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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICES ADVISORY COMMITTEE

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PUBLIC WORKSHOP - MEDICAL DEVICE SERVICING AND REMANUFACTURING ACTIVITIES

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M E E T I N G

(8:05 a.m.)

DR. SILVERSTEIN: Good morning. If everyone could find their seats, we're going to be getting started. So just a few logistics before formally start today's sessions.

Number one, someone has lost their cell phone, and it can be found at the registration desk.

If you were not here yesterday, there are restrooms out this way in the halls. There's Wi-Fi, there's no password, so hopefully you're able to get on. We have coffee and water in the back.

If you lost your copy of the agenda, there are some at the registration desk, but we have just a half-day session, and we have two breaks as well.

So, with that, Dr. Shuren, who's the Director of the Center for Devices and Radiological Health, is going to provide some opening remarks.

DR. SHUREN: Well, good morning and welcome, everyone. As you heard yesterday from Bill Maisel, CDRH's mission and vision is not just to assure that U.S. patients have timely access to high-quality, safe, and effective medical devices, but also to assure that devices on the U.S. marketplace remain high quality, safe, and effective, and servicers play a critically important role in meeting that objective.

In May 2018 FDA issued a report on the quality, safety, and effectiveness of servicing of medical devices in accordance with Section 710 of the Food and Drug Administration Reauthorization Act. The report, in part, discussed some of the challenges and opportunities for assuring or continuing to assure the quality of servicing, including around the adoption of quality management principles, addressing cybersecurity and evidence generation to assess the quality, safety, and effectiveness of servicing. One of the actions we committed to take is to issue guidance to better clarify the distinction between

remanufacturing and servicing, which was the topic of yesterday's session of public workshop. Today we turn to other aspects in the report. As we noted in the report, we did not identify systemic problems with device servicing, recognizing that the available evidence is limited. What is clear is that all of us share the common objective of assuring devices are high quality, safe, and effective, and that all of us believe in the critical role that servicing plays.

However, there are differing perspectives as to what, if any, steps should be taken to assure or continue to assure high-quality servicing. Regardless, I think we can all appreciate that technology and our ecosystem continually changes, and therefore, even in the absence of overt problems, we must continue to evolve to assure the continued safety and effectiveness of medical devices.

Given the variety and complexity of both the issues and the technologies subject to servicing, we believe that the best approach to determine any additional actions should be through a collaborative effort involving all the key stakeholder communities. We were encouraged that there are nascent collaborative discussions, and what we would like to achieve by the end of today's session is the following:

- First, to determine if there are areas or those areas or issues that original equipment manufacturers and independent service organizations both believe are important for assuring high-quality servicing and may warrant additional actions to maintain that objective;
- Second, to determine whether there is a shared interest to identify and implement those actions collaboratively;
- Third, if so, identify the entities that commit to participate in that collaboration, and the entity or entities working together that should and would serve as the convener for this collaboration; and then, finally,

- To establish time frames for deliverables.

FDA appreciates and respects that there are different perspectives, and many of the challenges previously raised are not easy to address. We also acknowledge that within Washington there is continuing interest in collaborative solutions but also a desire that the FDA be more assertive if the community cannot reach resolution. Now, you know that's not our preference since our measure of success is that nobody is happy. So if everyone around the table here is miserable, we're doing a good job. And if all of you are wretched, we're doing an excellent job because part of our vision is to strive towards excellence in wretchedness, and we're very good at that.

Now, should there be sufficient interest in and commitment to a single collaborative effort with timely deadlines, FDA will commit to actively participate and continue to report out on the progress made to Congress and our other customers.

In addition, as long as the outcomes of collaboration are not contrary to our statutory mandates and are in the best interests of public health, we will strongly consider adopting and supporting the results of the collaboration and would consider taking appropriate actions if recommended by the collaboration.

Should there be interest by OEMs and ISOs and others in the device ecosystem in addressing shared objectives and solving shared problems on an ongoing basis, parties may wish to establish what we call a collaborative community, which is one of CDRH's strategic priorities over the next 3 years. A collaborative community is an ongoing forum where public and private sector stakeholders come together to achieve shared objectives and address shared problems on an ongoing basis, in an environment of trust, mutual respect, and shared accountability. What's a little unique in that undertaking is that we, as government, do not lead it; it's not our effort, but we participate as a member of the community, and as I mentioned, if the actions that come out of that collaboration are not

contrary to our statutory mandates, we believe, in the best interests of public health, then we would be willing to go along where the community would go for a solution, and that is a very different approach to the standard approach we usually take in government. And, of course, if that is where the community wants to go, we would engage with OEMs and ISOs in that collaboration and ultimately go in the direction where the community wishes to go in.

