models that are being covered? Are there multiple features that maybe are used or options that customers can purchase? Are there supplies and accessories to the device that need to be covered? Some of those may have specific tests

that are only applicable if the device has a certain configuration.

Things that mount on the wall, for example, if we don't know they mount on the wall, we certainly don't test the wall mount, which is a part of the 601 series. If it mounts on an IV pole and we don't know that, we can't test that configuration.

It's generally a good idea to have the configuration that's covered by your test report match the configurations that you're submitting to your regulatory agency -- one-to-one match -- and there aren't any questions.

Then we usually ask questions like is someone going to come up and come to our lab and set this up for us, show us how to use it? Will there be any required testing or support on site during the testing? And we'll talk maybe a little bit about that more when we get to essential performance, which it hopefully doesn't surprise you I'll talk about the essential performance as well.

The next area where we have a lot of discussions and conversations has to do with the documentation review compliance. So we talked a little bit about -- heard 544 and 187 mentioned. It's been a long time since I've -- those standards. Who here knows those? Oh, I'm surprised. That's more people than I would have expected.

So even in 2nd Edition, we were in a scenario where it was easy for a manufacturer to kind of toss a device over the wall to the testing lab and say test it for me, and a little bit of time later, a test report would lob over the wall in the other direction, and everyone was sort of happy about that because we had primarily a standard that was a test, an electrical and mechanical test. We did have requirements for labeling and instructions for use.

But now, in 3rd Edition, we're looking at much more documentation. We look at primarily, for most, we do three things. We look at risk management, we look at usability, and we look at software. And for each of those, there's a requirement for a quality system, so procedures to be in place, as well as documentation for the device or devices that we're

testing, so what we would call the output documentation for a specific device.

We still do look at the instructions for use. Those are not usually a big deal. We talk about labeling. We do see a lot of noncompliances with labeling, but that's not where we spend most of our time. While we do find some issues there at a fairly high rate, which we'll talk about later, most of the time that we spend in evaluation is on the documentation reviews. The risk management review and the software review are probably the two biggest ones.

So those are things that I think most laboratories have put together some information that they share with their customers to help them understand what it is that we're looking for as a testing lab, how to best present that information to us so we can streamline that review process, because we know that does take a significant amount of time.

The way I usually explain it is we've set up some forms, if you will, that we send to our customers to give us a treasure map to the information that we need rather than sending us on a scavenger hunt. So usually we'll say if you want to pay me to go on a scavenger hunt, you can do that, but most people will choose, knowing the option to give you a treasure map, to use that instead of a scavenger hunt.

So when we talk about documentation, one of the key things is essential performance. So this has been mentioned a couple of times already. And I just want to make one thing a little bit clear about what the testing laboratory typically does. And I don't, of course, speak for all laboratories. Our lab is a CB testing laboratory, the CB scheme, and I've participated in the past in a group that was responsible for setting the requirements under the CB scheme and providing training for CB scheme labs on what to do specifically with the risk management process, which includes essential performance.

So the definition, I don't think we've talked about that. It's the performance

necessary to achieve freedom from unacceptable risk. If we go back to 14971 and look at those terms very clearly, the manufacturer is responsible for determining whether or not a risk exists and whether or not a risk is acceptable.

So if a manufacturer comes to a testing laboratory and says I've done my analysis and I've determined I have no essential performance, we don't typically argue about that with them because it's their responsibility under the standards to make that determination. What we do look for is that that decision is consistent throughout everything else that we look at.

So if we're performing tests and we find that the result of a test leads to something which is very clearly an unacceptable risk to the patient, like we see leakage current being exceeded as a result of some of the testings that we do, or if we're looking at a device that's monitoring physiological parameters and there's an accuracy issue, and we know that that device type being inaccurate is unacceptable to the patient because it may cause harm or death to the patient, we'll flag those things and say we found something that happened during the course of our testing where we think this question may need to be reconsidered.

Also, we look at the documentation. So if we see things in the risk management file identified as falling under that definition of essential performance, and we see that there's a failure that could occur, and it leads to a risk that's identified in the risk management file as being unacceptable, now we have a decision and documentation that doesn't back up that decision. So we'll typically flag those things to our customers and say we found some discrepancies in the documentation or the testing that we've done, and we think we need to go back and look at whether or not you have essential performance.

I do think, in my opinion, when we get to Amendment 1 of the 3rd Edition, or what we call Edition 3.1, it's a much more clear process for the manufacturer on what they should be doing to determine essential performance. But we do see a large number of

devices where the assessment indicates there is no essential performance, and our test report will identify that that was the conclusion of the review required in the standard in clause 4.3.

We try not to judge whether or not -- especially when we're looking at risk, the bar is not you have to convince Alex that your risk is acceptable. The bar that we're judging you against is have you done what's required in the standard? The standard requires an assessment; have you done the assessment? Try as much as possible to remove my opinion from that assessment. Certainly, you don't want to have to meet Alex's requirements. You want to meet the requirements that are documented in the standard.

Once we know what essential performance is, what do we do with it? Mostly it's documented. There are, as Leo mentioned, a number of places where we actually verify the essential performance. That could cause us to have some interesting conversations about how we do that. In some cases, it's not even possible for us to verify that it has to be done by the manufacturer, and we typically work those things out once we know what that essential performance is and how it has to be documented.

The other thing that's important is to make sure that the documentation that we're given that we have to review is final form. If we don't have final documents, it can cause delays. There are a number of the standards that require us to see that verification and validation for software have been completed and approved. So if your device isn't that far along, we can't finish our assessment if we're including a software as part of it.

Historically speaking, looking at risk management documentation, usability documentation, it is not something that testing labs have been doing for a long time. Third Edition came out in 2005. It was towards the end of the year, but it really didn't gain traction globally until sometime around 2010, 2011, became a requirement in some jurisdictions in 2012 or later. So we don't have a lot of experience even though the

standard has been around for a while. We have been still using 2nd Edition or still using Edition 3, which doesn't contain some of the same requirements as Edition 3.1. So the testing labs are still, I would say, in a learning process, in some cases, of trying to figure out what the requirements are.

The next thing is how do we handle when a device changes during testing? And, again, this is really a communication issue. If we know up front that something is going to be not final in the construction that's sent to us, maybe we can skip some tests and perform them later. Maybe the enclosure is not final plastic, and so we won't do all of our mechanical testing on the enclosure. If we know those things up front, that's fantastic. We can plan that into the testing cycle.

When should we begin testing? I think there's an understanding that the earlier we begin testing, the faster it can be done or the sooner it can be done, and the sooner the device can get on the market. But we do have to make sure we understand -- again, this goes back to really that question of scope -- what tests can we perform on the things that are being sent to us? If there's things we can't do now because certain parts of the design are still in flux, those should be communicated so we can ensure that we do testing on the appropriate construction that is going to represent what the device is going to be when it's placed on the market.

What happens if it changes during the testing process? We may have to repeat testing, which can add cost and time. Certainly, that doesn't lead to a lot of happy faces when that happens.

How do we handle -- so software is kind of the same thing. Software is actually probably the thing right now that causes us the most issue with being fluid while we're in the process of testing. If the software is constantly changing, there are certain tests we may not be able to do, we might have to repeat, and it causes a little bit of headache on

both sides.

We generally assume if something is causing a delay for us and we're not happy about that as a testing lab, the manufacturer is probably two or three times less happy about it than we are, because really it's your schedule on getting that product to market that's important, not necessarily the testing lab's schedule, which is usually a piece. We know we're at the end, generally, of that process. So the delays on our side are not good.

How do we handle generic options or features? Again, a test report can only cover what's submitted for testing, so we can only cover the things that we can look at. It doesn't mean we have to test them. If we have an analysis that says this construction or this set of patient cables or this pulse oximeter probe, these are the ones that represent the worst case, and we have a justification for that, we can make a test -- and we'd have to test that. Adding things in the middle is not --

So dealing with noncompliances, I mean, this is really, again, just communication. Most devices that we test have some noncompliance that crops up during the process. If it's documentation, a lot of people might think that's easier, but when we were looking at quality system documentation, we understand that most of the time the traditional person at the manufacturer that interfaces with the testing laboratories is probably not responsible for the risk management process. And so if we identify something that needs to be modified in the risk management process, it's a whole different cycle of people, time, and effort that has to take place.

The key thing is to make sure you know what the expectation is from your testing lab and how they're going to handle noncompliance. Are they going to tell you right away? Are they going to wait a week? It's very important to know you give that information as soon as possible. Obviously, we have impacts to cost and time. Those are the biggest things that we usually deal with.

And then the last thing I want to say about the tension that's caused is labeling. Nine out of ten projects that we work on have some noncompliance associated with labeling. And labeling, I mean instructions for use or physical labels that are on the product. In many cases, it's things that were missed or things that maybe the instructions for use don't match the labels that are on the device, but it's in nearly everything that we do; we see noncompliances associated with labels. And that's certainly something where we could do a better job as an industry to avoid some of those things.

One of the key places we see that, and this is a little bit out of our laboratory scope, for the most part, is our labeling requirements in -1-2 for EMC. And more than 90% of the time, we actually see those labels not being included on the device and in some cases not being included in the evaluation by the EMC testing lab. So if they're not evaluating the content of the label as part of that evaluation that the EMC lab is doing, again, that's something that should be dealt with at the early phase, in the contract review period, to make sure you know you're getting a full assessment against -1-2 or a partial assessment.

It's also important to understand the risk management process does allow you to do some interesting things with labels, but I think I'm running out of time, so I'll not go into any more detail now.

And another key point is there is a difference -- the standard has two types of symbols -- I'll say it that way -- symbols and safety signs. They're different. They have different meanings and different purposes. One is in black and white, and one is in color, and it's important to understand when one is required versus the other. That's one of the common issues that we see is using a symbol or a safety sign would be required.

So last thing that I have to say before I step away is how can ASCA help? If we're going to move forward, we certainly should look at what we can improve on. I think the most important thing is the ASCA program has the set of requirements that we know have

to be applied in order to get a ASCA-accredited test report so that every testing lab is doing the same set of tests -- not tests but same set of standards applied as a minimum requirement.

We can also understand there's questions about "not applicables." Maybe there needs to be some requirements in the ASCA program on how those are documented.

