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BREAKOUT SESSION II
60601 BASIC SAFETY AND ESSENTIAL PERFORMANCE

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M E E T I N G

MR. TAYLOR: Okay. So how are we going to get started today? We were just having a side conversation with Steve Margis about this idea of the conformity assessment being done, something more than a test report, something less than certification. And that might be one thing that we want to explore this morning. If that is the case, what do we want to call it, to avoid confusion? Because, you know, the biggest problem that we have over and over again is semantics, what is meant by the words.

And so let me just ask you all. What did you -- what stood out to you yesterday? What do you identify as the gaps? And I heard a number of comments yesterday after we formally closed that we really didn't hear very much from the manufacturers whether this -- it sounds like something that you want to be involved in or not or what characteristics it has to have to garner your involvement. So let's start there.

FEMALE SPEAKER: I would want to make sure that if there are people on the phone with questions, that we also get those because I don't think we heard anything from any of those individuals yesterday. And surely they have some.

(Off microphone comment.)

FEMALE SPEAKER: Well that's actually more of a comment.

So one of the things yesterday we talked about was stakeholders. And I think a group that we missed was the actual clinicians. We did talk about patients, but one of the things from a manufacturing perspective that we struggle with is a lot of the tests and the standards really don't reflect actual clinical practice.

So I think some of the information that comes through ASCA that could be fed back to manufacturers and testing labs of what is an actual test that would make sense from a clinical perspective, which we would need clinical input from. So I think they're important to be part of the standards, the SDOs, as well as important for manufacturers to get the

voice of that customer so that can be fed back into -- and that information could come from FDA reviewers, of what they've seen that makes sense.

MR. FITZGERALD: So that was the sole manufacturer's voice.

MR. TAYLOR: It's early in the morning. Do we need to order in some coffee?

So seconds before Scott threw the ball to me, someone handed me some notes from yesterday. Let me just take a quick look and see what they say, but we really do need to -- I think some of you who were listening yesterday and haven't spoken probably have some thoughts that need to get out on the record.

MR. FITZGERALD: Well, there's one thing that I recall yesterday that stuck in my mind, and it was a reference that was made to 16149, I believe. And I said that when Scott returned, that I would grab him and have him comment on it.

So the question that we had yesterday, when you were in one of the other breakout groups, was it was related, if I recall correctly, to the progression of where are we going with regard to MDSAP and other things like that, and how the standards are becoming so unwieldy and so large that a return to simplicity is something that some people would like to see, and that 16149 might be an opportunity for something in the future.

I demurred from passing my own comments on that because I know that Scott has been involved in some of these -- yes.

CAPT COLBURN: All right. Yeah. Thank you, Brian.

So, yeah, ISO 16142 is titled the essential principles document. And then there's a -1 and -2 in that series, -1 for medical devices, -2 for in vitro diagnostics. And they're pretty recent standards, and they were designed to match the essential principles from the document developed by the Global Harmonization Task Force.

The essential principles now is being updated, of course, because, you know, we had a standard that published, so it makes sense that everything that that points to now gets

updated to make that standard not as relevant. But, in part, we also had a massive update come out of Europe with the medical device regulations that have really changed a lot of where things are going.

So the IMDRF, and I don't see our reps here today for that, but we just had a meeting last week actually, discussing the essential principles guidance that was out for draft over the last couple of months and is designed to go final this year. That work will be reflected back into the ISO/TC 210/Working Group 2, a standards document of 16142 to see how can we take the essential principles and grasp how they talk about using standards to meet those essential principles or those desirable characteristics that the regulators are hoping manufacturers are starting to meet that platform that will eventually -- the desire for that is to try to develop a single review type format that multiple regulators could consider utilizing from the IMDRF perspective and then try to share that with other organizations as well.

It's much in its infantile stage at this point, but the idea is to -- you know, I'm advocating, from a standards perspective, how can we make sure standards can be a part of that? How can we make standards more fit for purpose to meet the, you know, the objective criteria that a regulator would like to see in the final reports that are coming to, you know, supplement a declaration of conformity? And then what are the pieces of the puzzle that are filled in through the use of standards? And then what are other pieces that are left over that maybe standards don't address that the manufacturer would be required to submit in a package that would go forward?

ASCA -- I'll be frank. ASCA really was not in -- when we thought about this and we were rubbing our heads together, trying to figure out what are we thinking of when we were developing this program, you know, we did see a potential relationship, but this program was not specifically designed to meet that because that doesn't quite exist today

yet.

Yet what is not -- what doesn't exist that this program will create is that information loop, that relationship loop that we don't quite have with the accreditation body community, with the international community where accreditation is also discussed and with the testing laboratories, and that's what we discussed with yesterday. And if we can build the confidence in those areas through this mechanism in ASCA, I think then we can find better ways to utilize tests, the testing that's being conducted, the test reports that are being utilized.

Where are those test reports coming from? Is there some sort of certification or accreditation that accompanies that? And how can you develop, then, something that, to Jeff's point yesterday, would help support the different platforms that a regulator is doing, whether it's something FDA is doing with the Expanded Abbreviated 510(k) program, with a third-party reviewer program, with a just overall standards general program that we have, or to ASCA or to serve other international needs?

And so I think -- does that help a little bit, build some perspective, what you're looking for?

MR. FITZGERALD: It does, yeah. I think it's possible to contemplate a future where compliance with a standard, a published standard, forms part of a regulatory portfolio, but in another way, it might only be that a part of the standard forms the relevant aspect of regulatory compliance. And the way that the Europeans have tried to parse this is by putting an Annex Z at the back of these standards, in the EN standards, where they outline the essential performance mapping to compliance with that standard.

I think that that goes to the aspect of the heavyweight aspect of these, of many of these standards, where it is now a very expensive and a very difficult proposition to contemplate how your device may meet some of these standards. Maybe there's, you

know, some future in a -- I suppose it's decades away really, a future where you'll be able to pick and choose the requirements that apply based on the essential principles.

That's probably the answer. I'm not sure that we're going to get there from here. We need to do something before that. And ASCA, I think, is it's one possible solution for a lot of devices.

MR. TAYLOR: Okay. So let me then try to provoke a discussion. Great.

FEMALE SPEAKER: You know, I'm trying to kind of figure out and distill the kind of essential mission of this program. You know, I know that in addition to the existing relationship between the FDA and the manufacturer, I mean, manufacturer with testing lab, you want to establish also a relationship between the accreditation bodies with FDA and maybe ideally with the international community as well.

I wonder, I mean, how that would really kind of, you know, facilitate, as you say, consistency and predictability in regulatory review, in more specific sense, you know, how that would attract a manufacturer and testing lab to really join the program. You know, what are the really, you know, I mean, substantive advantages for them to really, you know, attracted to do that? I mean, and how do we really improve the review consistency and predictability? I just try to figure out, you know, the more specific kind of advantages and missions.

MR. FITZGERALD: Yeah. It's a good point. Remember that we're not trying to fix the problem with -- or if there are any problems with 601. We're really trying to identify whether 601 is a viable candidate for an ASCA program that's going to move forward anyway. And while each of us may look at the entry of 601 into the ASCA program from their own stakeholder's perspective, we have to be sure that each part, each stakeholder community is going to get a win out of this.

And you raised the point that it -- you know, what is it about this program that might

form the win for manufacturers? Well, one part of it might be the removal of some doubt. And another part will be the managing of the project on their own timeline. And another part of it might be that they had a commerciable product that they can, from their either testing lab or their CB or whatever, that they can commercialize internationally because at the moment, between marketing agencies, they have such a product. But they don't have that yet between the regulators in those areas.

This program might lead to a reciprocal acceptance. It might be a path forward for reciprocal acceptance in multiple jurisdictions. I hope that answers that particular question, although I would very much prefer to hear the win elicited from the mouth of a manufacturer, if we have any here.

MR. GROB: Good morning. This is Alex.

I'm not a manufacturer, but I'd like to hear the answer to that question as well. As a testing lab, we see the value -- so I'm not in marketing. Let me say that first. But we see the value if we can provide a product to our customer where there's a higher level of confidence -- I won't say guarantee, but I think ultimately that's where we'd like to go, that this test report -- because we know what we're doing. We have a method of communicating with the FDA on expectations, training, etc., all the things that I think the ASCA program can offer to a testing lab. We see a value in adding that as a service that we can provide to our customers, the manufacturers.

But, of course, if they don't see any value in it, then there's not much point in our involvement. So we've had many discussions internally about whether or not we think our customers would pay for that type of service if we were to offer it, because we know there is obviously some cost associated with us getting in this program. And so we're trying to figure out whether or not manufacturers are seeing this as a value add as well.

MS. LAROCHE: Hi. My name is Marilyn. I'm with Nemko Canada.