So, with that, I will now turn it back over to Josh to talk a little bit more about today and start with introductions of today's participants.

DR. SILVERSTEIN: Thank you, Jeff.

So before we were holding this panel, we spoke with all of the panelists, and we asked them to start off with three items, but we're going to start with introductions, including their organization, if applicable, describe recent or current efforts to collaborate with other stakeholder groups, and then, three, identify areas they feel most amenable to collaboration. And so I'd like to ask all of the panelists to maybe just take 1 or 2 minutes maximum, and we're going to start with Amra.

MS. RACIC: And because I'm going first, I get more than 2 minutes, right? Just kidding. So thank you for this opportunity. Thank you to the FDA and everyone for putting this together. So my name is Amra Racic, and I am with Medtronic's corporate regulatory advocacy and policy group. Our job is to focus on identifying, leading, executing on Medtronic's global regulatory advocacy initiatives. We also work on internal policy, so we develop internal policies, revise them, make sure that they're distributed to our teams, training and things like that, everything to assure compliance. I've been in the healthcare sector for close to 20 years, a little over 10 of those spent with Medtronic and most of it really in a reg affairs function. So what can I say about Medtronic? I think most of you are probably familiar with who we are. It happens to be the biggest medical device

manufacturer in the world today. We, all 86,000 of us, are located in some 370 locations worldwide in 160 countries. Two of our devices are picked up every second of the day to help improve a patient's life, so think about that, two devices on a daily basis. So in the course of an hour, about 7,200 devices are used to help improve a patient's life.

Our company is divided into four major businesses: CBG, MITG, RTG, and diabetes. And in terms of servicing, our two main businesses are primarily affected, so our cardiovascular group and our minimally invasive group as well, so devices that generally would need a repair range from blood collection processing devices to various ENT equipment, neurosurgery equipment, as well as ablation devices, just to name a few.

Our servicing organization is also quite large. We have some 2,000 individuals that work in that space, and their mission is really pretty straightforward, too. They start the mission, just as Medtronic does, with the patient and service provider's safety. So we keep that at the forefront of everything that we do. Only individuals trained on specific product lines get to service that particular product line. We work with many authorized service providers around the world. We only use parts from our supply chain, and we do not sell our parts on the open market. Servicing, we really see that as very much a team effort; obviously, from technicians, engineers, regulatory, quality, supply chain, customer service, these are all cross-functional partners that need to come together in order to make this happen.

As far as the two additional questions, Josh, so recent events to collaborate, so as I stated, we work with many authorized service providers around the world. The hospital role really depends on the product line, the agreements in place. It's very much a risk-based individual approach. We work with biomeds as well to try and get them up and running; however, we haven't really invested too much in that space. There just doesn't seem to be much interest. And then also we've organized an ELP, where FDA has come out

to one of our facilities and kind of observed the operations of servicing, and I think it's been a valuable lesson for us all. As far as the areas more amenable to collaboration, certainly there are many, and we are more than happy to participate and encourage participation, of course. I think our key is as long as these collaborative communities don't take over any sort of quality management requirements, if they're not intended to replace quality in any sense, and also we want to make sure that our intellectual property is not compromised in any way, that's key. So certainly there's opportunities. I'm happy to work with the FDA and the rest of the organization.

Thank you.

MR. TREVINO: Good morning, my name is Scott Trevino. I lead quality, regulatory, and medical technology at TriMedx, a large independent service organization that manages well over a million assets. Today I'm here to represent the Alliance for Quality Medical Device Servicing and speak on behalf of that alliance.

The alliance was formed as a direct result of the recent activities that were discussed yesterday and really in response and preparation for response around the report that came out in May. We consist of a number of large ISOs. Our membership includes Sodexo, TriMedx, of course, Aramark, Crothall, ABM, and the InterMed Group.

And a brief update on what the alliance has been doing: In response to the request to consider and work on the four topical areas as a collaborative community, our alliance decided to start by pulling together a wide segment, as we saw it, of folks and participants in the market. So we held a summit a couple weeks ago at the end of RSNA in Chicago. We invited directly OEMs, providers, ISOs, third parties, as well as participation from AAMI and ECRI, so a small group to determine what interests and identify what interests may exist, common areas for potential work around the four topical areas. So, of course, we discussed servicing and remanufacturing, as well as strengthening cybersecurity practices, promoting

the adoption of quality management principles, and finally, fostering evidence development and the collection of data. Briefly, what I would say is around the first topic, there was common ground reached and identification of what seemed to be, in our opinion, a need for more work in this area, and what I will mention is we are going to publish a summary of results from that meeting as well and publish those. It's a little soon after the meeting, so we should have it out early next year. So we think there's common ground there to be had. Again, this is a first foray into that arena.