Help us define essential performance requirements. The FDA has a lot of experience, as Brian mentioned, looking at essential performance from 10 years, I think, at least, prior to the 3rd Edition, including that as a requirement. So that information could certainly be shared in some way between the FDA and the testing labs and the manufacturers to help offset some of these issues where a manufacturer says I have no essential performance, the test lab says your analysis looks good, we didn't find anything that disputes that in the documentation, and it goes to the FDA, and the FDA says, well, you know, for 20 years these types of devices have been expected to be X, Y, and Z. So I think that's good.

And then the collection of knowledge -- I think Scott mentioned this earlier -- having -- once those connections have been made between the different stakeholders, certainly there can be training opportunities to help everyone improve on all sides so that we can -- again, the goal, I think, is to shorten this whole process of the testing as part of the submission and the regulatory filings.

And that's it. If you need to contact us, that's how you get to us.

(Applause.)

MS. LEAMAN: Okay. So I'm the last speaker for this session, and I have a little time they've left me, so I'm going to try to keep my remarks brief. I'm Dana Leaman. I'm with National Voluntary Laboratory Accreditation Program, NVLAP. And so I'm coming from the perspective of an accreditation body.

I've just got a couple slides. The first thing that from all of the talks today that we've talked about is that we want to make sure we're on the same page as far as the terminology use. So just to be clear on what an accrediting body does and its operations, an accrediting body is an authorative body. And I'm using definitions from the 17011 standard. And we make statements about the conformity assessment bodies that demonstrate those laboratory activities that Warren referenced in his presentation earlier, prior to lunch. So we make a statement about their competence to do specific laboratory activities. And so we are independent, third-party entities that make these statements.

How do we do that? We do that -- I mentioned 17011. That is the international standard by which we meet. I think it was brought up earlier about in one of the questions, how do you know the accrediting body is competent to do the task that we're doing? And we are recognized to meet a specific standard, so that outlines general requirements for us to perform our activities. And then we develop within our accreditation schemes, you know, based on specific standards, the requirements. And so in this particular case, with ASCA, it would be based on a 17025 scheme.

One of the other questions, and I think some of my other colleagues mentioned in their talks, is the scope of accreditation. So much of what we need to do within the ASCA program is define what specific items does the accrediting body need to make a statement of confidence. So if the laboratory is performing an activity, what are those activities? And the scope of accreditation is the public document that someone would use to determine if that particular laboratory is competent for that task.

And so we need to be clear on what those specific methods -- we've mentioned 60601, the biocompatibility methods. What needs to be specifically called out on this public document that's issued once an accrediting body is ready to make that statement of attestation about that laboratory and those laboratory activities?

And so this is the slide that I want to spend the most time on because I think this is the one that's the most critical. And it raises two important questions that an accrediting body needs to understand to operate in this space. So you need to define what the set of requirements for actually assessing that laboratory to be competent in this space, what are those, what are those requirements? So we have 17025. That establishes general requirements for the accreditation of that testing laboratory.

But if there are requirements in 17025 that are too general, what are the specific requirements? Are those in the method? Is that in 60601? If it's not there, where is it? Or do they need to be developed by the scheme owner? Are those requirements that need to be developed in collaboration with the stakeholders in the program?

One that specifically comes to mind, Warren mentioned in his talk earlier today, that in statements of conformity, the 17025 standard allows for these decision rules. So when you make a pass/fail judgment about a particular measurement, what's the criteria for making that pass or fail decision? Well, that decision rule, is it acceptable to use a probability of a false accept of 2% in this space when you're making that decision? Is 2% acceptable? It might not be. You may need to use an uncertainty calculation that is at a confidence level of 99% instead of a 95%, which is typically allowed in the 17025 space.

So there are specific requirements where we may need to develop additional items outside of 17025 and, you know, the requirements that are in -- so we need to clearly understand what becomes the set of requirements. And I think the speaker before me talked a lot about these sets of requirements, because the test lab will have to apply these requirements in their operations, and they will actually be assessed how well they do that. And so we need to clearly define what those requirements are so that, then, the test lab can meet those requirements and we can assess them and there can be confidence in the work that they're performing.

The other thing that would have to be developed in this space, in looking at this scheme, would be we need to have the appropriate expertise to actually assess the test lab report. So the accrediting body is going to establish a program where we actually frequently visit the test lab, and we will need to take in experts into that organization so that we can have an understanding that they are competent to perform those methods. And so we would have to have that technical expertise.

Well, what defines technical expertise? Is it that the person worked in that space for a number of years? Do they have a specific degree? So we need to develop that criteria. So those are two key aspects in the development of the ASCA pilot program that I think an accredited body would need to answer before we could ever think to launch from, you know, the accreditation program in these spaces.

So I think that those two questions would be the two things that I would leave you with, and that way we can have time for some questions from the audience.

(Applause.)

MR. TAYLOR: Great. So it's 2:25. You all know the -- musician's credo: We may start late, but we always end on time. So we are on time. We do have a couple minutes for a couple of questions, but let's just talk about what comes next.

We're finished with the talking heads portion of the program, so we're going to move to our smaller breakouts now. Those folks who are dialed in online, as Scott mentioned earlier, you will need to disconnect and dial into the WebEx for the -1-2 or the -1-8 breakouts. Those of you who are sticking with the main standard will remain in this room. And I think we probably want to have you circle up in the front of the room, so then we can talk to each other and gather around the microphone so the folks who are online can hear what's being said in the room.

Let's see. What other logistics do we have?

So I think you all agree with me that the panelists have kind of laid out some of the challenges that we face from a bunch of different perspectives. Dana just very nicely tied up what our job is in establishing this accreditation scheme, and I think we barely scratched the surface. But we're done talking at you now, and it's time for everyone in the room to join into the conversation.

And what do you want to add to that, Scott, and then maybe we do have time for a question or two?

CAPT COLBURN: Yeah, we can go with the questions.

MR. TAYLOR: Okay. So any questions? I mean --

CAPT COLBURN: One logistical. For the people that have dialed into the Adobe Connect, I apologize. We're experiencing some audio problems. But we're asking for everyone to please mute your phones, your speakerphones or whatever device you're using. I think that has created some of the problems. We do not have the control on this side for that, like any web -- creates havoc. So please try to make sure you've muted your phones.

Yeah, we can go ahead and continue to have some questions. We can always go late and end early.

UNIDENTIFIED SPEAKER: I'm a reviewer -- I have a question about the identification on the verification of the essential performance. I think sometimes it's really clinical judgment, so I wonder if the testing lab, we will be able to do that or not? Normally, it's kind of the -- clinical -- there's like a bench testing to give some idea of whether --

MR. TAYLOR: So it's actually clearer in the standard that the essential performance is defined by the manufacturer, not by the test house, and I think that's a great question, and it's often a challenge. You know, there's a two-part challenge when it comes to essential performance. The first is determining what the essential performance is and

coming to an agreement as to what aspects of the clinical performance of the device are necessary to not have a loss of safety. And the second is how does the test house, in conjunction with the manufacturer, measure the essential performance while the testing is being conducted. And that, I believe, will probably have to be -- involve a discussion between those two parties.

Alex, do you have -- anyone else want to comment?

MR. GROB: Yeah. I think the only other thing I would mention is that, in some cases, the testing lab can do it because the essential performance may be something that we can easily test because it's called on in a particular standard. For example, the production of an ECG waveform -- heart rates or rejection of pacemaker pulses. Those are all easy things for a testing lab to do. But if it involves some sort of clinical information or a very complex test procedure, sometimes we have to work with the manufacturer to do that. It may not be capable -- or possible to do that in our laboratory.

And when we run into those situations, we have to figure out how we're going to do that, where it's going to be done, and in some cases, when, because there may be 10 tests that require the verification of essential performance. Are we going to do that 10 times? Are we going to run 10 tests and do it once -- or twice -- once before, once after? But it's a complex discussion, where there is essential performance if the testing lab can't verify --

MR. EISNER: And I have one additional thing is having a discussion with FDA from the manufacturer's side during a PRISA (ph.) meeting would be a great way to deal with that question and maybe get the lab involved at the same time, which would be unusual probably, I suspect, but may be a good collaboration to -- in a sense.

MR. TAYLOR: Okay. According to Verizon, it's 2:30 now. Do you have something short, since you've been standing?

MR. MUSE: Yeah, I do. Thank you. Roger Muse (ph.) -- we talked a little bit about

the accreditation bodies and competence, comments earlier about inequivalencies. And to that end, you know, we've been working with scheme owners for a very long time, with various -- from toy safety to the DoD ELAP to you name it. There's a bunch of scheme owners that we worked with. And the programs, for the most part, have gone -- have been wildly successful. We're able to infuse the technical specificity for that program, for that industry, and accomplish what they want to accomplish through that.

The one issue we ran into the inequivalencies of -- on assigning number of days to a specific scope. So I know that we're probably really far away from that piece of it, really far away from getting to that piece of it, but with specified, the DoD ELAP program was one example where you have one AB saying, you know, they're still qualified, they're still recognized, and they still do a great job, but they look at a scope of activities plus the scheme-specific requirements for that lab, and they look at it, and they say this is 5 days or this is 6 days. The other accrediting body looks at it and says this is 2 days.

And it's going to be very hard for the FDA to assign days to each lab to -- scope. But maybe there's some room later while you're going through this program to have some considerations as you're reviewing annually, or what have you, the accrediting bodies to look at that aspect of it. I think that'll help with the equivalency of what you're trying to do.

MR. TAYLOR: Okay. Thank you very much. I just saw a couple of nodding heads up here. It's past time. I guess we will reconvene in our smaller groups at 45 minutes past the hour. And thanks, everyone, for being here.

(Applause.)

(Off the record at 2:32 p.m.)

(On the record at 2:48 p.m.)

CAPT COLBURN: So, all right, I'm going to go ahead and hand this over to Brian and Al. You can see up on the board we're kind of working on some principles here, our goals

for the program, and I'm not going to read those for you because you can either see them or read them yourself.

But, please, if you have a question in your head there, bring it up. There's more than one mike. We'll throw one at you. But please do ask questions. You know, I had a lot of nice sidebar conversations, a lot of people asking, oh, what about this or what if that? We need to hear that in a session like this so that way it gets, you know, dictated and we can, you know, take all these things into consideration.