I have a question about the testing laboratories. Are you considering only NRTLs or maybe labs that only make CB reports? And you only considering 601 or 1010 as well? Because it could fit in.

MR. FITZGERALD: Well, I'll answer the bit about 1010. We've seriously considered that 1010 should be admitted to the process early on. But we have limited resources at this time in order to accommodate the space that 1010 would occupy. But it's a logical extension of having 601. In other words, if you have 601, you might as well have 1010, and you might as well bring in some of the 80601 standards too.

There's a lot of behind-the-curtains work that would need to be done in order to do that. And maybe it's better to start something small and then grow into it. But the point is well taken.

MR. TAYLOR: And others have thoughts about that?

FEMALE SPEAKER: You know, as a reviewer, I think I can foresee a scenario where the manufacturer would be interested. If you can streamline the, you know, testing report format, the form would really provide the reviewer as a very, how do you say, trustworthy, critical elements of testing, and I don't really need to really to ask more questions from them. And that would really speed up the review process. And that's one of the advantages, I think, that probably manufacturers will really enjoy, I think.

MR. EISNER: Leo Eisner.

So yesterday in my presentation, I talked about potentially -- and this is something we talked about last week in the ASCA workgroup, is doing some type of summary report that's specific to the FDA requirements that cover like the NAs, if there's a change to the device, what's the regulatory analysis to -- which the manufacturer probably would do, not the test lab, trying to ease changing the existing test report, just doing a couple page summary that hits the key points that will hopefully make the process easier. But what all

that is has to be decided and then put into guidance, I suspect.

MR. TAYLOR: Yeah, so --

MR. EISNER: Whatever the scheme is.

MR. TAYLOR: -- maybe put into the scheme. But so what should the elements of that report include?

MR. GROB: This is Alex Grob again.

I think what Leo says makes a lot of sense. So I think most testing labs, I won't speak for all of them, but I think it's a fairly common practice for us to be using the IEC TRF, the test report forms, in some way, shape, or form. So that's a very long document. The 601 test report form, I think, is about 110 pages or so, empty, before we start filling anything in. It has a lot of places to put information. I can see the value of a summary that would, I assume, be defined as part of the ASCA program, explaining some of the key items.

Like when we have a verdict of not applicable, it can mean a number of different things. So it can mean that the requirement wasn't applied because the construction of the device doesn't require it or allow it to be applied. It could be that the testing lab doesn't have the capability to perform a specific test. It could also mean that the manufacturer requested the test lab not perform the test.

So when we use the CB scheme format, we're restricted, if you will, by the verdicts that are allowed in that form. We have pass, we have fail, we have not applicable, and we have not evaluated. But not evaluated is a highly restricted verdict, so we can only use that in certain areas. And I don't think, as a testing lab, we would want to be in a situation where the ASCA program was having different definitions for those verdicts. But I certainly see the value in explaining, when something was not applied, the reason why.

So maybe you have a summary page that says, here's the following requirements that were not applied based on the construction of the device not falling under the scope of

those requirements, and list them out. Here's the requirements that were not applied because the testing lab doesn't have the capabilities or it wasn't included in the contractual arrangement between the testing lab and the manufacturer. These requirements were not applied, and list them out. And here's the ones that were not applied because the manufacturer didn't want them to be applied, and list those out.

And I think that may help at least one of the things that we talked about yesterday that's currently a little bit of a struggle.

MS. LAROCHE: Hi. This is still Marilyn from Nemko Canada.

Regarding the similar testing, if you're a CBTL lab or any labs that use IEC form, you still have to write down your assumptions and what you have considered before doing any testing in your similar test and the TRF. So I don't see why it would change, because it's already there. It's already -- the policy is you already have to do it. So I'm not sure about the other labs, but at Nemko, we really identify what are we doing in the similarity of testing and what's the context in which the equipment has to be tested.

MALE SPEAKER: Yeah, I think, you know, I definitely agree with Leo and Alex. And I think all of us, from a lab perspective, we obtain this data inside our project files. We just might not be servicing it inside the test report.

And then I know, taking a page from a couple of other certification schemes where we put, I'll say, additional emphasis on mandated review, and then especially compliance to essential health and safety requirements of I'll say even things like the low voltage directive, we might require, in those reviewer checklists, additional commentary, right, above and beyond that NA.

And so just simply, whether you call it a summary report or a checklist or a review form, some way to capture that additional information. Right. And maybe we can just create our test report form here and have another column for that comment. I don't think

it's rocket science to get that information into your hands. And that seems like -- I'm a classic oversimplifier, but that's all you need to satisfy why is this an NA. Right, so --

MR. RODRIGUEZ: Elmer Rodriguez, product safety.

One of the values that I would like to see come out of this program is actually see what the FDA requirements and guidelines are going to be, because as a test lab, when I actually evaluate a product, then the declaration that I'm making is that that particular product either meets or fails the particular standard. So when I say it passed, it passed to the requirements of this standard.

So going forward, when I do an evaluation for any manufacturer, should I say the equipment actually meets and complies to the requirements of 60601, 6950, 1010, or even 368 that is coming online here real soon, or should I say it complies and meets the requirements as per the FDA?

CAPT COLBURN: Sure. I can add, we had a few comments brought online. One was a question. I think it's a question we can answer relatively easy. It's "Just for clarification, will they ask a program apply to manufacturers' own test labs?" And what he means by -- what he's referring to as accredited test labs to ISO/IC 17025, which would be part of the medical device manufacturers' own, you know, laboratories.

And I think we've been very clear on this that, you know, yes. The answer would be yes. If you have a lab, as a manufacturer, that's accredited through one of the accreditation bodies that would eventually become part of this program, to the standards that are in the pilot, then the answer would be yes.

Is there anything that you'd want to add to that, Brian or Al or anyone else in the program?

MR. FITZGERALD: No. And I come at this from the perspective of the essential performance now. I think it's fair to assume that the manufacturer's best placed to identify

and certainly best placed to verify the essential performance. So I contemplate a business model -- of course, I think the marketplace will decide what that might be, but I contemplate a business model where a test lab that is functionally competent and able to look at the areas that are in the standard with respect to basic safety can work with a manufacturer to develop a bespoke essential performance verification scheme where much of that is witness testing.

It could be captured and placed in the files. What this would require, though, is elements of engineering judgment. And I've heard over and over again in the last couple of days that there is a reluctance on behalf of some of the labs to go out of their safe zone and move into an area where engineering judgment is applied.

Well, if that's the case, we may end up with many fewer test labs in the scheme than would otherwise be healthy, but we may end up with test labs that are functionally better connected to what we perceive as one of the essential domains of patient risk. So that may be a necessary consequence, if you contemplate it, if you play that game through.

MR. TAYLOR: And I guess going one step beyond that is, you know, the FDA is charged by law with judging the safety and effectiveness of the product or its equivalence to a product that is already deemed to be safe and effective. So if we are to outsource any aspect of our review, if I can use that crude term, then what is the value proposition of that?

And the premise on the table is that the test labs have the engineering expertise to make some aspects of that judgment that have to be well defined and within a reasonable scope for an outside entity to do. And then there has to be some value to doing that earlier in the process than would otherwise be done with the traditional thing of just before we go on the market we talk to the FDA.

So we're talking about moving some aspects of that independent judgment up in the

product development cycle, where there's more value to be gained by getting that independent review earlier. What -- and it's not --

(Off microphone comments.)

MS. STERLING: Yeah. Joan Sterling with Intertek.

I mean, that's not a test laboratory function. So if that's what the FDA needs, then they have to think about how they put that into the program. It's not a traditional 1705 test laboratory function. I mean, essentially, the FDA has to tell us, the service providers for the program, what you need in your program, and then we all will determine if we can provide that service.

MR. TAYLOR: I don't think we're ready to tell. We're asking. And that's really the purpose of this workshop. So -- yeah.

MR. QUINLAN: Good morning. Barry Quinlan of SUD America.

Is the FDA planning to become a 17065-accredited certification body? Because you're sort of merging 17065 and 25 together and trying to put all of this in one sort of package. You're talking about the role of the test lab slightly changing and using some form of judgment where we're heading towards is what -- the evaluation phase in 17065. So I'm just trying to get some idea if you're going to become 17065 accredited or follow the principles of 65.

MR. FITZGERALD: So I think that that's an excellent question. And I think that we're probably already doing it. As to whether we would formally seek an accreditation to that effect, I'll let that up to our political masters. But we have someone right here in the room who would probably be involved with that. Moi, she says?

(Off microphone comments.)

MR. TAYLOR: No, she doesn't.

MR. FITZGERALD: You don't? Okay. Okay.

(Off microphone comments.)

MR. TAYLOR: Someone else in the room?

MR. FITZGERALD: Gordon Gillerman.

MR. GILLERMAN: Good morning. This is Gordon Gillerman from NIST.