On cyber, I'd say there's also common ground that was reached, at least in that group discussion around, you know, inventory and devices, cyber events, patch management, training, and a number of other areas I think we'll discuss more today.

Around quality management principles, what I would say is that that's a little less clear. I think there is a lot of interest, but I think more discussion is necessary to understand what that means. And, finally, around data and evidence development, I would say, similarly to quality management principles, a lot of passion, a lot of opportunity there, but again I think more clarity and specificity is needed to determine what particular opportunities exist. That's all I have.

MS. FEDERICI: Good morning, my name is Tara Federici, and I'm Vice President of Technology and Regulatory Affairs for AdvaMed. I manage a very active working group that focuses on third-party servicing issues.

Just a little bit of background: I've been with AdvaMed for 25 years, so I have a long history with the industry. I've certainly seen the changes of the industry over the years towards more complex, more technical devices, which I think pose greater challenges for servicing, particularly if you're not using quality systems or trained in those particular devices. I've also seen, you know, an increasing number of challenges for the industry as a whole. It is harder, and there are more barriers to getting devices to market. There are

more demands for intellectual property of companies to be shared. So those all create challenges for the industry as a whole, which are going to influence the industry's thinking in this space.

When I was asked to participate on this panel, I was asked if I was participating in any collaborative communities, and I said, well, I'm not aware of any, so obviously I haven't been asked to participate in any communities. It's a little difficult to participate in a community if you have to go searching for it, and it's not clear how you would find a collaborative community if you're not an invited participant. But, obviously, I would think that OEMs would be a key stakeholder in a collaborative community and should be a relevant participant.

We have given some thought to kind of the principles surrounding the use of collaborative communities. So if AdvaMed were asked to participate in a collaborative community or more than one collaborative community, we would prioritize participation in collaborative communities that are listed on a publicly accessible website as a collaborative community that includes FDA as a participant. I mean, obviously, I think we all are aware that part of the reason we would constitute a collaborative community is because you want to help shape and influence FDA's policy and thinking in this area, so we would prioritize those with FDA participation, and we would hope that FDA would publicize the collaborative communities that it is participating in on its website.

As I said earlier, we would hope that those collaborative communities would include the key and relevant stakeholders, because if you want to achieve success in this area, you've got to have the right parties at the table, you know, and from a housekeeping perspective, we would want those entities to be seeking input on and publicizing agendas, listing times and locations with meetings, and allowing web conference and dial-in options, and maintaining records and minutes of meetings and participants. Those are all just good,

you know, meeting management principles.

So, with that, I think I'll stop and then, you know, I assume we'll continue to have an opportunity to dialogue, and we have some other thoughts.

MR. ANBARI: Good morning, my name is David Anbari, and I'm here wearing two hats. My primary hat is the CEO of Mobile Instrument Service and Repair. We're a 40-year-young company that repairs surgical devices and instrumentation for hospitals and health systems around the United States; we have a national footprint. Some of our services are provided on location at the hospitals, and we actually do the work there to help minimize the downtime on the equipment, and then some of our more advanced services are provided from our repair centers across the U.S.

The second hat that I'm wearing is I chair the Association for Medical Device Service Organizations, which is a trade organization that we formed to help advocate quality systems, risk management principles, and promote collaboration among any organization that services medical devices other than just the ones that they manufacture themselves. So it is wide open, wide open to manufacturers that do multi-manufacturer servicing. So that's me.

In terms of collaboration, through our trade association -- and I guess the easy part of this is everything that I talk about is really both my company's position and the association's position, so it makes it very easy. In terms of the collaborative things that we have been doing as an organization, we have worked very diligently to interpret the ISO 13485 standard to an independent service organization. So we've gone through individual requirements, one by one, to reinterpret those, understand them, and make sure that there is an intelligent application of that to a service organization. We've done much the same thing with the risk management ISO standard as well. And my colleague Gary serves as our executive director, and he'll speak a little bit more about some of the other industry

organizations that we have engaged with, ranging from AAMI standard setting; in some cases we've worked with other trade associations or professional associations specific to the types of equipment that we service. Clearly, one of the biggest opportunities for further collaboration is to better engage manufacturers. You know, we've made some efforts in that regard, but to be fair, if we don't find a door that's wide open, we tend to turn and move on to the next thing, and I sincerely hope, through this workshop and continued activities afterwards, that we can look for more common ground with manufacturers, you know, give them greater assurance that, no, we're not trying to stand in the way of the quality of your devices; we're trying to help your end user/buyer community maximize their return on those devices, ensure their safety and ensure their efficacy in the long run. That's probably the single biggest opportunity that I see to move things going forward. So, with that, I'll pass it along.