Our goal from this in developing a scheme is not to create a scheme that no one likes when we publish it. This is our pre-draft kind of approach to developing a guidance; getting the input before asking for your input is really the strategy, and that helps make things work a lot better from an approach, rather than us write something and show it to you and you go, uh-uh, I got to hammer on this one.

So let's work together in developing this, and our esteemed colleagues from OSEL, Brian and Al, will help lead this facilitation, and we have a couple other experts in the room as well, so here you go, sir.

MR. FITZGERALD: Okay, Al, over to you.

MR. TAYLOR: Okay. So you can see that we're two professional facilitators here.

So I do want to call your attention -- Scott said he wasn't going to read this slide to you, but this is not the goals for the ASCA program. These are our goals for this afternoon, okay?

And we want to find the value proposition for every stakeholder. And there's been a lot of allusions to that, starting with Dr. Shuren. And the first thing he said this morning was he recited the CDRH vision, patients having access to high-quality, safe, and effective medical devices of importance, first in the world. And so that's how does -- so the challenge is what are the value propositions for our stakeholders? And the second

challenge is how can we use the ASCA program to add value? How can we design the program?

And Dana's last slide right before the break was here's what the scheme has to accomplish. Maybe we should put that up on the screen again because, you know, that's what we're trying to look at here. What is the value proposition for different parties, and how can we build a scheme that advances the value to all of the stakeholders?

So we've got a list of questions that we prepared in advance, but we decided not to have more PowerPoint, so we're not going to display the questions. But I just at this point want to throw it out to the group, then: Who are the stakeholders? And we don't have to write it down. That's one of the beauties of this: Because this session is being recorded and transcribed, we can just spit it out, and it will all end up in the record.

And I guess the other ground rule that we probably should talk about is we're in some sense kind of brainstorming today, so there are no bad ideas. We're not going to be judgmental. On the other hand, if we see somebody say something and every head in the room is doing this, then one of us facilitators may make a note of that out loud so it gets onto the record that a lot of people thought that that was a good idea.

So, again, we're not going to disparage any ideas. We're not really arguing. We're trying to get ideas on the table.

So who are the stakeholders? And let's pass the microphone around and try and do this as informally as possible and get as many people speaking as having something to say.

MR. FITZGERALD: I'll say one thing before we hand it to the audience. Leo, in his presentation, identified consultants as a possible other constituency. And I think that we should take that seriously. Too often we think in terms merely of conformity assessment and impartiality, etc. There's actually a role for consultants in nearly every business. And I put it out there that maybe there is the possibility of a formal stakeholder being defined as

a consultant.

MR. RAMALEY: Thank you. This is Grant Ramaley representing the Dental Trade Alliance. I think one of the things that comes to mind as stakeholders is 87% of our members are small manufacturers. We make devices without essential performance. The 80601-2-60 actually says dental equipment does not have essential performance.

This definition that we've been reading that you've written down so kindly for us in your handout, as you can see, is somewhat cloudy. And I think that without really nailing down what that means and how it's going to be assessed, that could be really important because the people who wrote the IEC standards meant for that to be a threshold for which additional risk mitigation activities are going to be taking place. And that includes application of a more robust software evaluation to 62304, potentially more robust evaluation of the usability standard 62366, which somebody had mentioned earlier.

All of those things, once you reach that level, that threshold, is important but I think that, without really having a better definition of what essential performance is, could be a real hardship for smaller manufacturers and lower risk manufacturers, device manufacturers.

MR. TAYLOR: Thank you.

Okay. So there are two microphones, and rather than having one go back and forth, if you have the -- if you want to be the next person to speak, wave at the person. Brian and I will be running around with these microphones, so if Grant is using my -- wave at Brian. And who's going to be next?

MS. EMRICK: Good afternoon. My name is Robin Emrick (ph.), and I am a consultant, so Leo, thank you. I was excited to hear you speak. And my current client is in med device, and actually, all my background is in pharma, so I've learned a lot being with them.

And as far as the role with this, I find that my current client at times, it seems a lot more of a checkbox exercise for them as they're trying to decide what aspects their device or modification to their current device is going to need to comply with, and I think that anything that gives a little more structure around that and perhaps maybe clarity to kind of make those decisions more uniform as far as what their, you know, essential criteria are going to be and which tests are really the ones to look at it, I think that will help them and help me help them.

MR. GROB: Hello, this is Alex. Should I stand up? No? Okay. I'm on? Okay.

I have a concern, and it deals with the stakeholder -- I guess the testing lab and their relationship with the accrediting body.

So I think we invited staff from the FDA to come to our lab last year. And we had an open conversation where we shared one of our concerns in looking at what we think the FDA's expectation is for the testing lab under ASCA is that we can be accredited in a way that is robust enough that you trust us to do the testing without maybe at some point in the future having to verify our competency because the accrediting body has done that for you.

The concern that we have is our main 17025 accreditation is done by A2LA, and we don't view that in any way as a technical accreditation. So we have been audited by folks from the EMC arena, from power conditioning background, from the automotive industry. We have never been audited by someone with any experience, knowledge, technical capabilities whatsoever in the medical space.

So to some extent, we feel as though the accreditation, of course, has its validity for different things, but we don't treat that as a method for us to prove to ourselves or to anyone else that we know how to run a leakage current test for 601, because honestly if the assessor said I want to see that and we demonstrated it for him, he would have no idea whether we were doing it correctly or not.

And I don't know how the ASCA program can bridge that gap or if the FDA has put in any thought about what additional requirements might be for the accrediting body to ensure that they have the technical expertise to conduct the audits in a way that would give you that answer of you know the testing lab is running the test correctly, because right now, at least the registrar that we use, we don't feel that that's a service they're giving us because they have no idea what tests we're supposed to be running and how we're supposed to run them.

MR. FITZGERALD: This has been something that we've considered in the core group, and it is something that goes frankly to the way that we're organized as well inside the Center for Devices.

We have sort of, obviously, a management political structure the way that any organization does, but we're also organized into subject matter cadres as well. And if this is going to flower and take root, we strongly feel that our subject matter experts should not just be reviewing reports, not even reviewing reports. They should be out there getting the standards where they need to be with regard to what our stakeholder viewpoint is, helping the accreditors to identify competence, staffing the feedback loops that we want to set up between our accredited test labs and ourselves, and participating in a much, much higher level than we currently are because, if you like, we've locked ourselves into this one vector of communication that is with the sponsor alone. And what that has resulted in is an inability to consider all of the other stakeholder needs that we would be able under ordinary circumstances to be able to contribute to.

So we are aware of that, that issue. We've heard it from a number of labs, as a matter of fact. And we've even gone as far as to consider whether participating or requesting to participate as a scheme owner, for example, as a technical expert on an accreditation audit, would be a conflict of interest. And we've been told openly that it's

not.

So this is something that is definitely in the cards. Whether we can sustain it, I don't know, because it's probably going to come in batches. In other words, there's going to be large areas where people are applying, and we're going to have to subtract a large number of resources. So that's logistics. We can work on that with the accreditors and with the test labs in question.

But thank you for that question. It's a key question that we do need to address in our scheme design.

MS. STERLING: Thanks. Joan Sterling with Intertek.

And to follow up on that -- I mean, and there are accreditation bodies in the room that can speak to this, but when we receive an accreditation, there's two layers there, right? One is basically your system, and the second is your scope. If you're doing medical and no -- if you're going for a medical scope and no medical auditor is coming, then there's a problem, right?

So when we receive a scope, the auditor has to be qualified for that particular scope. That's the second piece of it. And so that's something that the FDA certainly should be investigating for each accreditation body that they choose to work with to make sure that they have the proper experts to do the scope that you need. So I'm surprised that you get a scope without an expert there.

And in the bigger picture, you know, what we're talking about today is conformity assessment at large, and that's not only testing, you know. Consulting is a piece of it. Design review is a piece of it. There's all these different layers involved. And however you choose to design your program needs to have some of those built in there, because from what we heard earlier in the presentations, you know, if you're getting reports in that aren't addressing things that should have easily been picked up in a design review phase before

you ended up having to spend FDA time and energy looking at a project that wasn't ready, there's a missing piece in there.

UNIDENTIFIED SPEAKER: So I was going to actually add onto that. In some of the other schemes that exist around the world, there is the opportunity to do peer assessment, and that means that the scheme owner has set up the rules and the requirements, and they have trained, for lack of a better word, individuals that provide peer assessment. And those individuals may have the technical understanding of how tests are run and such, and they go out and they help administer along with the accreditor the technical aspects that need to be taken into consideration.

So you have quality aspects, you have scheme aspects, and you may have technical aspects about the standard that perhaps -- though FDA is very knowledgeable in some areas, I don't know how many of your staff have actually done testing in a laboratory and understand how to run the tests and are the tests being performed correctly. And if you are relying on the data that is coming out of those tests being done correctly, do you need to consider or is that something that could be considered as you put the program together going forward, i.e., technical peers going out and assisting with those accreditations?

MS. LEAMAN: So Dana Leaman with NVLAP. So, of course, I'm from an accrediting body, so I'm surprised to hear these because from my perspective in my body, 17011 requires that we have competence of personnel. And that would mean that our subject matter experts -- and I alluded to that in one of -- my last slide. The second question is what technical expertise do we need to define? So is that a particular level of work in a particular field for a number of years to be determined as an expert? I know in many of the programs that we have in NVLAP, we have a 10-year requirement of a person to have worked in that field before they're allowed to even conduct an assessment.

Brian mentioned that it's been posed that maybe some of the FDA personnel would

be used as technical experts, and that's certainly allowed, and that's something that NVLAP does in many of its programs, is we use experts from the actual scheme to be either observers of the assessments that we do of the test labs or even participating as an expert in the actual assessment of the test lab and feeding into our process.

So I'm surprised to hear that, but again, I think as we move forward with this scheme, so that we alleviate those concerns, that we look to 17011 and that specific requirement, and then as a group, you listen to the stakeholders and understand, okay, what expertise do we need to define within the program so that when you have an assessment of that test lab, you have confidence that the right expert was used to assess them, you can have confidence in the results that are coming out of that test lab, because without that value in the program, I don't know that you will address the concerns that you have today.

Thank you.

MR. FITZGERALD: Well, there's another transitive, if you like, confidence element to put on the table here. That is, if we can't be sure that there is expertise in the test labs, then we need some other form of quality assurance before it gets to the manufacturer, and that goes to whether we need to consider a certification body type or some crypto-certification body in between.