So I think, generally speaking, at the National Institute of Standards and Technology, we are working closely with the federal government agencies, and we are promoting the use of the international standards for conformity assessment.

Generally speaking, there's not a lot of value for many of the regulatory bodies or the final approval authority to actually become third party accredited. Right. They have the confidence of society already, but having a path to look at the value of having an internal process that would tend to follow the international standards for conformity assessment has become very valuable to many federal agencies. So I think that's something that perhaps the FDA could consider as it moves forward in this work.

MR. GROB: Hello. This Alex Grob from MECA.

Just I guess I would like to, since we're in a public forum, officially state that we would hope the FDA did not need to become the accrediting body, that accrediting bodies that already exist would be used. The reason for that is we, as a testing lab, have a number of bodies that accredit us already, and adding another to that list is certainly not something we would jump in line to do unless the value was very large for that.

So, again, missing the question on whether or not manufacturers see value in the program, we probably would not rush to get accredited by the FDA as an additional accreditation if we didn't have a large number of customers standing next to us, saying we'll do this and we're willing to pay for that service. That, you know, that's again, my opinion.

FEMALE SPEAKER: Regarding the, you know, kind of allocating the essential performance testing to the testing lab, I think as a reviewer, I see a great challenge, because

I have to say, we have to go back to standard definition of essential performance. I think it's not very clear. That's the first difficulty. I mean, unacceptable risk is really sometime in the eye of the -- I won't say the eye of the beholder or some -- in the eye of the person who is really looking at it in clinical indications.

And with all devices with diverse clinical indications, I think it would be really a burden to a testing lab to really figure out that. I think maybe the manufacturing together with the FDA can figure out that. But I do think the standard definition needs to be more substantive in defining this. I think it's very difficult for some cases.

MR. TAYLOR: Okay. And I just want to walk back something that I just said. We're not talking here about outsourcing our review of safety and effectiveness. We're talking about outsourcing the independent assessment of the conformity of the device to a recognized standard. And so it's a much, much narrower scope, and I just want to make sure that's clear.

MR. MARGIS: Thank you. That's an excellent segue to the comment I was hoping to make. This is Steve Margis from UL.

I don't know -- as I'm speaking, I don't know if there's an opportunity, whoever's working the displays, but in the ASCA write-up, there's a diagram. And if it's possible to bring that up, that would be wonderful, if we can speak to that for a second. But if we don't have that, I'll continue to ask the -- you know, kind of comment, in any case.

We're having a lot of good discussion around standards and test and elements of how we interpret the requirements. I'd like to circle us back to what I think we're really here about, which is how can we assure the success and definition of the ASCA program?

I think one thing that's challenging is we're kind of tap-dancing a little bit around the value propositions to the various stakeholders. And I think if you -- for the people who've read the write-up, right now there's a line that shows that the manufacturer may do an

attestation and make their declaration to the FDA for review.

Oh, there you go.

So, in here, we're talking about the manufacturer in the green stream either using some type of approved source to be able to make their declaration -- 17050 in the bottom right is self-declaration from a CASCO profile. There's this one stream between accreditation body and test lab that hopefully is going to provide some value, which provides those stakeholders with a reason to participate, for the submission to the FDA.

How I like to envision this is I think part of the challenge is we're looking at one line that goes to the FDA. And because it's not very descript, we can't break it down into its more discrete pieces to pick apart where those values are.

So I'd like to propose a visual for people to think of in their mind, is that between the manufacturer getting the test report and the submission to the FDA, if we think of that as a funnel and it starts from the wide side of the funnel to a narrow side of a funnel. And in the wide side of a funnel, there's all kinds of responsibilities and obligations that you have to report to the FDA.

The activities that we do under ASCA hopefully, as we define them, will ease the burden of that funnel. The goal is that as many pieces of that package as possible can be pushed through -- I'm going to use a new term, if it's okay. I'm going to call it a confidence intermediary, somebody that you can assess and qualify and determine has a certain level of competency such that when you receive that element of the overall package, that you can have -- confident as the FDA, through your roles and procedures, that that piece is covered, which will provide value to the manufacturer, that they'll have the confidence that they'll be able to move forward efficiently. You'll have the desire from the conforming assessment providers that by passing these conditions, they'll be able to provide value to the manufacturer and develop business for themselves.

So I think, to me, the line is an excellent area for topical discussion of within an FDA package there are a number of elements. And by going through these procedures, here are the elements that we're going to be able to put aside and say we have confidence, and here are the parts that we the FDA, no matter what and under any given condition, have responsibility and will be taking those actions on.

And I think that we will then, from that discussion or from that resolution, be able to more easily articulate the value propositions from all sides. So I would offer that I think the core or kind of the elephant in the room around value depends on just what is it in the overall package that we're going to be able to satisfy and help that's going to help drive turnaround time. Is it going to help drive cost? Whatever those things are, then everyone's going to be able to step back and say, oh, I see my value proposition.

So I guess I would offer that up for consideration.

MR. FITZGERALD: So right at this time, Steve, our thoughts are limited to standards. Maybe they shouldn't be. Maybe we should think out of that box. But right now it's limited to standards. And so the natural thought process would have been to take those that are looking at standards and see what else they can do in order to help. So that's our thought at this time. We welcome additional constructive thoughts. We are open to it.

MR. RAMALEY: This is Grant Ramaley with the Dental Trade Alliance.

I think this is really the slide we need to be looking at because this really is actually what the whole ASCA program is, embodies. And there are so many different parts to it. But, again, and we've heard this repeatedly, what value is it to manufacturers? And they're going to look at the cost. They're going to look at the necessity. When I look at 60601, my first goal is to meet the regulatory requirements, and first and foremost, they come -- on the 60601 side they come from Brazil, China, and Korea, and OSHA, and the equivalent of OSHA in Canada.

So we can't get into those markets without 60601, so we play by their rulebook. So we may use the IECEE CB scheme for Korea. We use 2nd Edition for China. We use the ILAC system for Brazil. And we use the OSHA accreditation scheme, because if we want to get into those markets, we have to play by those rules. So what rules will manufacturers have to play by ultimately to justify paying to participate in the ASCA program?

And then when you look at the different elements of this graph, the accreditation bodies are going to have requirements with holding the test laboratories accountable, not only to 17025 but additional criteria related to competencies in the areas of risk management or usability, because when you talk about the 60601, Edition 3.1 as it stands now, those are normative standards, which are actually more in the sphere of the management system side, the 17021 accreditation standard. So those parts have to get worked out. Will they add cost?

Competency is ultimately what accreditation is all about. And I think developing the competency criteria is going to be the focus, but until we understand what the concerns are relative to competency on behalf of FDA and others -- and I believe they're there. I mean I have some real issues with laboratories doing assessments of risk management files and usability evaluation reports and that sort, even software. Those are areas that will have to be looked at on the competency side, that will have to be additional requirements probably for the testing laboratories, that the accreditation bodies will also have to have competencies in terms of their capacity and ability to assess those competencies.

So additional competency requirements for accreditation bodies, additional competency requirements for testing laboratories, those are the things that ultimately will affect the cost to the manufacturers. And manufacturers aren't going to pay it unless they've got a necessity for it.

MR. TAYLOR: So, for clarification, if the ASCA scheme specifies that the ASCA

accreditation body or accreditation bodies is a signatory to one or more of the international accreditation arrangements, does that satisfy one of the concerns that you have?

MR. RAMALEY: I think, you know, and it's a good choice of words, that you have this called the scheme owner. And when I look at this as -- scheme owners who are part of ILAC and IAF multilateral recognition arrangements definitely can participate in, you know, using the IAF or the ILAC MRA marks, which give them those test reports, the recognition to be accepted globally.

We look at, you know, if there's 2,000 manufacturers in China that sell here, we have to consider that there's what, 10,000 or more foreign manufacturers that would have to participate in this. So allowing them to participate through something like an ILAC MRA means that you would go there, say we want to be a scheme owner and we want to create this program called ASCA, and work with those other countries to build in this program to theirs and attach it to the ILAC MRA. So, yeah, then it would have value. And you probably, because you are the U.S. FDA, attract other ministries of health to recognize the program.

CAPT COLBURN: Gordon.

MR. GILLERMAN: So I can't tell you how this is going to work out, but I will tell you that in a lot of other federal agencies who've chosen to leverage accreditation, they use in many times the participation and signatory status and the peer review system that goes with ILAC and IAF potentially as a prerequisite to participating in a federal government program.

So it's not that that's all there is. It's that's the minimum requirements for an accreditation body to be considered to have the kind of competencies and management systems in place that the federal government agencies need to rely on. The federal government agencies often have additional requirements for the accreditation bodies in order to make sure that the technical competency evaluation and the systems in place, that

the conformity assessment bodies meet their needs.