MR. PHILLIPS: Thanks, Dave. Good morning, my name is Robert Phillips. I work for Siemens Healthineers. I'm the head of quality and regulatory for North America, which includes kind of the U.S. and Canada. As you may know, Siemens Healthineers is a global manufacturer of clinical diagnostics and medical imaging equipment, but we're also a servicer of that equipment, and we're also, interesting enough, a third-party servicer of other manufacturers' equipment. So I think when we look at this entire servicing ecosystem, Siemens Healthineers actually wears three different hats, and we're very interested in participating in collaborative communities and supporting any activity that affects increasing servicing quality in this entire ecosystem.

From a collaboration perspective, Siemens Healthineers has certainly participated in various trade association and standard-developing organization activities to increase knowledge around servicing activities, whether it's the participation in the development of a white paper or the participation in the standard itself. We also recently participated in

the Association for Quality Medical Device Servicing collaborative community that occurred in Chicago a few weeks back. And so we are, again, very interested in continuing supporting this industry, continue supporting the service activities across all stakeholders, and certainly want to participate in more collaborative communities as we move forward.

I think when I look at our opportunities, and maybe this is low-hanging fruit, maybe this is, you know, Dr. Shuren, where we have shared interest. I think the two areas where we could continue to collaborate very easily on, one is around training, and the other is around documentation requirements.

So on the training aspect, I think there's two majors to that training. One are the general training aspects of the technology that occurs in the field. So, for instance, if I take an MRI system, what's the theory of MRI and what are the operating principles of MRI? And I think having that knowledgebase for all of the servicers that are performing MRI servicing is going to be really helpful for them to perform that risk management activity that we've talked about in the past, of what are they doing, why are they doing it, and what's the impact of what they're doing.

Then I think the next step in that training is providing product-specific training, and that may be around each manufacturer's particular product, but it also may be around the clinical utility of each product attribute or enhancement or opportunity with that product itself.

And so I think that's just the next layer above the general theory and operating principles of a product line, and I think that gives every servicer an opportunity again to understand what the impact of what they're doing has on the overall operation of the device and potentially to the patient and the operator safety and efficacy of the product.

The second component that I mentioned was around documentation because I think when we go into an account and we perform servicing, I think it's really important that we

identify what the current configuration of that device is that we're servicing and the configuration of the device as we leave it. That ensures that the next servicing entity that comes along, whether it's Siemens or any other company, understands the starting point for where they're at. They should also be documenting what they've done, if they changed out parts or parts were changed out, what's the provenance of those parts, if they know, so that we can actually trace back any issues with those parts back to the vendor itself. And so I think this is information we all can agree on that would be helpful within a service record itself. And so those are the two areas that I think we could continue to collaborate on moving forward. I'll hand it off to Rob.

MR. KERWIN: Thank you. And thank you. And thank you, Dr. Shuren, for your opening remarks. So I'm with IAMERS, the International Association of Medical Equipment Remarketers and Servicers. I've been their general counsel for 24 years now, and I had the privilege to appear before Congress, the Energy and Commerce Committee, on IAMERS' behalf on some of the legislation, and you know you're really doing well when I'm appearing in front of Congress and I get a text from my daughter that says, Dad, I can see your bald spot on the top of your head.

(Laughter.)

MR. KERWIN: So things are good. But we are very interested in the collaborative communities. Diana has published her thoughts about trust, and I'm sure she'll elaborate more. At the suggestion of MITA, Peter participated in some association discussions with AMDSO and with a representative of ACCE, and we've talked to TriMedx about getting involved in having further discussions.

In our initial discussions, we were attempting to establish some boundaries; you know, could we get an agreement from those participating that concomitant with this, that they would be ceased lobbying on the very same issues -- we continue to follow, as perhaps

many of you do, in the U.S. Congress, what has now been millions of dollars spent by manufacturers and trade associations on servicing issues. Would that money be better spent on things such as the training programs and the collaborative communities? We have not seen that there is an agreement to cease the lobbying activities in this area, and that speaks to the trust issue.

And we've got some asks that we think our 2018-2019 asks in connection with this end-of-life issues. Many of our regional and rural hospitals, which our 130-member association serves, continue to have equipment which is functioning well, and we ought to be in a position where we can receive some support on end-of-life issues because these hospitals may not be in a position to buy new equipment, and we think there's some value with that.

And, more recently, one OEM has been doing an MRI software upgrade, ostensibly with enhanced security, specifically changing from a 20-digit service code to a 100-digit alphanumeric code, and our ISO members are telling me that they're not getting access and connection with this. We don't think cybersecurity should be a place which has an effect, perhaps collateral, perhaps not, to exclude choices for the hospital in using independents.