We would prefer that it is clear and evident whether a manufacturer has complied, has met the requirements, has identified everything that needs to be identified, and that their "not applicables" are actually not applicable and why. If that's going to require something other than expertise, then we would need that as well.

So it's kind of a transitive confidence in the test lab, but it could be considered on the table, at least at this point.

MR. TAYLOR: So these microphones are directional. So if you talk into the side of

the microphone, the level goes way down. So for the folks on the phone, who we've had over 200 complaints so far this morning that they couldn't hear what's going on, you have two choices. Either point the thing at your tonsils or get very intimate the way the rock stars do, okay? That's for the benefit of the folks who are listening in on the phone.

MR. MARGIS: Hi, Steve Margis from UL.

Just a few comments along this thread of discussion. Looking at the materials up there, based on the discussions this morning, based on the presentation from Warren and others, a few things I'd like to clarify. In the questions, we have reference to an ASCA scheme and an accreditation scheme.

I guess the first thing I'd like to provide as input is, at the end of the day, this is an ASCA scheme. This is an FDA scheme, and as such, the FDA should be setting those boundaries. Of course, we're all here as stakeholders to contribute to that. We welcome that opportunity. But at the end of the day, this is an FDA decision and, as such, an FDA scheme.

So starting from that position, I would then go forward and say based on the discussion that just occurred, in the current drafted materials, there's a flowchart, and the flowchart shows testing coming into the FDA. But at the same time, the language that's in the materials say that the FDA's objective is to try to reduce the amount of potentially redundant review or to lessen the burdens of review.

I would go back to a comment I made this morning and say that we're hyper-focused on this term "testing" and we're hyper-focused on this document 17025. I would put on the table or suggest for consideration that if we take some of those words out and we put the word "conformity assessment" and "conformity assessment bodies," we can open up a lot of new opportunities for innovation with this program.

As an example, if I provide test data for a particular test -- here is the test

temperature, here is the result; here's a leakage current, here's a result; that becomes part of a package. I give it to FDA. FDA must do a full review. FDA has to look at what is the context of all this data and why did we do it in the first place.

If we take that one step further and we couple it with a quality system or a design review or a consultation of some sort, as we move through the different opportunities of conformity assessment, to me, that is where some of the values come from and where the FDA can have added confidence that the materials you're receiving not only were data but they were data in context, and that context resulted in a review and that review resulted in a decision of some sort.

I think as you consider that kind of spectrum of opportunities, industry could have different paths to you, you know. If you have an industry group who wants to follow the path of doing the more traditional here's my dossier and here's my approach, they may have to work with the reviewer and have that all checked out. If they go through a process where the organizations that you're working with have been qualified and determined to be competent to do some amount of work, as they go up through that spectrum, that could reduce some of those burdens.

So I would suggest just for consideration that if we maybe move slightly away from 17025, slightly away from the word "testing," looking bigger picture to conformity assessment, I think we have more opportunities. And, you know, accreditation does have a place in that; peer assessment and other things all become opportunities.

So I guess I'll stop there and maybe join again later in the conversation.

MR. TAYLOR: So I'll certainly agree that testing is just one element of what's required, for example, by 60601. There's also elements of inspection analysis. We want to rely on the expertise of test houses that is not necessarily possessed by FDA, not necessarily possessed by manufacturers, to do the testing, the analysis, make the engineering

judgments that they are so skilled at doing.

Who's here from a standards development organization? What's the value proposition for you? Not to put anyone on the spot.

MS. CHO: I don't really know what the value proposition would be for us. Hi, my name is Hae Cho. I work for AAMI. I'm also serving as the TAG administrator for the IEC 62A and 62D and TC 62, and then I also serve as an officer of the IEC 62A and 62D. So this document, of course, is something that I work on all the time.

As far as value proposition like we're kind of -- because we don't deal with the conformity assessment side at all. We don't deal with the testing side of it. Of course, we work with -- you know, our members are involved in that. So we're kind of here just to listen in and to see what we can add into it. Tomorrow I think someone from our organization will do a little speech a little bit about that.

But like what's a question that you were asking? Was it just -- someone over there?

MR. ALLNUTT: Thank you. Hello, so I'm not going to answer your question directly, but I'm with -- yeah, I'm getting to it. My name is Jason Allnutt, and I'm with IEEE, which is a standard development organization.

And this is a bit of a chicken and an egg question when it comes to SDOs, I think, because like the lady just mentioned, you know, we don't get too far involved with conformity assessment. Of course, the group that I'm involved with does, and the approach that we take at IEEE is through conformity assessment that should lead to further development within the standards, correct? And then you have a life cycle of your standard and hopefully your conformity assessment program that's continual and evolving.

So for an SDO, I think, you know, the reason I'm here is to hear about it and observe. And what they could take away from this is, you know, as standards evolve and develop, hopefully lessons learned and use cases that come out of this conformity assessment

program can get evaluated within the SDO development of the standard.

So, aside from that, standard adoption is another benefit that I see from a program such as this. You guys talked a lot about IEC standards. I'm waiting to see an IEEE standard up there, but anywho, that's all.

DR. STROPE: I'm Elaine Strope from Dynatek, and I just wanted to make a comment about the standards that have been coming down over the last several years. We've served on standards organizations for many years. And the standards seem to be getting less prescriptive. It doesn't tell you exactly how to do a particular test; there's not a recipe that you can follow.

So the implementation of a particular standard is difficult because it's pretty much do the right thing, you know, with all these considerations. But in the end, you don't have any acceptance criteria to say, yes, that passed, no, it didn't. You simply have your results, especially in newer fields. In maybe safety or leakage current, which are not my fields, those are more defined. But the things that we test are not defined, and we don't even know FDA acceptance criteria. I don't think it's a standard thing yet.

So when you're working sort of with a vague standard or a standard that is in development, and it's 5-year cycle, so a lot of things can happen there, it's difficult to know what your acceptance criteria are or whether you are conforming to anything.

MS. ATHENIS: Hello, everyone. I'm Karen Athenis. I'm from A2LA. What I was going to add to it is because we know the 17011 was recently revised and published, and the 17025 as well, it adds a lot more flexibility for both organizations in this accreditation process. And so looking at that and looking at the flexibility and trying to decide what ASCA doesn't want to be flexible, what needs to have hard and fast rules, would be important for this program.

MR. TAYLOR: Okay. Thank you. Anyone else?

(No response.)

MR. TAYLOR: So let me throw out another question, one that Brian has asked already. Are the 601 standards appropriate for ASCA? Why or why not? For the pilot. Certainly, you know, if the pilot is successful, we would envision that 60601 would be incorporated. Is it appropriate to start with 60601? And why or why not?

MR. RAMALEY: Yeah, as a representative of Aseptico -- Aseptico makes dental equipment, active dental equipment -- a lot of times we're looking for a standard to use for regulatory purposes to check off the boxes. Is it electrically safe; so we need a standard for that. So where is our go-to standard? I have something that I'm going to put a battery in. Well, I've got to do 60601 because that's the one that's on the board. So we go there for electrical safety testing.

But Korea decides that we're going to be part of IEC CB scheme, and so now we have to do usability analysis, which is potentially $100,000 more in costs just because I have a battery in this thing. So the attachment of the normative standards, the collateral standards, such as usability software 62304, these things just become add-on costs that are built into the base electrical safety standard and have skyrocketed from what used to be 11- to $13,000 test into something that's like $150,000 just because I have a battery in it.

So I think the question is, is the standard going to continue to remain this way? And can you even evaluate something like use errors at a test lab? Or is a newer version of 60601 coming out that will break it up a little bit more so we can get our product tested just for electrical safety?

MR. FITZGERALD: This is an excellent question, and it goes to, I think, a question -- a larger question for the 21st century, that the day of type testing has passed. Now standards are whole-of-life cycle at some point, where the testing prior to putting it on the market is just one section of the entire life cycle. And Grant's point is that, you know, the level of

complexity, the weight, if you like, of the standard is now militating manufacturers to try to find reductions.

I'm sensitive to that, but I think we have to stick with our idea of alignment. Many manufacturers and many manufacturers' trade groups would prefer to have international alignment rather than the dissolution of such alignment. So I sympathize with your observation, Grant, but I think it's probably a ship which has already sailed. People are moving towards greater and greater complexity, greater requirements, both in the life cycle, vertical, horizontal, and everything else.

And alignment and all that goes with it is the way that the world is moving, including these standards.

MR. GROB: I guess I'd like to answer three questions. The first one is, is 601 suitable? I think it is, but possibly the scope of what it's used for during the pilot program may be reduced. So if you're looking at testing, electrical and mechanical testing, maybe not including things like the quality system reviews, which will make it a little bit easier. So if you put it in the pilot program to accept the electrical and mechanical test data, it's something similar to like what we had under 2nd Edition. And maybe for the ASCA pilot program, that could be all that's necessary. So that's the first question.

The second question deals with does a testing lab conduct the usability assessment, and I think the traditional testing lab for 60601-1 does not. What we do is we verify that the manufacturer has completed the usability assessment, and that may take a number of different forms, from documentation review to a full-on usability study typically done by someone else. There are testing labs that offer that, but the traditional 60601 testing lab, if you look at the -1-6, IEC 60601-1-6, or 62366, we're looking at the results of the usability evaluations that are documented in what's called the usability engineering file. We're not conducting that analysis on our own.

And then I forgot my third question because I didn't write it down.

(Laughter.)

MS. GWEN: What I wanted to respond to, what Grant had to say, it occurred to me that it -- and maybe I'm missing the boat on this, but it sounded like your situation with your device and your little battery and now the pricing is tenfold what it used to be, potentially it sounds like that is like a smorgasbord of testing. But something that rings with me is risk-based testing. Like does 150,000 capture the risk of your system better than the $13,000 version of the testing does? That's something that's not clear to me.

To say that more testing is available but we have to pay for it, I don't know that that makes the product any safer or better, so I just want to see where risk is being represented in price.

MR. TAYLOR: So let me just say that Brian and I have answered stuff, probably all of these questions, but don't be looking at us and talking to us. Pretend that we're not here. Forget you're in an FDA facility and talk to each other and talk about us behind our back, okay?