CAPT COLBURN: There's a few comments here that I could go ahead and read. They're not in the form of questions. Let me try to pull them up. This is kind of dealing with the same topic in the international scene. This one's more specific to the CB scheme discussion. And I'll just read the comment for what it says here. There's three subsections to it, and it kind of follows a little bit of the last discussion. It says -- and I think we can have a discussion on this after.

"If a lab is part of a CB scheme, they most likely are having good technical audits. If a lab is accredited by a known accrediting body, they are having good QMS audits. If there are gaps between regulations and standards, these could get into the CB scheme as national deviations. If that were to happen, then the FDA should be able to trust the work that was done by that lab, with one possible exception. The work does come down to the individual engineer or engineers responsible for that work."

The second part of that is, "The IECEE CB scheme has a regular lead assessor training, and these individuals are supposed to be conduct good technical audits." At least that's the understanding of the commenter.

And then finally, and I think this was kind of based upon discussions that were going on regarding the normative requirements or some of the additional requirements in the 601 series, it says, "The IECEE CB scheme trained the labs in risk management for 8 years, what to look for. The member labs have stepped up quite a lot. They also did some training around review of usability and software."

The experience from the commenter is that "Often lab personnel are more aware of standards-based risk management and the process of ISO 14971 requirements than are the manufacturer personnel who have not necessarily been trained adequately to the specifics of the standards when they're coming with what they feel the requirements are."

So maybe we can have a little discussion on that. This is just the review point from one place, but I think it's more specific to the IECEE CB scheme. I know we have people in the room involved in that area as well, if you want to speak to any of that.

I know when we first came to a meeting to talk about electrical safety, and we asked the question as, you know, for labs that are accredited to the 60601-1, and I think Hamed -- I don't know if he's in the room right now -- asked the question, and we asked, so are you accredited using, you know, the requirements that are placed into under 14971? And I'll admit, the feel we got in the room wasn't, you know, yeah, you know, right away. I think this was, you know, this is a challenged area because there's a lot of, you know, subject to be built in with risk management and understanding, where do the responsibilities lie and where would that be appropriately maintained?

I think though, from an ASCA perspective, that's the work that we're trying to do, not to place responsibilities where they shouldn't be but how to make sure, when a client's coming or a sponsor's coming to a laboratory or to their own lab and they're identifying the basic safety and essential performance requirements from those standards, as appropriate, that there's something that's not there today that ASCA provides to help make the correct decisions so that way we have a more complete test report that's coming back for the regulator.

Now, whether that's adding in additional work to, you know, the CB scheme or some sort of guidance or additional work into the standards as some sort of handbook or other means, I don't know. But that's -- part of the issue, from a regulatory standpoint, is we don't see the issues being addressed through the risk management file as appropriate. And we know it's not the responsibility of the testing lab. That's why we don't ask the testing lab the questions. It's the sponsor's responsibility.

But what can we do to improve it is really why we're here, you know, and we'll never

get to a more, you know, multinational, single review platform or third-party review platform even through a certification scheme if we can't improve the relationship of understanding of the standard itself. And some part of that responsibility falls on the Agency to identify what are the requirements. I think Grant mentioned to that, you know, what does FDA want? You know, say it. Put it out on paper somehow.

It's -- we're with you on that. We believe we have a lot of responsibility to this, to bridge what is a manufacturer and a laboratory going into contract for, and how does that give some better feeling that we're going to get a declaration of conformity with the appropriate information under the competencies that we're comfortable with, to not have to dig back in and say, redo this, we didn't see that, why, back and forth.

I don't know if there's any discussion.

MR. FITZGERALD: So just to follow up on that a little bit, what I'm hearing is that if we lay out what it is we expect for this type of scheme, in addition to what is already being done and commercialized in international standards conformity assessment like the CB scheme, etc., and if we were to do that in terms of expectations to the regulator constituency, the manufacturing community rather than to the test labs, then at least the status quo, to the extent that the status quo exists and is good enough at what it does right now, the status quo would be preserved, and we would get what we want.

But remember, we're only one stakeholder here. That would be something that, within the limits of political constraints, that we could do anyway. The idea, though, is to have a community approach to getting this done, to the extent possible, and to getting it done in a manner that precludes an excessive amount of questions at the regulatory review point, to get that cake baked before it comes in FDA's door.

So that would be, I think, one of the overarching goals of ASCA. We're not here to talk about the -- well, we are. We're not here to specifically correct any processes or

requirements in the standard, the 601 standard itself, because it's only a candidate standard for this scheme. It would be -- you know, we can contemplate that if it's too difficult to do this, that we select something else. ASCA will go forward.

If we're not mature enough, either as an industry or as an agency to do this, we don't have to do it. So we're looking for ways in which our regulatory paradigm becomes easier, becomes more transparent, more -- if you like, the term du jour is "least burdensome." And it's extremely burdensome if we find problems at the point of regulatory review.

Driving those things upstream is one of the goals of the ASCA program. So suggestions on how to accomplish that within the scope of 601 would be greatly appreciated.

MR. GILLERMAN: So I think you said one of the key words, and you used the word "community." So for the programs where I've been involved with federal government agencies who have used standardized industrial approaches to conformity assessment, one of the real keys to success is the ongoing communications that these systems create between the accreditation bodies, the laboratories, conformity assessment bodies, and the agencies themselves.

There's really not a lot of mechanisms for the community of accreditation bodies, the laboratories, to understand the expectations and share information about challenges with new products and new technologies, interesting situations where products don't really fit into the technical requirements and standards and how they might approach that.

And normalizing that across the body of, in this case, laboratories who would testing for medical devices has a tremendous value in the process. It sets the norm for the process, helps the organizations who are doing those conformity assessment activities understand what the expectations of the regulatory bodies are in the process, and helps the FDA or

other regulators have more confidence in the conformity assessment information that they receive and have to process.

FEMALE SPEAKER: I think a very easy starting point is if you can -- I know the gentleman from -- no, the lady from Canada mentioned about the commentary for the NA, NE testing results. Right there, I hope that it can be added to the report, with references to -- where there's the pointer to references that substantiate such decision. And that would be very good for the reviewer to really grasp it and then not, you know, asking many questions between manufacturers and reviewers.

The other thing is, regarding essential performance, I hope that the standard -- you can kind of more clarify definition of essential performance and the testing requirements. That's really, I think, needed. Then we won't have, you know, many no answers and no essential equipment, no essential performance, where there may be essential performance.

MS. LAROCHE: This is -- oh, sorry. This is Marilyn from Nemko Canada.

Regarding your essential performance question, this is clearly the defining summary of testing. So I'm not sure what else we should add in there because it's already defined. If a lab is qualified, it should be able to define what is the essential performance of the equipment it's testing and what the assumptions are before doing any testing. So that should be included in that section. I'm not sure which else we should add in because that's the policy of the IEC world.

MR. GROB: This is Alex.

I know we're talking about essential performance, and I think a couple of things we have to keep in mind, so the definition of the standard is very short. But that's not necessarily by accident. The reason is if we look at the scope of 601, it's intended to cover all medical electrical equipment. So the standard itself is not going to be able to define essential performance for the entire population of medical electrical equipment that exists

in the world.

One of the reasons that we have Part 2 standards is the intent of the 601 series is that the Part 2 standards will take and define essential performance where it's identified as something that's necessary for a specific type of device. So, for example, if we look at 60601-2-25 for ECG, it defines essential performance for an ECG. Certainly, we can't have that defined in the general standard for everything.

There's also products that don't have Part 2s, which is why the standard lays out a process by which the manufacturer -- and that's the part I want to make sure is clear -- the manufacturer has to identify essential performance. The testing lab's responsibility is to ensure that the manufacturer has identified essential performance or conducted a review to determine whether or not they have essential performance. And this is clearly spelled out in the standard. The evidence of that is supposed to be documented in the risk management file.

So the testing lab, when they're looking at compliance, their job is to see did the manufacturer do it? If they did, what was their conclusion? If they didn't do it, then they should have an issue that they need to address with the testing laboratory because the standard requires it be done.

If they've determined there is no essential performance, again our policy is we make sure that that answer is consistent with everything else we see as part of that overall testing activity, which includes additional documentation reviews and physical testing in a laboratory. If we find that there's a disconnect, then we go back to the manufacturer and say, you've said there was no essential performance, but here is evidence that we have found during our evaluation where we think maybe you need to reconsider that.

But ultimately the standards, both 14 and 71 and 60101-1, are very clear; that's the manufacturer's responsibility to identify essential performance.

FEMALE SPEAKER: So, Brian, I think you hit on one thing that's really important to us, and that was your use of the word "transparency." And unless we, as service providers, have some level of transparency to what the reviewers actually need, we don't have the ability to be that bridge between the manufacturers, the labs, and the reviewers.