So we feel, also, that as much as we wish collaboration, there needs to be accountability, and we're hoping FDA will reestablish its phone number and its contact person in connection with potential trade complaints so we can have accountability. I mean, the reality is multi-vendor has been working successfully, and many of the manufacturers have the very same issues as independents. So we're hopeful that something can be done. Maybe it needs to take place at the C suite level to have OEM full participation, but we're still talking, and we're here to talk further.

Thank you.

DR. SILVERSTEIN: Sorry, Pat, before you get started, I just wanted to remind

everyone to take maybe 2 minutes, 3 minutes, because we still have about 10 people left on the panel. Thank you.

MR. BAIRD: Thank you for the reminder. I'm Pat Baird from Philips. I'm a former software engineer, okay, so if you couldn't tell by the hair, but now I work in standards and regulatory. I have an absolute passion for collaboration, and so I'm active at AAMI, active in MITA, active in AdvaMed. I love working with other people, seeing other people's point of view, refining my world view.

I am a member -- there is a recently launched, very much in its infant stage, there's a benefit-risk collaborative community. We had a meeting, I believe, a month ago as a kickoff, and it was just sort of trying to figure out what it is -- what are potential projects for us to do, and it was things that, well, we're not going to be writing FDA guidances, but instead let's take and share some practices, some ways to take and implement things; can we identify some things that we think, as an industry, we can do better and share some of those practices with each other?

I was also thinking about the AAMI supportability task force, you know, that we had for several years. They developed a white paper on service-level agreements, sort of what are some things that you can think of when you're writing your contract with a vendor so that we can both be, you know, on the same page when it comes to the needs.

One thing that we had talked about and kind of put on hold, and I'm curious about feedback from this group here, is I'm wondering what makes for a good service manual. How can OEMs do a better job? And, again, not an FDA regulation, but if you have -- I'm getting thumbs up from some of the audience members already on this concept. My wife happens to be a technical writer; she writes manuals. Let's give her some feedback on what makes for a really good manual. What is it that's going to help meet your user needs? I think the better we can understand that, the more we can work towards that.

Some possibly future topics for a collaborative community: We had talked at the AAMI editorial board about having some articles talking about the advantages of having a quality system. You know, it isn't all negative; it isn't all burden. There are actually some really good ideas there on how to run a business. And this wasn't suggested by a manufacturer, by the way. So this was part of that theme, can we make some of these concepts less scary, you know; can we take and explain things in ways that people would understand?

A few years ago I was giving some training at AAMI, and I had to have a couple slides to do a quick overview of risk management concepts, and people that know me know I pull funny photos of everyday life from Facebook and from other places, and I used these examples to demonstrate some of these things. The AAMI staffer liked the slide so much, she challenged me, and then I developed a 45-minute squirrel-based risk management training where I communicated all of the concepts of proper risk management using photos of squirrels. So I think that that's easy to relate across industries, and being able to use just those funny everyday kinds of concepts, you understand that.

And that leads to language barriers are often a problem. We were working in AAMI on an early cybersecurity guidance. The security folks used words like vulnerabilities and exploits and threat vectors, and those aren't words that we know in the medical device field, certainly didn't know a couple years ago. I wrote a little Rosetta Stone annex in the back that says, you know, when a security person is using this word, this is the medical device word and concept that we know, and just take and help translate that. That worked so well, we -- I had a team, and we had to do some safety assurance case work for an FDA product submission. I taught them the concepts of safety assurance cases. I measured how fast they were making progress. I realized the terminology was tripping them up. I translated, wrote a Rosetta Stone that translated the safety assurance concepts into the

concepts they already knew; the team was seven times faster the very next day, okay? So having to write language, understanding what the others are actually meaning is an incredible barrier, and I think that we forget about it a lot.

I realize I'm probably running out of time, Josh, so I did want to throw out the concept also of a potential collaborative community. It sounds like, Jeff, you need some sort of mature -- a misery index to measure your success, so I think some metrics on how miserable you're making the collective communities here, we can work on, you know, what exactly those measurements would be.

DR. SHUREN: Yeah, let's not stop at miserable; let's shoot for wretched. Let's go all the way.

(Laughter.)

MR. BAIRD: All right, thanks for the clarification. With that, I'll shut up.

DR. MAISEL: Good morning, I'm Bill Maisel. I'm at the Center for Devices and Radiological Health. I direct the Office of Device Evaluation, and I'm Acting Director of the Office of Compliance. You know, other than to say, as has already been stated, we're open to collaborating in whatever areas our stakeholder group thinks are most important. I will cede back the rest of my 2 minutes and 30 seconds precisely and evenly divided among every stakeholder that is here.

DR. SILVERSTEIN: In case I haven't introduced myself yet, Josh Silverstein, I'm going to be moderating today's panel, and I cede the minute and 45 I have left.