UNIDENTIFIED SPEAKER: Yeah, I just want to say even from the perspective of a reviewer, I also found this problem of some of devices, maybe they can just downgrade the complexity into just doing a certain test rather than doing all the umbrella of tests. And sometimes the essential performance is rather kind of ambiguous. You really -- I think no should be an answer too, but I don't know whether no is an acceptable answer or not for some of the things. I mean, it's not very clear in the standard. So I think that those questions need to be discussed as well.

MR. EISNER: Leo Eisner, Eisner Safety Consultants. I was up front earlier.

So a couple things: So the 601 series of standards doesn't always align with the voluntary recognized consensus standards of FDA. A great example is 62366-1 is what's in

the system now as of February of this year, where 60601-1-6 calls out the older 62366. That's something I gave you guys training on a month or so ago.

And I forgot my second question.

MR. GROB: Perhaps I can give you time to remember yours. I just remembered mine. The question was on whether 601 is being revised to change. The answer is yes. There's actually approved work for Amendment 2 to 60601 along with work to revise a number of the collaterals and particulars to address the comment that Leo just made.

And there's also approved work for the 4th Edition of 601 that will start roughly immediately after the publication of Amendment 2. But I wouldn't expect that those will make things easier. But if you want to know what is on the list, those things can be downloaded from the IEC website, and what we call the long list, which is things that are being addressed in Edition 4, and the short list, which is things being addressed in Amendment 2. So there is work in process right now to change those standards.

MS. CHO: So I just wanted to mention that the IEC 60601 series will be undergoing a big revision starting within the next couple of years or so, and we are actually looking at the structure of the 60601 series. And hopefully -- and we have actually for the structure aspect of it, we are trying to get some regulator input into it as well. I mean, the standards are developed not for the regulators, of course. It's voluntary standards that, you know, consensus standards that everyone should be utilizing. However, we understand that especially the medical device standard 60601 series are heavily used by regulators.

So we are going to be seeking some input and such going into the new structure. We don't know how it's going to pan out. It might not be the regular, you know, documents that you see with the different parts. It may be something wholly different, or it could stay the same, but I wanted to mention that.

And if anybody had any suggestions or anything, you could always get in touch with

me and let me know because we are thinking about all these issues.

And one of the possible value propositions that we've been struggling with, with our SDO as well is when you're writing the standards, to develop some kind of -- because with the IEC 60601 series, as with all the IEC standards, we do have the IECEE, you know, doing the test report forms, but this is a little bit different, what they're asking for. So keep in mind how the regulators may interpret certain parts of the standard.

So I think we're going to actually internally think about what we can do with our members to, you know, go along with this program if ASCA gets going and to see what part that we can play in this arena. Thank you.

MS. STERLING: Thanks. Some of the concerns I've heard are about the changes in cost of testing based on a number of things. But I think what I've been hearing is about entering international markets as opposed to the requirements that the FDA has for products coming onto the U.S. market. And those are two different things.

And so while many manufacturers do want to enter multiple markets around the world, that drives some of this, even if it is not applicable to what the FDA is working on. So we're dealing with an industry that luckily has a global standard and with incremental editions allows multiple market accesses. But today we're talking about what the FDA is requiring, and so that may be something that the FDA has to consider in how they design this program because it is impacting the bigger picture because I think people are getting confused about what's required for U.S. access versus what's required for global access elsewhere.

CAPT COLBURN: So I just want to speak real quick to that. And, you know, yes, we are a U.S. federal agency, but in 21st Century Cures, it was written into our law that, yeah, we recognize standards, but we have to take into account how manufacturers rely on those standards in other international markets in accordance with how we implement the use of

those standards. So we do -- I'm waiting for that crystal ball. I ordered it on Amazon. It's still not here, but you know, we need to learn how to look left and look right.

And part of, I think, what ASCA can provide if properly applied is to feed what is it that we're thinking of, but also get the input of what others are using and have a platform that can allow for an international approach that meets our needs but also the others.

And that's why I also chair the IMDRF standards working group because I'm trying to get what is it that they're looking at in standards, you know, not only in how they're made, but how do they create their acceptance criteria, how do they want testing done, why do certain countries have to have testing in their country, you know? All those types of things are things that, you know, might be similar in another country too. And so why? And a lot of times it's because it's written down in some formal law somewhere, and it's that simple. And we may find a different approach. This is the building block that we want to start on.

MR. FITZGERALD: I think to some extent I agree with your observation. We're prisoners of the current mindset that testing needs to be done over and over again and that the currency of medical device market placement is a test report form. I mean, that's a paradigm. Paradigms can change.

You know, if we can find a better way of doing that, that's fine, but right now we're right here. And this is the scheme that we're going to try and pen, moving forward for ASCA. I'd like for us, for example, never, ever to see a test report ever again in the history of humanity. It's a dreadful thing for us to have FDA people hyper-qualified in all kinds of scientific disciplines going over the drudgery of reviewing not applicables. This is just a waste of public funds, frankly.

We have to do something better than that moving forward, and if we have to change the paradigm, I'm fine with that. If we have to rely on an intermediate certification step, we can take that into account too. Do we want a full-blown, you know, to recognize a full-

blown certification? I don't know. But in the spirit of breaking with paradigms, I'm willing to listen.

MR. QUINLAN: Hi, this is Barry Quinlan from TUV SUD America. Sort of touching on a little bit what Joan just said, it's not necessarily specific to 601, but do you see the ASCA program going into a similar direction to the MDSAP program, where the regulators get together and come up with some common framework? I'm not sure if you're familiar with the MDSAP, but do you see that? Is that maybe a future goal, to go in a similar direction?

MR. FITZGERALD: Scott can speak to this, wherever he's gone. Is he around anywhere?

Scott can speak to this in authority, but we have discussed this as sort of an outgrowth. But remember that we are in a very, very immature state here at the moment. We're looking to change the paradigm. We're looking to get things smoothed out here domestically.

A couple observations, I would say, is that Japan has done a very, very good job in crisply defining a whole new conformity assessment paradigm. That is something that we've looked at. Very, very involved, a lot of work done up front. It's taken them years to put together a map of device types through device characteristics, through applicable standards, through applicable testing requirements, certification. They've knit together a vast tableau in Japan.

But an MDSAP-type approach would need for us all to have enough commonality for it to be worthwhile sitting down and negotiating away our prerogatives. That can come in the fullness of time, I have no doubt.

And when Scott gets back, I'll ask him to comment a little further because I think he's a little closer to that.

MR. GROB: Just from my experience, my company sells into about 100 countries,

and I just got back from China where they were doing some testing on our product because they're using an older version of 60601 EMC standards. Korea is very specific that we use a CB scheme. But most of the rest of the world will just accept our test report, especially if it's backed by the ILAC MRA. So if I can show that the lab is accredited, say, by NVLAP over here, which is a signatory to the ILAC MRA, I can show that the lab has that certificate, and it's immediate passport into the rest of the world, where those other countries have signed the same MRA.

So that system already exists. I think the particular issues here are that 60601 is an odd standard. It's not a true conformity assessment standard, and the people who are developing it should probably pay attention to how conformity assessment is normally conducted. 17025 is based on making sure that when something is tested accurate, the measures are taken when there's an acceptance criteria that's being assessed.

But when you get into soft requirements, you know, measuring -- looking at the risk management system or checkboxing whether someone has completed a usability analysis, that's -- those are unique problems of 60601 that are probably going to have to get dealt with. And I think the ASCA program has the potential to look at that more closely and determine whether 60601 evaluation to the 3.1 with all these soft requirements is really -- if you can really accredit it just using 17025 because there's so much more going on than just testing the product.

MR. EISNER: Leo Eisner again. So one comment I heard earlier, I think, from the FDA perspective is to get the regulators more involved in the standards development process. And I think that's great because I don't think that exists at least in the 601 world as much as maybe in some other -- some of the particulars have it, I know, but the general standard, I haven't seen that a lot.

And I think your requirements versus what the consensus process has been so far

may be divergent. Having it added in wouldn't hurt. But it's going to be a long lead item because right now, 3.2, the second amendment is in draft. It's probably going to come out in 2012, 2020-ish, ish. Fourth Edition is already on the books, but we haven't started on it. The earliest it's going to come out is 2024. And so, you know, that's fairly long lead items to consider. So the sooner that happens, probably the better.

MR. WYMAN: Chris Wyman, Intertek. A couple of things. I hear us talking about standards, right? I live with standards every day with the top 10 industries, so I have the job of dealing with the medical manufacturers face to face, going back to engineering, working with my certification department, working with VP of government affairs, launching these products globally, right?

So I see that there's like a lot of overlap that we look at when we launch a product and we talk about standards and how we position our clients, right, meaning the client wants to test against 60601 but they want to go to China, right? So China, 2nd Edition. Then you look at the EU, right? But one thing is the standard is harmonized at the end of the day, right?

So you can take that data in those test report forms and submit them. But we're getting, I think, going around in standards and what should apply versus what shouldn't, but have we thought about looking at device categories, meaning simple to moderate to complex? Because when I'm dealing with a medical manufacturer, that's what I want to know. I want to know is this a simple product or is it a multi-monitor with, you know, four Part 2s to it. So maybe taking a different approach to it might help us.

MR. TAYLOR: So at this point, maybe I'll make a comment. People sometimes ask me what the FDA perspective is on this or that, and my response is there are 1,500 of those, and that's just in CDRH.

So take this with a grain of salt, but my colleagues and I make judgments every day

about how good is good enough and how bad could it be and still be acceptable in some cases. And ironically, a lifetime ago, when I was working in product development in the aerospace industry, we faced exactly the same questions. So I think it's the universal question for engineering.

And what we've been talking about here for the last 10 minutes or so is how should essential performance be evaluated? How should acceptance to fuzzy criteria be evaluated? And that's actually one of the questions we had on our list for you all, so thank you for providing those perspectives.

But for us, working with the -- to develop this ASCA program, we at the FDA struggle to have the expertise to look at every product that comes through our door, and we don't get the luxury of picking and choosing which areas that we can focus on and which areas we can ignore. We have to deal with whatever we get. And so we're always looking for ways to get help in making those basic judgments about how good is good enough or how bad can it be and still be acceptable.

And to the extent that we can leverage the expertise and the worldwide system of maintaining the competence of test houses to help us make those judgments or even, dare I say it, to make those judgments for us, that's really what we're looking for here. And the question is how can we structure this program to make that work for everybody. And the discussion you've been having is great.