So, you know, while all devices are different and, you know, as mentioned here, there's certainly not a standard for every possible scenario there, if the CB reports that are currently being used by the industry is a starting point, then the question becomes what can we mine from that report that will condense it to be something that a reviewer can use to move forward in a more efficient fashion once they get that?

And so I think that's probably a discussion that has to happen between the service providers and the FDA as to what they're looking for in that perspective.

MALE SPEAKER: Yeah. And this can't be brought up enough, I mean, the problems that this creates with not having a clear enough understanding. And one of the things that comes to mind, if you look at the FDA guidance documents on software or the 6304 standard level of concern, all of that is set there so that we understand the level of risk and the level of work that's expected.

And essential performance is not clinical performance. Yes, they're related. Clinical performance is -- everything has clinical performance, but not everything has essential performance. So not knowing what has it -- and I got back from a testing lab in China, and the test engineer said, well, if -- everything has essential performance. If they didn't have it, if things didn't have essential performance, nothing would work. And I said that's not what essential performance is.

Regulators don't understand this, what the meaning of essential performance is. I've talked with FDA people who say that dental equipment has essential performance, yet the -2 standard says that they don't.

So the amount of work that we're talking about is -- manufacturers are going to push for my device doesn't have essential performance. And the labs are going to say what? Well, we base our decision based on what the rationale, what we're given by the manufacturer. What if we're wrong? What if we're trying to, you know, justify getting out of a whole lot more building in risk controls?

And so I think that is -- without having solved that, and I think this could play a critical role in, you know, your competencies, and how can you assess the competencies to people who understand how to actually identify whether the lab is enforcing a proper review of that part of the test standard?

MR. TAYLOR: So I -- can -- I'm going to -- sorry. I had my hand up.

But so this business of essential performance is something that's been a pet peeve of mine since before I joined the FDA, and that is that the tendency of standards writers and regulatory agencies to take perfectly good English language terms and give them meanings that conflict with their natural meaning. And essential performance is a classic example of just that. The natural language meanings are often very vague and ambiguous, and a given word, if you look in a dictionary, can have multiple meanings and -- but definitions and standards should not conflict with all of them.

And the problem with the term "essential performance" is that every device has performance that's essential to satisfy its intended use. And that's essential performance. But in 60601 it's off the table, completely off the table. It's irrelevant because essential performance in 60601 is defined as that clinical performance that the absence of which leads to unacceptable risk. So that's just a narrow subset of what any rational person would think of as the essential performance of the device, right.

And that's the crux to understanding this dilemma that we have with the term "essential performance." And I'll go just a little bit further and say that Brian and I, as

engineers, even though we work for the FDA, we would never presume to define what the essential performance of a medical device is because we're not clinicians. We're only engineers. And that -- to the extent that there is a FDA review of the essential performance claims made by the manufacturer, that is done by the clinical review divisions in FDA, not by the engineers.

And since we don't expect conformity assessment bodies, test houses reviewing 60601 to have medical expertise, they should not be judging the essential performance of the medical device. However, as Alex says, if they see something that looks pretty glaringly out of focus with standards that they're familiar with that do specify essential performance, like the -2 standards, then yes, they should probably have that conversation with the manufacturer. And then the question should be, should that conversation be reported in the submission to the FDA?

So, again, I'm trying to be a little bit provocative here, but there is an awful lot of confusion, and I hope that helps a little bit.

FEMALE SPEAKER: Well, I'm sorry about that. I mean, I think the essential performance standard -- I understand that I shouldn't really be so specific because I cover, you know, so many different kinds of devices. But I do think it's kind of ill-defined in a way that -- leaving nobody kind of responsible or to clarify it. It's like -- and then coming to the reviewer's hand is only like -- I think the manufacturer leave it to the lab, and the lab doesn't really have a responsibility. But then somehow it just -- and then reviewer has to try to think about the device in clinical indications, all that kind of things.

I just think it's really leaving nobody kind of responsible to clarify the issue, and I do think it needs to be clarified.

MR. TAYLOR: So I do think the law does assign responsibility to the manufacturer, plain and simple. And to the extent that anyone else looks at this, it's an independent

review, and that's really where the discussion is, is who should do that independent review, and how's the best way to accomplish it to the benefit of all stakeholders.

MR. GHODS: This is Hamed Ghods from FDA.

Just clarifying, defining the essential performance is the manufacturer's job, but verifying the risk associated with that essential performance is engineering work. So in my opinion, the labs and FDA engineers should look into that perspective.

MR. DAVIDSON: Well, I kind of lost sight -- Dean Davidson with Intertek.

I kind of lost sight of where I was going, but I do want to make another oversimplified comment, right. Thinking about -- and again, the act of certification, and if we can say FDA approval is an act of certification, right, that always starts with creating a certification plan. All right. One of the first steps in any project inside a testing lab leading to certification is sitting down and looking. Hey, how are we going to approach the test? What do we need to do? And how is this going to go from here to certification?

So it seems strange to me that we're not talking about pulling that decision making forward in the process here. And maybe we are and I missed it, but, you know, it seems like such a simple concept to introduce, to prevent, you know, at the end, oh, hey, this device, we have all these questions, when we can answer most of those in the front. I don't know where that fits in all this but --

MR. FITZGERALD: So are you suggesting that some -- well, who should be doing this certification plan?

MR. DAVIDSON: Well, the certification body, right. You know, in a traditional product certification scheme, the certification body does this. Right. Our accreditors assess our ability to do this. And it's just an inherent part of what we do.

FEMALE SPEAKER: I don't quite understand, you know, how the certification will help solve the problem of clarify. All these issues come to the review, and the review can

get back to you very quickly. And that's really an incentive for the manufacturing to kind of join these programs. So I don't know how the certification can help.

MR. DAVIDSON: Well, just one simple example, and I'm not an engineer here. I don't evaluate products but, you know, a lot of discussion around essential performance and how to define that. So do that at the beginning, right. Sit down before you start a project and understand what do we need to be looking at here from an essential performance perspective.

FEMALE SPEAKER: Okay. Do you think that standard should define that as well?

MALE SPEAKER: So just to comment, so generally speaking, a certification is to a specified set of technical requirements. FDA approval is much broader than certified to a specified set of particular technical requirements. So the kinds of certification that certification bodies do, even for electrical medical devices in the current world order, is a much more limited system than what the FDA approval encompasses, right. The parameters and attributes of these products are much broader than what's undertaken by any single standard or even a series of standards.

So the FDA's task is very, very broad. And if you look at the value proposition in this program, it's to start peeling off the well-standardized, well-understood technical requirements of medical devices and so that the FDA doesn't need to expend their valuable resources doing that work. So the stuff that's already well understood, where standards provide the path to a tolerable residual risk, I think, is kind of the sweet spot for programs like this. The idea that any single private sector certification body is going to have the breadth of competency necessary to do a certification in lieu of what the FDA is currently doing isn't really plausible today.

MR. DAVIDSON: Yeah, and that's not really where I was going, but I can appreciate that. I'm just saying, have the discussion early, right.

MS. STERLING: Sorry. Brian, I think this was your previous comment, where you want things to happen upstream, right, which is what we might throw in the bucket of design review. Right. Manufacturers, while they're developing their products -- while -- manufacturers, while they're developing their products are really looking at what do I need to do to make sure, at the end, I comply with what I need to comply with. Right.

And the incentive to make that happen, for some manufacturers, is that when they get to the testing process, it sails through. You drop it in the laboratory or the certifier, whosever doing all that; it goes through because you've already designed it to be compliant.

But you can't make manufacturers do that. Some do it very efficiently, and some do not. I mean, we see products, and our industry has done a number of studies on first pass compliance. So if I'm a manufacturer, it's to my benefit to make sure that my product comes to the test lab, and it goes through on the first pass. I don't have noncompliances. I don't have to go back. I don't have redesign it. But not everybody does that.

And in certain specific sectors, the first pass compliance rate is, you know, maybe 20 percent, not even. Right. So it's a very difficult thing. It makes sense to do it on the face of it, but not everybody does. And so we see a lot of noncompliances.

MR. FITZGERALD: So one thing that we heard yesterday, I want to bring it up again, is with -- and I have my own experience with this. We heard that one idea might be for a manufacturer who engages in a Q-Sub meeting with FDA to bring along a liaison with their testing organization and at that point begin to contemplate what the FDA requirements for that particular product are.

We're doing this already for other technologies, which are in that essential performance universe. And it is from my perspective -- I invest a lot of my review time in these Q-Sub meetings so that the reviews are 20 minutes' work. That's 20 minutes that's going to happen 9 months away, but it's 20 minutes' work if I go to as many Q-Subs as

possible.