MR. FANSLER: Good morning, my name is Gary Fansler, and I'm the Executive Director for the Association of Medical Device Service Organizations, AMDSO, a little less of a mouthful. In the interest of time, I won't go through what our members do, as David clearly did that, and jump right into some of our collaborative efforts that we've been working on for the last several months, having conversations with many groups and the

individuals around this table, trying to establish where areas of interest are that we can agree to help promote patient safety and quality repairs. And it's interesting that, at first, we all seem a little bit hesitant because we're not sure how the others are going to view us and our opinions and we want to make sure that we're doing what's best for our organizations that we represent while keeping in mind the patients and the community as a whole.

And so with that, areas that we think that are available and amenable to collaboration, we would start with data to establish baseline, and you've heard that, so I won't go into a lot of detail, but the more data that we can collect and the more baselines that we can establish, the better value metrics we can have and determine the job that we're doing to make sure that we are keeping patients safe and promoting quality repair.

Also, promotion of quality management systems: You know, unfortunately, there are organizations out there that haven't adopted those, and so we want to encourage them to try to help everybody to be more aware of how important that is to make sure that you're doing correct and proper repairs.

And I would say, lastly, an area is to establish and promote best practices for education and training of technicians. You know, there's no certification today, and I know that some manufacturers don't provide that training to just anybody who wants it, but I think that if we put our heads together, we could really come up with best practices on what that would entail, things like training processes and curriculum, documented training skills evaluations of the technicians that hopefully would lead us to a technician progression and path. That, then, would allow us to actually have some technician competency controls so that we could know that the people working on the instruments are qualified and able to provide that quality repair that we're looking for.

So, with that, I'll turn it to Rob.

MR. JENSEN: All right. Thank you, sir. Rob Jensen, President and CEO with AAMI. Our mission basically is about collaboration and the safe and effective use of technology, so this is kind of center mass to what we do. AAMI's made up of several different organizations. It's basically the AAMI core which does systems development -- I'm sorry, software -- standards development, like we talked about yesterday, 14971, 13485, 60601, and a lot of the rest that you would be familiar with as well. We have a healthcare technology management department that works with ISOs and some of the in-house facilities. We have a training department that does both industry and individual training. We also have a certification institute that certifies biomeds, radiology equipment technologists, and healthcare technology managers, and an industry certification for certified industrial sterilization. We also have a foundation, and I won't go into that here; it's our charity effort, and they primarily work on diffusion of proven research across the health community.

We have a lot of members and stakeholders that are from all sides of this particular debate. We have very large and influential OEMs who are part of our standards development efforts and have been for most of our 52 years. We also have individual healthcare technology managers at individual institutions. So it ranges the whole gamut, and being at the center of that particular tornado, you can imagine that our misery index can be high, given certain consequences of hearing both sides of the argument and being in the middle.

From the collaborative community standpoint, we've been doing some work with MITA and ACCE on a small effort just to kind of get a feel for what this could look like. As already pointed out by Scott, we were invited to the alliance meeting and saw a lot of positive things there, just like we have here. From a roles perspective, we're open to discussing any role that the community feels like we are the best organization for. I don't

want to really lay out and presume, at this point, how the community feels. Unlike some of the other communities here, we do not do advocacy, either legislative or regulatory. We really depend on the data and the facts and present that to all of our members and stakeholders and share it equally, and it's up to those folks to come to the conclusions that are best for their business and the patient safety in the end.

As far as a recommendation goes for collaboration, the one recommendation that we would have is to do something small and tangible and get some more wins. I don't think it's a secret that there are some trust issues among the community, and if we can work together toward some specific and tangible results in a relatively short period of time and build that trust that things can be accomplished as a community, I think we'll all be better off.

Over to you.

MS. JOHNSON: Good morning. Diane Johnson, Johnson & Johnson, and I have to say, with that light in my eyes, I feel a little bit like I'm sitting on the stand. So, Jeff, you've achieved your goal; I'm already miserable here.

(Laughter.)

MS. JOHNSON: Johnson & Johnson makes a wide variety of products, single use, reprocessed, re-sterilized, you name it. We have hardware, software, and capital equipment. We repair instruments. I wouldn't say we remanufacture, but we certainly upgrade capital equipment at times. We use some internal staff to do repairs. We use a lot of third parties. Some of our activities are executed at the hospital level by the clinical engineers. All of these folks have in common the fact that they are trained, and everybody is qualified as a third-party vendor, and in the instance of -- we have a lot of third parties. There's contractual agreements around who is responsible for what. And we think a couple of issues that we feel are very important associated with the contractual agreements is the

MDR reporting, which is important for monitoring and ensuring patient safety. We also think cybersecurity is very important, and a lot of times, you know, there is a natural tension between usability and security, but as we become more and more connected and our devices are used to be just sitting in the hospitals now are going -- becoming vectors into the entire network. We really think that keeping the devices secure has to be top of mind, and I think that as you start to kind of give more and more access, that could become a potential issue. We also very much agree with the way the quality management system has parts, changes, and vendors, and things of that nature validated in terms of the product performing as intended.