MR. GROB: I have a comment not along the same lines but kind of -- I was looking at the list up here again. So the first one is value. There has to be some value to the ASCA program for it to be successful. And we've discussed that within the confines of our laboratory, and we think we have a fairly decent understanding of what the value would be for us to participate in this program, to support the program. But ultimately it really doesn't matter if we find value in it if manufacturers don't.

So I would be curious to know if manufacturers that are in the room, if there's any still here, what you feel would be the necessary things to make the program successful, because as a testing laboratory, we understand there will be some form of investment on our side, and it's one of those situations where if our customers see value in that, then we'll do it, but if our customers don't see value in it, then whether we see value or not is irrelevant.

MS. GWEN: Hi, I'm Pamela Gwen, and I also work with Underwriters Laboratories. So one of the questions up here is to identify suitable candidate standards for the scope of the pilot. And we've talked about 60601-1. I'm assuming we're talking about the 3rd Edition plus Amendment 1.

So my question as we go forward with this is that is a standard -- I mean, we talked about alarms, we've talked about EMC, but that is a standard. What is the program thoughts as we develop it for products that have particulars that apply to them but are not covered under the program, yet a manufacturer wants to utilize the Part 1. And how is the program going to deal with that and how are we as a laboratory, if we're in the program, supposed to deal with that, because this -- you know, a small subset of products that really are Part 1 only that don't have other particulars that may apply. And I don't understand and I haven't heard anybody talk about that.

MR. FITZGERALD: So how would you like it to be?

MS. GWEN: If I were queen for a day? God help us.

MR. FITZGERALD: You are queen for a day.

MS. GWEN: So there are, depending on the particular rights, there are requirements that modify the base standard, supplement the base standard, or replace. But there are still oftentimes parts of the base standard that are untouched. So we don't want, in my opinion, you don't want the program to say, oh, I want to participate, I'm going to ignore

that Part 2, but it does shut down quite a bit of opportunity of where data could be generated or conformity could be generated that are still perhaps beneficial.

So I would like to consider some guidelines around when you can use the Part 1 and take data to submit to the FDA and when it's not acceptable because the Part 2 has modified it. So I would like a hybrid program if I were queen for the day.

MR. TAYLOR: Manufacturers?

MR. FITZGERALD: You could be queen for a day too.

Manufacturers, manufacturers? Going once.

MR. RAMALEY: Well, just as a manufacturer, I mean, ultimately -- and he raises a good point, what do I need this for. I mean, GHTF published guidance on use of standards, said they're voluntary. The gold standard, the ultimate gold standard is the essential principles. So how are we going to meet that? Really, the standard that I feel is most important of all is 16142, because that's the one that tells you how to apply what standards to meet those essential performance requirements.

So at the end of the day, I'm going to look at the ASEAN market. I'm going to do the ASEAN MDD. I'm going to look at Europe. I'm going to do the new medical device regulation. I'm going to meet the general safety performance requirements any way I can. And I'm going to use whatever means I can, whatever way I can afford it.

So if ASCA adds value to it, well, I would do it, but I don't really see that it's going to add value on that end of it because it's not an international program. It's an FDA program. And standards are voluntary here. In fact, we've been pushing FDA to hold on to the 2nd Edition because of the cost. And OSHA has for that reason.

At the end of the day, a lot of our customers ask us for a UL mark, and we have to decide whether we're going to 3rd Edition or 2nd Edition. And if we got to get into Canada, we need to -- I'll mark that little C on it next to our UL mark. And, well, I guess we're going

to do 3.1 if we think we're going to sell enough there.

So it is really supply and demand for us. It really is a cost issue. And we really will make decisions that are driven by costs, which means ASCA has to prove itself as something capable of getting someplace we're not able to get to without it.

MR. TAYLOR: Okay. Let me throw out a couple of other questions. So a lot of these questions we came up with come from earlier discussions we've had with various stakeholders and one-on-ones in small groups. But one of the issues that comes up fairly frequently is how to deal with the issue of test labs consulting -- providing consultancy to manufacturers. And we're just interested to see if anyone in the room here has any thoughts on that topic.

MR. WYMAN: So a few of the test labs out there also have consulting services. At Intertek, we call it assurance. So Intertek has an entity, Intertek of North American Services, right, where we are accredited, we have the 17025. We also have another entity, which is Intertek USA, which is just a pure inspection business without any accreditations whatsoever.

So, with that, I believe some of you have heard of the third-party program, the 510(k). We have moved some of those reviewers over into that inspection. So now they're really the true consultants. I think the lady in front of me mentioned concerning consultants for this program. I would actually back that. Some of the top, you know, stakeholders that I work with at Intertek are consultants, right, so -- but again we have to separate the church and state. Our consultants or our assurance members are not in the test labs, and they're not able to consult on those projects. So there is a fine line between certification and consulting.

MS. ATHENIS: And to that, I would just add that already different types of accreditation have been brought up, not just in 17025, but in 17020 inspection, it actually

addresses issues of consulting and how you can separate those two functions within your organization so that you don't have that risk to your impartiality. So those might be sections you could look at and incorporate. If you didn't want to use the 17020, you certainly could use the sections of it that address that.

MR. MARGIS: This is Steve Margis, UL. I think your question, if we dig a little deeper into it, at the end of the day, it's about independence and impartiality. I think when you look at the holistic question of do consultants have a role in medical devices, I think the answer is a definitive yes. What role are they going to be able to play within the confines of a program like ASCA might be an exterior role supporting the manufacturer and being part of that through a consultant role.

But in doing that role, if you have objectives within the system to reduce review due to independence and impartiality and competencies that are associated, then those organizations might have to carve out a different part of their business because they do not have independence and impartiality such that they could fulfill the secondary role within the ASCA program.

So I think at the end of the day, it's a much deeper question. Certainly it plays a role, and the role is going to be dependent on how we carve up the different steps.

MR. TAYLOR: Okay. And let the record show there was a lot of head nodding in the room.

MR. GROB: Only thing I would add to that is I think maybe we have to agree on what consulting is before we can decide whether or not it's acceptable. Certainly, if consulting is being done, it should be separated. I think that's very clear.

But if I'm in the testing lab and I'm running a test, and suddenly earth leakage current as a result of the testing that I'm doing becomes touch current and is accessible to the operator or the patient and exceeds the limit, in my experience I know there's probably

one of two things or maybe two of two things that are causing that. And we can certainly tell the manufacturer you probably need to get another power supply or another EMI filter, unless you want to do something more substantial on your device. I wouldn't consider that to be consulting. I would if I said you should go buy power supply model XYZ manufactured by so-and-so and it will solve your problem. That's consulting.

So I think there needs to be clarity on what is considered consulting versus a testing lab being able to utilize their experience, which to some extent is what a manufacturer pays us for, to be able to, if we identify a problem, at least help them figure out where to go to find the answer to fix it rather than fixing it for them. That would be consulting. But if I helped them figure out what they need to do, I would not consider that to be consulting. That's my personal opinion.

UNIDENTIFIED SPEAKER: I would consider that to be consulting and coming from a certification body perspective.

MR. TAYLOR: Okay. And a lot of people said yup to that too. So it is, I guess, a tricky question.

MR. EISNER: So talking about consulting and test labs, test labs at least in the 601 world that I've seen over the past many year, they'll do early reviews, which I think are fine. They may give feedback, but they're not usually giving very -- they'll give more broad feedback. Or a manufacturer may ask here's my solution for an isolation of the device, will it meet the standard; saying yes or no or giving a little more feedback I think is still fair. But if they say, yeah, replace this with a power supply XYZ, I totally agree with what Alex says.

So there's a fine line. And there was a difference between what Alex said -- and I didn't catch your name --

DEAN: Dean.

MR. EISNER: Dean said. And there's going to be a variation there. There's variance

in everything I've seen. Like I said, with essential performance, there's total variance in what I see from manufacturer X to Y of the same exact product. It's not going to be identical. And so coming to a common essential performance -- I'm switching gears a little bit -- is not going to be an easy challenge. And I'm not sure how we're going to do it yet.

UNIDENTIFIED SPEAKER: I just want to piggyback on your comments because I think, you know, I think there's -- in the process of the presentation, there's a suggestion of developing standardized report format, which is a framework to show kind of critical results. I think that's really important because then you can kind of classify the complexity of the devices and then maybe some of the tests not be necessary. And then also the critical results or -- that you -- to be presented. So that would be very good for a reviewer as well to reduce the load of work.

MR. TAYLOR: So, yeah, and this is a problem for FDA reviewers as well, as you can imagine. Sometimes it's kind of obvious to us how to resolve a compliance issue. And perhaps there is no harm in pointing that out to the -- to our customer, your customer. But often I've found that even though I know a way to solve a problem, there's a much, much better way that I hadn't thought of. And being from FDA, if I say here's one way to solve it, the manufacturer is liable to say, well, I should do it that way because the FDA says. And if there's a much, much better way than the way I thought of, I'm much better just keeping my mouth shut than giving them advice that's maybe okay but not as good as what it needs.

The other issue is that sometimes when these issues come up, then it raises concerns about whether the manufacturer has the expertise that's required by ISO, you know, 13485 with the quality system regulation. And so this really is a tricky question.

And I guess in saying how should we deal with the issue, the real question is what, if anything, should the ASCA scheme that we prepare say about this that isn't already covered by 17025?

MR. MARGIS: Steve Margis again. One way I've heard it described, if we take all the language about design, manufacture, distribution, all the stuff that comes from 4.2 of 17065, and if we take all of that chaos, I guess I'll call it, out of the system, I have heard a couple people that are very strong in the CASCO circles describe it in a simpler way. Is the output that you give an input to another process?

So if I give feedback to someone about a test that's noncompliant, if I give feedback to them about the application of the standard, if I give feedback to them about the type of noncompliance they have, that's information. And that information is going to be used by them to develop a result. As you suggested, if I give them an example of a result and now they apply that result and give it back to me, from the standpoint of independent and impartiality, can I say arm's distance and say, well, you didn't quite do it the way I said, so now I'm going to reject it? You start to get to a point where you are put in a difficult situation.

And so as soon as that output that I gave you became an input back to me, that's a way that I'd like to have people think about that issue, because if you think about the issue that way, if it's just information so they're going to draw a solution, there's some room there for discussion. If it's an output that's going to come back to you that you're now going to have to make a judgment against, you should question if you maybe went too far in what you've provided.