This is one aspect here, this notion of basic safety and essential performance, let's just keep it at the basic safety level here, that it has gone under the radar for Q-Subs. I've never been to an FDA Q-Sub with a sponsor where elements of basic safety have ever been discussed at all. And I think that we're not taking advantage of the rapidly opening communications vehicles that FDA is placing out there for people to understand what the expectations are so that they get the design right up front.

MR. TAYLOR: Yeah. So I actually -- does ASCA need an education component to help manufacturers bring to the test house something that's fully cooked? Is that a solution? And how do we define and implement that, if so?

MR. GROB: A couple of comments. The first one is we were asked yesterday to identify if we had any questions regarding terminology that was being used. I have a minor planet-sized concern about recent terminology.

So we've talked about testing laboratories and testing and certification bodies and certification as if those two things are interchangeable. At least, that's how it sounds to me. My opinion is those two things are not interchangeable, and changing what's on the slide, which is testing laboratories and testing, makes this a completely different animal.

I work for a testing laboratory. We are not a certification body. So it's important to me to understand, if we're looking for the answer being a certification body doing certification versus a testing laboratory doing testing, then I'm in a conversation that I can't really participate in because I'm not a certification body.

Oh, and the other answer to the question that was just asked is yes, I think education is very key to ASCA.

MR. EISNER: Leo Eisner.

So, Brian, you mentioned something about Q-Subs, or pre-subs, a lot of people call

them, and questions around 601. I think it's a lot to do with they have become a lot more popular, the Q-Subs, in the last 2 years roughly. And the lifecycle of development, you may just be catching the front end of it currently, that you haven't really gotten a lot of those questions. But I see essential performance as a really good Q-Sub question because manufacturers really do need to take the responsibility based on what the standard says.

And as I think Al said, the law also says it's manufacturers' responsibility. It is not the lab's responsibility. They're confirming that it's in the risk management, that they did what 4.3 says. And if they've done that, that's what the lab is supposed to do, no more, no less really, other than Alex's comment about if we see something hinky, that just we see a big shining light that there's some type of mistake around it, we'll bring it up. But past that, what's their responsibility?

MR. MARGIS: Thank you. Steve Margis.

I'm hearing two things here, and I guess in the interest of trying not to go too deep and bringing it back to ASCA, I think one thing that we're hearing here is that the process that's described in the model, in future versions or as you develop and move towards guidance, show that it might not be a one-size-fits-all, that there may be conditions where you have specialized equipment where it warrants multiple touch points. And I refer to that as stage gates.

There may be some product categories where those discussions happening early and having a checkoff will allow and enable ASCA to be more successful. On the interim steps, that will lead to a more efficient solution. So I think one takeaway that I have is that as the guidance moves forward, there might be some consideration for that.

The other takeaway leads back to comments I made yesterday, which is the term and the context in the way that we're using the word "testing laboratory" in 17025 I think is causing some cloudiness. 17025, if we think back to Warren's presentation yesterday, talks

about the act of operating a laboratory and performing reliable, consistent results, performing a test, having data, and in some cases, issuing a statement of conformity that that data met a pass/fail condition.

Taking data to the next level and pushing it to evaluation or audit or inspection or some other type of conforming assessment activity goes beyond the basic context of 17025. And so to Alex's comment, I think it's a valid comment. And I think one of the ways to consider solving this realm of discussion is, again, when we move forward and move towards guidance, that that box that says testing laboratory needs to consider what are the elements of conforming assessment that we're talking about that will provide value, and then having the appropriate conforming assessment mechanisms connected to that.

If it's audit based, there may be -- the accreditation may go outside 17025. It may go into other areas. But by describing those elements that provide value of conforming assessment and moving away from the term just "testing laboratory," I think we can have a real fruitful conversation and hopefully provide value propositions based on those two considerations.

MR. GHODS: This is Hamed Ghods from FDA again. Just to follow up on what you said, Leo, you're correct. Clause 4.3 requires the manufacturers to define the essential performance and do the risk management and apply the mitigations. But who's responsible or who's looking to the mitigations to make sure those mitigations are adequately mitigating risk?

And I have another question for test labs as well.

MALE SPEAKER: Yeah. Back to that earlier discussion we had on 16142 and the mapping of -- again, you know, the standard of all -- mother of all standards is the essential requirements because that's what the regulators are asking us to checkbox for the regulatory submissions, at least internationally and in Europe. So the 16142 will map over

what exactly the 60601 standard is good for. And as we've seen in the Annex Zs for the 60601 version in Europe, most of the essential requirements are not covered by that standard.

So you could focus in on those particular aspects of 60601 that do checkbox those, you know, areas for electrical safety, mechanical safety, and focus more attention on just trusting those right off the bat, which I'm sure NLLAP and the accreditation bodies are well able to immediately accredit with confidence those parts of the standard. It's just, you know, when you start getting into the whole areas of, you know, those -- you know, the muddy waters of the risk management process and the collaterals, that's where it starts, the ASCA program starts to serve a bigger purpose.

MR. GROB: So this is Alex again.

If I can go back to the previous question about who is responsible for checking the mitigations, so I think again, 14971, if that's the framework that we're applying, it's clear that the manufacturer is responsible for identifying the mitigations, for implementing the mitigations, and for verifying the effectiveness of those mitigations, all clearly spelled out in Clause 6 of 14971.

But the testing lab does have some responsibility under 601, but it's a limited responsibility. So in the context of 601, there are a number of requirements in the standard where I have a test followed by a verification that the device maintained basic safety and essential performance, or it could be one or both of those. So in those instances we have a responsibility to verify whatever the essential performance was specified by the manufacturer has been maintained following those tests.

Those tests are fairly limited in the general standard. They're expanded in the particular standards. But I also think we should, in many cases, understand that essential performance is not quite easy to define when we look at the 601 context because ultimately

what the manufacturer's got to come up with is some sort of a limit. So we will test them to a limit that they've predefined, and this is all based on the definition. And if they go beyond that limit, then the resulting risk is unacceptable.

So the performance is actually, what do I do to stay within the bounds of acceptable risk? So the testing lab would verify, sometimes by a test specified in the standard, sometimes by a test specified by the manufacturer, but only when it's required by whatever other standard we're applying. So if 601 is being applied, if the device is not rated as defibrillation-proof, we're looking at verification of essential performance primarily after mechanical testing. The only electrical test that requires it in the general standard is if I make a device that's rated to be left on the patient when they're hit with a defibrillator. Then I have to verify it still maintains essential performance. But otherwise, it's all mechanical tests.

MR. FITZGERALD: Elisabeth.

MS. GEORGE: So I know I just walked in, and I sort of was asked to come in so that there was some perspective from the manufacturer. So I don't know all the details of everything that everybody's been talking about, but a couple of things that come to mind for me is, is that, yes, the manufacturer is the one that's responsible. We are by definition the one that's placing the product on the market, putting it into the hands. We are the one that is ultimately held liable when there's lawsuits. We're the ones that, you know, have all those responsibilities. We can go to jail, you know, all those wonderful things that are all associated with design, manufacture, distribution of a medical device.

Specifically with regards to ASCA, you know, I think the focus of these 2 days is supposed to be on the pilot, not supposed to be nirvana, the end state where -- you know, my personal end state is that we stop having an FDA recognized list of standards, that we have all standards recognized through some sort of an assessment that allows for

attestation where possible, because the standard's been written in such a way that it has safe, effective, high-quality requirements in the standard to make it easy, you know, and I wish I could say that's going to happen in my lifetime, but it probably won't.

You know, I just came out of the Alarms group, and we've been talking about, you know, which version of the standard, because they've got a new one coming out and all that, how to deal with the fact that -- you know, this complete list of standards that have been identified. I actually have a product, one product that could have every one of those standards with it and, oh, by the way, a whole bunch of Part 2s as well.

So some of the questions that we've been asking is, is that, you know, we want to make sure that customer test labs, you know, the ones that I've got in my factory fall into this as well, not just the third parties, because we make use of our own. We also have to answer the questions ultimately in this guidance, how to deal with the fact that there's a whole bunch of standards that our products are going to be identified as compliant to that are not part of the ASCA pilot. So that's going to be things to consider. But I think the ultimate ownership really does go to the manufacturer.

I did hear from some of the test lab, and I was a little horrified to hear this, that they're being expected -- they get handed risk management documents that are deplorable, that they can't even understand them. They don't follow a process. So that is where they do have some obligation because I think they don't want to test to something that they don't know what they're being asked to test to.

But we go into contract with them. Hopefully, we're asking for the right thing. Hopefully, they're pushing back on us as a manufacturer to tell us, you know, you can't ask just for the 7th through the 47th page; you got to do the whole standard. You know, you can't just ask for it this one way, because if you're planning on selling in a foreign country, or you're planning on selling in the U.S., there may or may not be national deviations that

you didn't design to, you know, all those things.