In terms of how we've been communicating with the other stakeholders, it's frankly been mostly within the context of complaint handling and returns and failure investigation and things of that nature. And so I think, from those experiences, where I think there could be room for some collaboration is around communication and in particular, you know, what is the minimum amount of information that we should be sharing in order to protect the patients and to facilitate, at a very minimum, those MDR type of training activities.

DR. JACQUES: Good morning, my name is Dr. Samantha Jacques. I am currently the Penn State Health System Director for Clinical Engineering, but I'm here representing the American College of Clinical Engineering. So ACCE has a mission to establish standards of competence and promote excellence in clinical engineering. We currently have about a thousand members and work to really promote safety and effectiveness, right, of all science and technology in patient care areas.

We do define a body of knowledge for which the profession is based and have a certified clinical engineering training program and certification program where we do train clinical engineers, and we really worked, I think, collaboratively across some of the other trade organizations. Our members have been part of some of these discussions that my

other colleagues have discussed. I think, as an organization, you know, similar to AAMI, we have members across the entire range of ISOs, right, all independent service organizations, all the OEMs, as well as those clinical engineers directly in a hospital. I do think, right, there are many things that we can discuss, right, that have been previously brought up. We're willing to have those conversations and really engage in some of that communication as long as, right, there's a really good faith effort on all of the parties' parts to really work towards that collaboration and communication. I don't have anything to add from a topical perspective from what's already previously been discussed, but we're really looking forward to moving this conversation forward after some positive momentum, I think, after yesterday's discussion, so thank you.

MR. FRANCOEUR: Thank you. Good morning, I'm Dave Francoeur representing Sodexo, one of the larger ISOs in the community. Sodexo is an organization that has several hundred FTEs, been in business for about 15 years, have over half a million pieces of equipment, and we have histories. We've pretty much gone without any quality issues, and we believe the program is a good program that people can replicate.

On a personal note, I stand here as a representative technician. Once in my life I worked as an in-house biomed technician. I worked for OEMs, I worked for an insurance provider, and largely I worked for ISOs, and the reason I'd say most of my career as an ISO is because I believe that there's value in numbers. And so if you look at an ISO and the way it's established, there's programs which are teams of individuals that represent quality and economies of scale from a procurement standpoint.

And the point that I'm trying to make here is that I think, as a community, we would benefit from everybody coming to the table and having depths of resources. No one entity, person, or organization is going to solve this problem. In terms of activities, Sodexo has participated from the MITA perspective, the IAMERS perspective. We've facilitated in trying

to bring awareness of this in terms of the MD Publishing, and through AAMI, we've participated in the ACCE task force, and most of all, we were one of the founding members from the Alliance of Quality Medical Devices. I think it's a great step; it's one of the only steps that I'm aware of in terms of a coalition and a collaborative community, and I think it's done some great things, and I would like to see that get fostered and continued on.

Around the perspective of what are the next steps and that type of thing, I would say that I think the FDA's done a phenomenal job in terms of providing the collaborative community toolkit. I think it's a great step in helping to demonstrate who should be at the table, which, in candor, should be everyone from patients to healthcare administrators to technicians to every type of servicer available and obviously OEMs as well. Everybody should be at the table; everybody should have an equal voice.

At the end of the day, my only closing comment would be is there is no one that's going to say that we shouldn't do something that would be an advancement in safety and quality. What I would say is if we're not going to establish a baseline from which we can then demonstrate improvement, I'm not sure that any of the efforts would be worth it. So those would be my closing my comments.

Thank you.

MR. WEEMS: Hi, I'm Peter Weems with the Medical Imaging and Technology Alliance, or MITA. We are the primary trade association and standards development organization for manufacturers of medical imaging devices. In terms of recent efforts to collaborate around these issues, as has been mentioned, we had some initial conversations with some of the other societies and associations around this table around potential interests and scope. I think those were, you know, productive discussions and discussions that we would certainly want to expand to be inclusive of the other associations and participants at this workshop and in the community at large. Additionally, over the past

couple of years, we have been working a couple of multi-stakeholder standards, some of which have been more productive than others. We spent much of 2016 working on a standard for quality management of servicing medical imaging devices. That was a useful process, if not a productive one, since it has yet to yield a final document, but I think that is a process that we would be interested in continuing in the future. Adjacent to this issue, we also manage and are currently revising the so-called MDS^2 standard, which is the manufacture disclosure statement for medical device security. Many of the participants in this room and others are involved in that standard, and if you'd like to be involved or learn more, please feel free to reach out to me. We want to be as broadly inclusive in the development of that standard as possible.