MR. TAYLOR: Anyone else?

(No response.)

MR. TAYLOR: If not, we will go on. So there were three issues that Alex raised in his talks. So the way they're written on this sheet of paper is how should test labs handle noncompliances encountered during testing, design changes, and how should TLs be involved in addressing labeling requirements? And, again, it's not really a matter of

answering that question, but the real question is should the ASCA schemes that FDA develops on behalf of our stakeholders have additional requirements other than what's required in the 17025?

MR. GROB: Is it okay if I answer one of my own questions? I'll send you the bill. So I think the answer -- in some cases, yes would be a very useful answer. So one of the things that we see sometimes is a struggle is we will get a device, we'll agree on a scope, we'll perform tests, we'll issue a report, and maybe 6 months or a year down the road, we'll find out that there was some issue with that test report for some reason, whether it was in a 510(k) or submitted to another agency. And we'll start trying to figure out why, what was the problem. We'll dive into our CAPA system, let's say, and do a root cause analysis.

And, generally, we'll find out one of the main causes for a test report to become less useful than it was intended is because the device no longer matches the test report because maybe the one that we tested was an early prototype and it had features and functions added before it was submitted for regulatory review.

So I think if there is some way that the ASCA program would require a capture of the device configuration, some of this information I think is easily put into if we're using the IEC test report forms. But sometimes we'll see even things in the instructions for use, and we'll say, well, you didn't give us that option for testing. In your instructions for use, it says you can mount this on an IV pole, but nothing that we got is mountable on an IV pole, so our report doesn't cover that.

So if there's some way that the ASCA program can make it clear in the interaction between the test report and the FDA when there's differences between the device that was tested and the device that's being submitted, because then maybe the issue isn't -- so, again, my bias, I'm a testing lab -- the issue isn't that the testing lab did something wrong, which may happen, does happen, but it may be that what the test lab was provided for

testing is not representative of what's being submitted to the FDA.

MR. MARGIS: Sorry. I guess I get the floor a lot today. This is Steve Margis.

The question is what beyond 17025 -- I think at its core, we have to remember that 17025 allows us to assess, you know, the ability of operation of a testing laboratory, which means it could be first party, it could be third party. There's some provisions in there for independence and impartiality, but at the end of the day, the scheme would probably have to drive the influence on where that line is because 17025 allows both.

The word that I keep coming back to is in the draft bulletin, I guess I'll call it, the description of the ASCA draft program, it says that attestation. And Warren said it very well in his presentation that a statement of conformity in 17025 is not an attestation. An attestation is an evaluation followed by a review that the product met the specified requirements.

So I think there's a lot of confusion or there's a lot of latitude being called for to use 17025 far beyond what it's fully intended for. And so the answer to what's needed beyond 17025, I believe, is that beyond 17025, as we said before, there's a number of next steps in conformity assessment. There's inspection activity. There's audit activities. There's certification activities. And there's currently a working group, CASCO Working Group 46, working on validation verification activities.

One thing most of those have in common is the four-eye principle, which is the review has to be done by someone other than the people who are doing the, for lack of a better term, evaluation.

So I kind of keep coming back to item number 1 on the screen, which is to me the value I have not really heard yet. I have some visions of where I think they might exist, but I think we're talking a lot about tests. We're talking a lot about standards. But to me, if we can't take the burden off the FDA reviewers, if we can't free you to do those special

activities and special projects and unique technologies that are going to allow these new products in the marketplace, if we can't take the existing products that have requirements that others can help take the burden off you from so that you could be freed to do those things, I think we haven't really made progress.

And I think that's where some of the opportunity is, is the exact question you're asking, what's beyond 17025. And I believe 17025 plays a key role but in and of itself doesn't provide the values to the group of stakeholders. So I guess my answer to you is it may be certification. It may be some kind of extended evaluation somewhere in between. But it has to be more than just a physical test. It has to be a test in context. And test is, again, probably a bad word because it's audit and test and inspection and a lot of other things.

So maybe not articulated very clearly, but there's much more mushrooming outside 17025 that will create lots of value and opportunity.

MR. FITZGERALD: I think you've articulated that very well, Steve. I think the question also revolves around whether -- a couple of things -- whether our concern with test labs is misplaced. Maybe we should be thinking of test labs as just a part of the system and that there is something other than just pure test labs that needs to be part of this.

The other thing that I want to point out here is that if you can cast your mind way back to my very first slide earlier on today, I asked -- sort of I pointed out that 601 and some of its standards are candidate standards. It is entirely within the possibility of reason here that 601 is not a good place to be in a pilot like this. The level of diversity, of sophistication, etc., is -- we can see here exactly how many different perspectives need to be taken into account. We're not replete with resources to do massive amounts of programs until they take root and are self-sustaining. And that's, by the way, another issue that we want this to be, is a self-sustaining process.

So if this is going to break the bank, so to speak, we may have to seriously consider other alternative plans. I personally think this is a huge win for patients if we get 601 in here, because I desperately want, from an FDA perspective and from a patient perspective myself, to see patient stakeholders represented with finally the essential performance characteristics identified and verified. How we do that, that's -- we can work that out amongst ourselves.

But I don't want for us to talk ourselves out of having 601 in the pilot here. So --

MR. WYMAN: Chris Wyman, Intertek. I just wanted to add on to what Steve had said, and I think he stated it very well. You have to look at the request from the manufacturer or if it was caught out in the field through inspections, right? It's what constitutes that device different. How I look at it on a medical product is it's either a simple report revision -- they're changing out approved fuses or relays or changing the manufacturer name, something easy, something small paperwork, right? Then you have to look at alternate construction. Am I using a different power supply manufacturer, a different battery manufacturer, right? So there's a lot of variables involved. Or is the manufacturer trying to come out with a Gen 2 product, and they're trying to say we think it's alternate construction, but we're kind of changing the enclosure, we're putting new boards in there, we implemented a BLE, a Bluetooth, right? At that point, then it's a new product, right?

So we catch that, right? And I have to report it back to my VP of certification. We work with the local labs. But -- and Steve, I think, you know, just to kind of simplify what he was saying, like it's really up to the manufacturer or else it's caught in the field on our follow-up services. So it's really -- there's two ways to look at it.

UNIDENTIFIED SPEAKER: Yes, I do have a question. Maybe the experts here can kind of educate me on this. I wonder how the accreditation test, you know, 17025 to really kind

of ensure that I can trust the leakage test from that testing lab, or can I just from the accreditation, that I trust that the leakage measurements or extreme temperature measurements from the lab are reliable or well done or done correctly? How -- that's really just a -- you know, a 17025 test just to --

MS. LEAMAN: So Dana Leaman from NVLAP. So 17025 would establish requirements for the technical competence of the laboratory in performing that method. So when an accrediting body would assess the test lab, say, for this particular test, we would ensure that they have appropriate procedures, that they can, if appropriate, calculate the measurement uncertainty, that they have trained staff, that they have the appropriate equipment. If there is a proficiency testing program or some kind of measurement assurance program in place, we would review the results from that program and ensure that they can get the right result.

So all those are pieces that are in 17025 that would be reviewed during an accreditation assessment.

(Off microphone comment.)

MS. LEAMAN: Oh, I'm sorry. So how often do we do those? So from my body's perspective, we actually conduct onsite assessments to do this every 2 years. But our laboratories apply every year to our program. So we do some form of assessment every year. If during the, if you call it -- I call it an off year, when we're not actually going on site to review their staff, we look at all their documentation to ensure there hasn't been any major changes, like they haven't had a huge staff turnover, or we ask for proficiency testing data to be supplied to us. And as long as there's clear indication that the processes are in place and they're still getting the right result, we won't do what we call a monitoring visit in that off year.

But every 2 years, we go on site. And many of my colleagues in the accreditation

community follow that model. Some go more frequently, but they are only looking at snippets. So they may do something called a surveillance assessment and go every year, but they're not looking at a full review of their program. With the model that NVLAP follows, that time on site, we do a full review of the methods that are on their scope. So I hope that helps answer.

MR. TAYLOR: And I just might mention -- this is really off topic, but FDA CDRH used to have a NVLAP-accredited lab, and it was a lab that tested radiation measuring equipment used by FDA investigators who enforced the radiological health part of FDA's mission. And so we've actually been through the accreditation process. That lab no longer exists. It's outlived its usefulness, but it was certainly a great experience for me to be involved with that actually about 10, 15 years ago.

MR. EISNER: Leo Eisner. There was a comment from Chris about changes to product. So I brought that up in my presentation. And one thing that we talked about the last couple weeks, the ASCA work group and Alex and I, is having some type of summary sheet instead of modifying the existing CB scheme report, which is a TRF which is a template already that's been working for labs for many years.

Sorry. Thank you, Brian.

So one of the questions is there's the significant guidance document, even though significance is not in the name, for the 510(k) process. That's not the same process that test labs look at for changes. Like a Bluetooth change brings in coexistence questions right off the bat, which not all safety test labs are going to know that's an issue. Maybe EMC labs would, but safety test labs, if they're the ones looking at the 601 report, wouldn't connect that always.

So one suggestion was the manufacturer does a change analysis from their regulatory group, or regulatory/engineering, because they always overlap, to explain why

testing is needed or not. And that becomes part of the summary report that when it comes back to FDA, they see what was done, and FDA can agree or not. And that way, the labs don't get bogged down by having to know all the different guidance documents that apply, because that's going to be a very hard ask, I believe.

MR. GROB: I'd like to go back to the question about competency. And, again, I'll express my opinion. I don't think that, honestly, we're relying on the accrediting body to guarantee that the test lab is competent. The accrediting body, I think, if I rephrase what I heard, would go in and verify that the appropriate requirements were in place from a procedural standpoint. So as a testing lab, we have to identify, obviously, what our scope is. We have to identify do we have the capabilities to run specific tests. And we have to train staff that will be running those tests.

The procedures that we have in place to do those things are under the scope of 17025 and would be assessed during our accreditation audits. But, honestly, it's the testing lab that owns that responsibility of ensuring that the staff is appropriately qualified and the staff is conducting the test properly and putting systems in place to be able to identify when there is an issue, and then following through the quality system procedures to correct those issues either after they've been identified or to detect them before they cause non-conformity work to be completed.