So I think the bottom line is, is I think that that, you know -- what we want to try to figure out is, is that how all of us can take the ownership and accountability, particularly in the pilot. The pilot is not going to have every manufacturer, every test lab involved in it that maybe it -- there are pre-subs that are taught, that Leo talked about, are valuable.

Part of the reason they've gone up again, MDUFA, you know, that was something that we said, and the interactiveness. So I think we do need to have more iteration. I've already communicated to my colleagues that I'm embarrassed how few manufacturers are here because we're not having enough of a voice. I applaud the test labs and the accreditation groups that are here.

So I guess that's all I have to say until I get the mike up there and can say more.

FEMALE SPEAKER: Yeah. I really thank the manufacturer, the very low manufacturers here to clarify some issues. But I do have -- I understand the -- my understanding is the manufacturers' role to really define essential performance. But then still up to FDA to judge if that decision is correct or not. So that really up to the standard as well.

I mean, I think the standard needs some commentary, or maybe the guidance can give more clarification to the requirement in the standard, because essential performance defined as something, you know, without it will be lead to unacceptable risk. But then you can say, what is unacceptable risk? And then you go back to the risk management. You see the, you know, high risk, low risk, medium risk. What is really unacceptable? And there's really -- that's really vague, very ambiguous.

And then the judgment of FDA, have to really judge whether the manufacturer's decision is correct or not. And that really need a guidance from the standard; otherwise, you know, still you can't reach, make a good judgment. And that would really hamper the

consistency and particularly the issue of the review.

I'm sorry, to add, a lead reviewer usually don't discuss the questions until they give the consult to the electrical safety reviewer. They don't discuss it with the manufacturer beforehand. So they don't know it. That's the problem.

MS. CHO: Hi. My name is Stacy Cho. I am from FDA. I am the third-party program lead, just to throw more confusing language at you. So right now, even being the third-party program lead, I'm going to be very careful about when I say accredited and certified. This is more of a comment towards -- just as -- and an FYI, because there were elements that were being discussed earlier about essential performance and going beyond the standard and how that relates that I realized is very similar to some of the things that go on with the third-party review program.

So this is just letting you all know that the third-party review program is a program where we accredit -- we call it the "formerly known as the accredited person's program" to confuse even further. It's the accredited person's program, and what it does is it goes in, we get the application. We provide accreditation to certain organizations and say, hey, you can go ahead and review a file using -- and what we call that as a third-party submission. And then when it gets submitted to FDA, that's when we will either -- we will concur with your recommendation.

And that third-party review entails that more comprehensive review processes that we're discussing now, where it's risk management, things that go beyond the standard, essential performance and whatnot. This is not to say that the third-party review organization is the final word because, you know, FDA is the one that ultimately makes the decision, and they're not supposed to act -- they are not a consultant.

But I just wanted to clarify because it seemed that there were some overlapping areas. And I wanted to let you know that there is a program outside of this that kind of acts

as an accredited body on that behalf.

CAPT COLBURN: So I asked Stacy to speak to that effect, just to help clarify that ASCA or the role FDA is having with ASCA is not to become a certification body to the testing labs where the standards are being incorporated for the pilot. There is an analogous type of certification program through the third-party 510(k) reviewer program, but that is a completely separate entity. And there are people in this room that have, you know, their organizations involved in the third-party reviewer program and manufacturers who have utilized it, but it is a separate entity.

That being said, manufacturers who are submitting their submission to either FDA directly or through a third-party review program can use the ASCA pilot, in terms of which standards they would want to have participated, and it would follow the same pathway, regardless if it was to be reviewed by a third-party review program or through the FDA as the primary review source.

So I just wanted to help clarify that because there were some questions online, and I think it came up a few times too, are we acting as a product certification type entity through ASCA? The answer is no. That's why there's only a small handful of standards that ASCA's addressing. You couldn't do a product certification through the standards that we have put up there. There's no way possible.

And even with all the standards we recognized, it is very rare where you can have standards complete all the essential requirements or areas that we would want to see for a full submission. I always say equivalent -- or conformance doesn't give you equivalence. It doesn't give you approval. It fills in a lot of pieces of the puzzle, depending on the product you have, especially if you have a product-specific standard. But it's never -- it's very rare that it's the complete picture.

Now, there are other programs, too, that are trying to enhance where standards can

fill in those areas more. Jeff spoke to that yesterday with the Expanded Abbreviated 510(k) program where FDA is looking to find ways to where our standards, you know, where are standards have gaps right now. And some of those gaps we discussed, you know. Where are the specific endpoints not baked into the standard or certain procedures that could be called up more? Where could we help fill in those gaps to feed those standards so they could be more appropriately, you know, the reports can more appropriately identify how they've met the endpoints that FDA has determined to be acceptable that aren't baked into the standard because of the way the standard is designed?

An extraordinary challenge, I would say up front, but that's the idea of the Expanded Abbreviated 510(k) program is to put more effort into the standards to try to overlap what might be missing to help a laboratory understand where are the boundaries of acceptance criteria, to help a manufacturer make a determination -- or not a determination but understand how their declaration of conformity would demonstrate from the testing that they, in fact, met the criteria that would be acceptable, so the declaration of conformity would have further meaning rather than some question.

Now, that's an entire different program, too, outside of ASCA. ASCA is designed to -- how can we build the confidence, after we identify some gaps where testing laboratories are accredited through the working of an agreement in an accreditation body. But what can we do, from the manufacturer to the testing lab, to improve that relationship by having a direct line into the testing laboratories to give some perspective on what is it that we're hoping that you would see when a manufacturer comes to you?

How could you improve your dialogue with a manufacturer before going into contract to ensure that the types of tests being selected are best representing, hopefully, what we're trying to see here? And what can we do to work with the manufacturers to improve either our guidances, the standards development that we have, all these extra

tools in these evolutions?

Thank you, Stacy.

MALE SPEAKER: Yeah. I've done the third-party review program, and then I can see that they'd be a stakeholder in this in some way because they'd be acting as a reviewer of the file. And if ASCA has a role in that, I can see that being important.

One of the things that came to mind is that this word "essential performance" keeps coming up, and it's really tied in to this other word that used to be even more ambiguous, which is called "state of the art." Fortunately, "state of the art" is defined in 16142 and 14971, and so you can look there and see. And we're really talking about, you know, how much work do I need to do with the lab if my product is across a threshold? And we're talking, what's unacceptable risk?

And I think the amount of control that we put into controlling that risk is going to be -- the state of the art is going to be what the FDA currently accepts as a profile of how much harm you may do and the probability of that harm. That's the risk. When it becomes unacceptable is when it's less -- or more risk than what's already out there in the market.

And so essential principles or essential performance are kind of tied together by trying to maintain enough risk control so that it's acceptable within the market. And I think it might help to look at the definitions for state of the art in terms of how we manage risk, how much risk control we have, so that when someone says, well, I don't need to do that because my product doesn't have essential performance, you say, well, everybody else on the market does this much, and you're not doing that, so you need to bring it up. And that helps at least bring the risk into that level of the state of the art, whether or not the product has essential performance.

MS. GEORGE: So I just wanted to comment on two items, one specifically with regards to the standards. Again, full compliance to any standard is not something that a

test lab can do. A lot of the items in that are the -- again, go back to the responsibility of the manufacturer. The test lab can maybe give feedback, tell us that it's poor quality, that our labeling -- maybe, you know, they've seen 20 labels from other companies; as was described, you know, there's some levels of threshold that they could give feedback on.

But I think that, again, the challenge ends up being is, is when you say ASCA certification to a standard, it's not just the test lab, it's not just the manufacturer. It's going to be that combined activity.

The second item is with regards to risk. And I think that one of the things that maybe some of the people in the room are not aware of, but at least in the 30-plus years that I've been in regulatory as in medical device industry, the risk management process, we've always had it. It's clearly far more robust today than it was 30 years ago. But what we do is there's -- it's many, many, many, many hours, locked in rooms, cross-functional teams, doctors; there is even lawyers sometimes in the room, God forbid.

There is every function in the room, and every risk is looked at. And just because -- you know, the company I work for, we've -- it started as Hewlett-Packard patient monitors, so we've been designing those for years. We don't just sit there and say it's been that way forever. We always have somebody that questions it. Marketing always has the risks really low. The doctors and the nurses always have the risks really high. There's lots of discussion.

You know, they want to -- a nurse wants to design everything so that it'll never, ever break -- sorry, Scott -- you know, versus marketing wants it as cheap as possible. There's that back and forth. Regulatory is usually there to push back as well because we're there to address the current interpretation of regulations, current interpretations of standards.

So the answer always is what is acceptable and unacceptable? It depends, is always the answer. And it depends on the environment, on the user, on how automated, how

non-automated it is, what it's connected to, its interoperability, the implications of, you know, wireless.

We were just talking about the alarms again. We were talking about distributed alarms. What's it distributed to? Is it distributed to my cell phone? And what's the purpose of that distributed alarm? Is it for just FYI, hey, something happened? Or is it truly, action needs to be taken?

So it depends. And there is no one answer. And one of the discussions we had in the other room as well was -- is that looking at the competition, looking at -- you know, you mentioned it, looking at what is current industry practice -- that's where a key stakeholder, that we mentioned it yesterday that's not here, are the patients and the clinicians because they are the ones that ultimately have to live with whatever the risk level that we determined was acceptable.

FEMALE SPEAKER: Well, thank you so much for all these information. But in considering of that, I mean, in light of that, I think maybe the guidance documents can really, you know, clarify some of the -- I think maybe the information all there. Either they're not really organized or scintillated into, how do I say -- maybe that guidance, all the standards should clarify that unacceptable risk can be quantified in some way in a risk management file. And then that would be very clear and consistent across the board.

You know, if it can be said, unacceptable risk means, in the risk management profile file, certain kind of occurrence, or risk profile, this is unacceptable, then, you know, then it would be consistent. And then it would be, you know, for the reviewer, the industry, would be all better off.

MR. GHODS: This is Hamed Ghods again, from FDA.

Just as we're going to write the scheme down the line and, you know, I've been thinking about this and how it can fit the particular standard into the scope of the scheme,

and I have a question. My understanding is the IEC's structured this way, that to evaluate the device, if there is a particular standard exists, you start with the particular standard, you work backwards to the main standard.

So, in other words, to have a compliance to the 601, the main standard, if there is a particular standard for the device, you have to comply with that or you have to -- it takes precedence. I have seen, in many situations, that I receive a test report for the main standard, and there is no sign of the test labs or the manufacturer have even -- they've thought about that particular standards or have evaluated those.

So when it comes to the particular standards, who does the determination that what particular standards are needed to be looked at for the device? Is it test lab? Is it manufacturer? Does test labs have any leverage on that? If the manufacturer comes and say, we just want to have the main standard, how you deal with this?

Thank you very much.

MR. GROB: This is Alex. I'd love to answer that question. And I think I made reference to that yesterday in the presentation, that really the first thing is figuring out the scope.

So you're correct that if a -- in the 601 series, really to actually claim compliance with the general standard, you have to comply with all of the applicable additional parts, which means the -1s, the collaterals, and the -2s, the particulars. That's what a full claim of compliance with 60601-1 general standard means, that I've applied and met all of the requirements from the applicable parts of the series.

But given the accreditation scheme that a testing lab might use, we certainly don't always follow that when we issue a test report. So if I'm working with a manufacturer, typically we'll say, looking at your device, we usually ask for something like the instructions for use, the intended use statements, to help us figure out what should be applied before

we get into the activity of actually doing the testing. So we're just at the scoping phase.

So we'll develop a list of the requirements that we think should be applied, based on information we gather from the manufacturer, which may include where they want to sell the device, in what countries, because we know certain countries have different requirements. Also, what type of report they want; if they want a CB report, we know certain things have to be included.

But it comes really down to a question of time and money. So if a manufacturer says to the testing lab, I understand that 60601-2-50 applies, but I don't want you to test it, we can certainly issue them a test report for the general standard only as long as it's not a violation of any of the accreditation rules that we're applying for the generation of that test report.

I know internally we have a practice where we would identify those items as this was not applied based on the manufacturer's request, but there's certainly nothing that requires us to do that. It's just something that we've decided to do for clarity, mainly because we don't want our test reports to be called into question. And this is one reason why we find our test reports have been called into question, because the test report is -- contains what it contains, and someone else like the FDA or a notified body or other regulator may look at it and say this test report should include additional information.

And our customer will come back to us and say, well, you gave us this test report, it didn't include all of this information. And we say, well, that's because you told us you didn't want it to be included, and you didn't want to go through the process of having us run those tests. Ultimately, it's because of cost, 99 percent of the time.

So we can issue a report that doesn't include everything that's applicable, but usually that's done through discussions with our customer, to make sure that they understand the risk associated with that. So that's the answer to that question.

The other thing I wanted to just quickly mention is risk is subjective. And I mentioned this yesterday in the presentation as well. So, again, the standards are clear. The manufacturer defines that level of risk that's acceptable. That means anything below that level is unacceptable. And I don't think, as an industry, we want to be in a situation where the test lab is the test or the deciding factor on whether or not risk is acceptable. That's really not our expertise.

You don't want to send a product to the lab and have Alex's requirements for whether or not your level of acceptable risk is okay. It's something that the manufacturer defines, and certainly should be defendable, but you don't want to have me judging whether or not your risks are acceptable because I will have a different opinion than the person sitting next to me in my lab, or the person sitting down the road at the competing lab, or maybe even someone else sitting within the manufacturer.

So it's something that we typically will say to our customers, when we're in a situation where we run a test and there's a risk review required, and we tell them this is what happened. And they may ask us, well, do you think that's okay? And our answer is you don't have to convince us that it's okay. You have to decide whether you think it's okay, and you may need to convince someone else, like a regulator. But you don't have to convince us. Our role is to verify that you have decided it's acceptable and document to that acceptance, not to convince us that it's acceptable.

MR. TAYLOR: Thank you, Alex. And at this point, it's just a few minutes before 11 o'clock, so any of you who has either a burning thought or a nagging thought that hasn't been expressed and should be on the record, now is the time.

MR. RAMALEY: I just want to, again, just remind people. From the Dental Trade Alliance, a lot of our customers are -- or members, I should say, are small companies. The people who do the risk management file is one person who's unlucky enough to be assigned

to also be the quality manager. And so a lot of the small companies -- and we'll look at the statistics, 80% to 95% of manufacturers are small, when they get to this part of doing the risk management -- and some of them have been doing it for a while -- they're perplexed when they get into the 60601 environment because they're trying to fill out these risk management file requirements for 60601 and being asked to do risk estimations for things that they've never seen with their products, even though it's a family-owned company that's been around for 30 years.

So there's a lot of wasted time trying to imagine a probability of occurrence or a level of harm because there aren't any with their products. And then they're spending $20,000 to fill out forms for things that are completely unnecessary.

So the reality is most of the manufacturers that are smaller are having real issues with the risk management file, when in the 60601 context, especially since they're taught within the 14971 context, more of a fault tree analysis approach, where you look at actual real problems in the -- out in the field and you address those, which can be semi-quantitatively, you know, positioned on a risk management file with some level of certainty because there's evidence of it.

So I just think that when we get into the whole issue of risk management within the testing lab, it's a real problem. I think the FDA needs to help. This could potentially help a lot in that regard because there's just a lot of missing components there.

FEMALE SPEAKER: I think I have burning issue as a reviewer, is I do hope to see that the unacceptable risk can be defined qualitatively or quantitatively in some way in risk management requirements. Maybe you must simplify it into some kind of just a risk management -- risk evaluation of the critical function, or essential function as they think. And then they can quantify this into something for even for state-of-the-art safety in a market, state-of-the-art risk and safety in the market, or some quantification that we can

have a very consistent view of this unacceptable risk, at least, I mean, relatively consistent, I mean across the devices of the same kind, so that will be really -- lead to very predictable and then consistent review.

MR. TAYLOR: So I guess I want to say that some small manufacturers make products that have large risks, and some large manufacturers make products that have small risks. And so I think that the size of the manufacturer is a separate issue from the safety of the device. And our obligation is to assure that the devices are safe.

On the other hand, we have to recognize, I think, as a society, and certainly it's on FDA's plate to recognize that there are situations where small manufacturers need a little extra assistance. And I actually think that NIST has programs to help small manufacturers and provide that extra boost, and they may be underutilized. So there's lots more to talk about in that area. But I did want to acknowledge what Grant had -- the point that he's made several times. And I think it's important to acknowledge that because the small manufacturers are probably not in the room, and they're not on the web because they're too busy doing what they're doing, so --

MR. FITZGERALD: I should also point out that many states have industrial outreach, industrial extensions, which can help facilitate many of these difficult hurdles as well. And perhaps we need to consider more outreach to those too.

MR. GILLERMAN: So just to follow up on Al's plug for the National Institute of Standards and Technology extramural programs, there is a Manufacturing Extension Partnership operation in every state in the union right now. So I'd encourage small to medium-sized manufacturers, if you need assistance in high technology manufacturing or these kinds of issues, to reach out to your MEP center in your state.

CAPT COLBURN: All right. Thank you very much. Al, Brian, I thank you for facilitating, and everyone participating. I think we've heard a lot of really good discussions.

And I've seen, over the last half hour, the other breakout sessions have come in to join.

(End of breakout session.)

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 23, 2018

Silver Spring, Maryland

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

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SHAYLAH LYNN BURRILL

Official Reporter