But to me, that responsibility resides within the testing lab to ensure that their staff know what they're doing. It's not something that we can rely -- we as an industry can rely on the accrediting body. You have to rely on the test lab because they're the ones doing the work; they're the ones setting those requirements. Yes, there's guidance in 17025, but the people who are getting their hands dirty in that work are the test lab. So if we can't trust the test lab to do it right, the accrediting body isn't going to be able to fix that.

MR. FITZGERALD: Well, what I'd like to do -- okay, I'll have a question after you.

MS. LEAMAN: Oh, sorry. I just wanted to add to what Alex was saying. So I absolutely agree with what you're saying is that you have to have confidence in the laboratory. But I think what the accrediting body offers and what accreditation offers is a third-party statement about your competence, that at that time, that snapshot in time, all those pieces were found to be in place and that it's just another statement about the laboratory's competence to do that. But, yes, I certainly agree with everything you said.

MR. TAYLOR: So maybe you should hold that mike for a question because I'm going to ask another question.

And that is clause 5.9 of 17025 talks about measure to assess the competence of the test lab. What -- and they mentioned proficiency testing, round robin testing. What means should the ASCA scheme specify to meet the clause 5.9? To me, that's a really tough question.

MS. LEAMAN: Right. I don't know that I'm going to have the answer to that question because there are so many pieces. Certainly, that clause has moved in the new standard, and I apologize. That standard is so new, I don't know -- I don't have the clauses memorized. I'm guessing that it probably is in either section 6 or 7 in the new standard, and it does allow for a multitude of ways to demonstrate that. So it may be the same things. It may be round robin testing.

I think that's something that the community would have to answer because the accrediting body is just going to look at what criteria you set and then what is found as acceptable. And then we determine if it's -- if the laboratory has demonstrated acceptable results, then they're fine. If it's not acceptable results, that's when we look at, okay, what corrective measures have they put in place? If they have multiple failures, does that mean that you suspend their accreditation? If you suspend their accreditation, we would then look at, okay, is there some notification to the scheme owner about that suspension

activity?

So those are all things we would consider, but I don't think we would on our own just establish, okay, what's the acceptable quality control measures?

MR. GROB: So to answer that question, hopefully the FDA does nothing different from what's currently available to medical device testing laboratories. There's other test labs here that hopefully maybe can actually tell me I'm wrong, but in my experience, there's a single source of proficiency testing materials for medical device laboratories. We use them for our CB scheme, which has requirements. And we've not been able to identify another source. And certainly that's caused us some trouble when you have a sole supplier, because if they don't have something that they offer for PTP, proficiency test program, that fits the scope of the testing that your laboratory can do, but you have a number of accreditations that require that activity to be completed by your laboratory, you're stuck.

So we've actually had to work with our AB to develop our own practice where we create something and we send it to other labs and have them run tests, and we effectively operate as the folks comparing the data to figure out whether or not we're doing tests correctly, because we have a situation where, as far as we know, there's a single source globally to provide proficiency testing for medical labs. So hopefully the FDA doesn't do anything different.

MR. MARGIS: This is Steve. Alex, just to elaborate on your comment a little bit, one, just as feedback for everyone involved, on June 3rd and 4th is the IECEE management committee meeting in France. And, ironically, France has made a proposal supported by the U.S. and a couple of other countries that is on the agenda for the meeting to identify and put in place a additional proficiency testing provider within the IECEE. That was driven in part by the U.S., but the ultimate proposal was made by France.

While that may not be directly relevant, I'll kind of try to draw back a case study of

where it's relevant. Proficiency testing is one example of a way to look at results from organizations and see if there's alignment, I guess I'll call it, amongst test results. Those programs and how they're developed have a significant impact on what you're trying to find and what you're trying to determine. One of the challenges we had with proficiency testing in the IECEE is that the programs are not always written to see how well you can apply the standard itself but sometimes how well you can apply a method, which may or may not be something you do every day. And that's been a challenge.

As Alex identified, we've had one provider for a long time. Without making judgments, we'll say I think they've gotten a little comfortable, and it's caused some challenges within the community. So whatever solution, if a solution is selected by the FDA for this type of situation, I would try to consider that case study as a challenge that you would have to overcome in time. Having variety of those programs, having opportunities in those programs is important.

Aside from proficiency testing, there's always round robin testing and other things. The one thing I would just caution us about proficiency testing, and I'll then hand the mike over, is we have to remember this. A CB scheme at its roots, the IECEE system at its roots is about taking data from one laboratory, giving it to another, and having that other body issue their mark. This program, this scheme, is quite different in that it's kind of a spoke and hub. Everybody is trying to provide enough resources so that the FDA can help meet its mission and objectives. We're not really talking about going body to body. And so the solutions that you look at and you consider should keep that in mind is that we're talking spoke and hub versus body-to-body type of interactions. And that might have an impact on the solutions that get picked.

I think Joan had a comment.

MS. STERLING: Thanks, Steve. Joan Sterling with Intertek.

I have something -- a question a little bit on a different topic here, and that's the previous 510(k) program. Many of us in this room were part of that program. Most of us, I think, today are no longer participating in that program. And so I guess when you're looking at this new program, can you help us understand maybe what lessons you learned in the rollout of the other one, things that maybe we can avoid in this new one?

MR. FITZGERALD: Yeah. So giving responsibilities to people without giving them the resources is what we basically learned from that, that it's physically impossible for, or has been in the past, physically impossible for people to make accurate comparisons of predicates without access to privileged information, which they cannot have. I mean, simple as that. That was just inadequate planning if you think about it.

What I want to do is spend the last 5 minutes here talking about subcontracting and partnering and keeping our competence level limited to what we are truly competent in but at the same time leveraging the supply chain that the community can provide. We know what some scheme owners feel about whether all information has to come from accredited labs. And we also know how some certifiers feel about using information that comes from other test labs that are not part of their own organization.

So what I want to do is put out there, do you have any suggestions, any feelings about the way that the FDA should behave when it comes to encouraging, permitting the interaction, based on competency and expertise, of labs with subcontractors in the supply chain and at the same time keeping the level high enough for us?

So we have an accreditor here who's going to tell us all about how that works.

MS. ATHENIS: Hi, there. Karen Athenis from A2LA. In response to that, the most of what I was going to say is that when you do subcontract and you're considering whether to accept the results of a subcontractor as part of this program, typically what they look at is the risk of it, is that something that's low risk and so an accredited test maybe isn't

necessary as part of the overall scheme versus what parts of the testing is critical and would have to be performed by an accredited organization. And that would be a determination that you would have to make as part of this program of, you know, what's considered a low-level test that you wouldn't need an accredited test for versus a high criticalness.

You know, for our purposes, we can't call a subcontracted test accredited unless it was performed by an accredited laboratory. So that's a limitation of what we can provide. Certainly, laboratories can subcontract their work, and they could call it, you know, accredited under their scheme as long as that was part of their accreditation.

MS. STERLING: So under the 17025 or 17065, for sure, there's clauses in there that deal with acceptance of subcontracted test results. And if we're carrying an accreditation, we can accept test results from a non-accredited lab under a number of portions of that standard. So as long as the accredited body follows the rules in accepting that information, that's something that's easily possible to do. Probably many laboratories in this room and cert bodies in this room do that.

And ultimately that becomes part of a report from the accredited body, and we have to take responsibility for it. So no one goes into accepting that data without some real investigation as to the qualifications of who their subcontractors are.

MR. MARGIS: Yeah, Steve Margis again.

While competence is certainly critical, I think one of the things where you have to use as a starting point when you think about subcontracting or alternate testing facilities is control of those facilities. You know, within your quality system, what are you doing to ensure the suitability of those locations that you're talking about? Are you doing assessments? Are you relying on other mechanisms?

OSHA has an interesting approach to this in that OSHA says we're assessing your program, and within your program, you have to demonstrate to us how you have control

over the data coming from those alternate sources, which is, of course, subcontracting. That's an interesting approach in that it allows us as a certification body in that case to go out, look at other laboratories, have a quality system in place to manage the capabilities and competencies of those laboratories.

In some other cases, I've heard regulators try to take a tactic of saying, well, if you're going to be in our program, you have to accept data from anybody that's on this list of laboratories. And where I would caution us on that is if I as a body am acting in the program, and I'm being forced to take data from someone that I have no relationship or control with, now you have issues of indemnification. You have issues and challenges related to taking responsibility for data of which you have no contractual relationships or controls in place.

And there are some cases, there are a few cases globally where regulators have taken that tact, and it's very challenging for the bodies involved because it's a high level of risk you're potentially taking on. And the likely answer that goes with that is not that, oh, we the government will give you indemnification for that. Certainly, that will not be part of the play.

So given that as a circumstance, consideration should be made that if alternate laboratories or alternate locations are going to be used for the generation of conformity results, how is it that the body can ensure that those results are suitable that they're taking to pass on to you given the criteria you establish, or is there a way that those bodies, if needed, can provide that data directly to you so that you don't create that challenge of having a body having to take data that they have no control over?

MR. HANNIGAN: Tom Hannigan with OSHA. And yeah, he's right. We do allow the NRTLs to, you know, set their own guidelines for how they're going to use third parties. But one of the requirements we do have, and it's fairly unique to our program, is they have to

be able to do the testing at one of the recognized sites as well. So we don't just say that, hey, you can push this testing off and not have any qualifications internally for it. We make sure that they do have it internally before they subcontract it out. I just wanted to clarify that.

MR. TAYLOR: Okay. And Verizon says it's 4:27, so in 3 minutes, the other breakout groups are going to rejoin us in here.

So I guess we should bring this to a close. I want to thank you all very much for the participation. Some of you who sat quietly in the room may have ideas that you will provide us in writing at some point. This last discussion reminded me that sometimes we engineers and regulatory affairs folks have conversations where we should be consulting with our attorneys, so when we publish the scheme, be sure and share it with your counsel when you're preparing your comment.

And the other thing I'll mention is that a few minutes ago on my cell phone, I got a severe thunderstorm warning for a couple of miles west of here. That's upwind. So it's here now. It will be gone by the time we go outside. And life should be good again.

MR. FITZGERALD: Thank you.

(End of breakout session at 4:27 p.m.)

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

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BREAKOUT SESSION II

60601 BASIC SAFETY AND ESSENTIAL PERFORMANCE

May 22, 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