In terms of areas that are -- that I see as amenable to continued collaboration, I think everybody in this room has expressed an interest and a commitment to quality in aftermarket technical support of medical devices, so I think there is a good opportunity to come together to discuss what consensus around quality looks like for these processes. I think there's also a good opportunity through a collaborative community for education, education around best practices. There's a lot of knowledge contained within the associations and, you know, within many of the other stakeholders, and getting together in a broad, large community would be a good megaphone to reach the thousands of other participants or stakeholders who are not here today.

I think, further along the lines of education, there are a lot of resources out there that can be useful for these activities. As was mentioned yesterday, there's a number of standards and regulations which can inform the difference between servicing and remanufacturing, but then also many of these activities exist within a regulated environment, and interpreting those standards and interpreting those regulations can be difficult. So I think there would be a good opportunity to get together and discuss how we

can be useful in interpretation of standards and regulations in some way and to some extent. And I'll stop there.

MS. UPTON: Good morning, my name is Diana Upton, and I'm the President of IAMERS. For some of you who don't know, IAMERS is a trade association of about 130 companies worldwide. We have members in 17 different countries. Some of you may know that I wrote an article earlier this year for DOTmed about collaborative communities. I'm in support of collaborative communities, and we did a little research on what it means to be a collaborative community, and the first most important thing is that you have to trust the people that are participating in the collaboration.

We're about to have our 26th birthday in May, and as I reflect on the 26 years, I think IAMERS is a really good example of a collaborative community. We are fortunate to have many kinds of members: independent sellers and servicers of original equipment such as GE, Siemens, Philips; subsidiary companies to them; leasing companies; online sellers; a variety of parts and specialty companies. I look across the room, and I think I counted 10 IAMERS members that are attending this meeting.

We like to subscribe to the big tent theory, and this is if you're ethical and want to elevate your game, IAMERS is here to assist you with educational programs, networking, and of course, we want to get to a level playing field. This isn't just lip service. We coexist on many issues and with a variety of stakeholders. When FDA announced its implementation of the unique device identification, IAMERS formed a committee with OEMs, independents, and other stakeholders, and we met as a committee with the FDA representation addressing these issues.

This was not a single one-and-done as we have had key OEM representatives present at most of our meetings, both domestic and internationally. These discussions have evolved around diverse matters such as overviewing of upcoming sales and service in the

marketplace and various licensing issues. Of course, we're aware that collaboration cannot exist on all levels. We're aware, and our OEM members are aware as well, that issues of access, service keys and training, equipment, it's not always optimal. We feel we've established a nurturing environment for collaboration, but likewise, we're aware that there's a lot more to be done on collaboration, and we hope that we can bring the parties to the table. I would mention that I think IAMERS did one of the first collaboration meetings in the spring of 2017 at Nationwide Imaging, where we had several people in this room. Gary was there, Dave was there, the FDA was there, there were people representing ACCE there, and that was our first attempt. We would also say that our next annual meeting is in Charleston, South Carolina, May 1st through the 3rd, and if it served the interest of the group, we offer April 30th as a day before our meeting where we would happily host a collaboration.

I thank you.

MR. LEAHEY: Thanks. Good morning. My name is Mark Leahey, and I'm the President and CEO of the Medical Device Manufacturers Association. We represent about 300 member companies, primarily the small to midsize companies in the industry but also have large companies as well. We run the gamut from the OEMs to an OEM who services their own products to entities that service others as well. So it really is a broad cross-section, and there's been a healthy discussion, and we don't have any formal alliances or consortiums, but we do talk with many of the folks around the table here, and I think there is alignment and consensus that continuous improvement should be the focus and the goal.

And there clearly are opportunities in which everybody can maybe put their cards face up on the table and advance and improve the process from a quality management perspective and other opportunities. And I specifically want to thank, you know, Bill, Jeff, and the folks at FDA because I think you do provide a unique opportunity for everybody to

come and put their best foot forward. I wasn't, unfortunately, able to participate yesterday, but we heard a lot of positive feedback about some progress that was made and, you know, MDMA looks forward to participating in any kind of variation or form of this group or others that want to advance improvements and high-quality servicing with industry, FDA, and others.

So thanks very much.

DR. SILVERSTEIN: Thanks, Mark.

So we have a few aisle microphones, and we wanted to provide the audience with an opportunity to provide any additional areas for collaboration in this community. So if you'd like to make a public comment right now, please come to the aisle microphones, identify yourself by name and your organization and areas that you think are most appropriate for collaboration. Okay, so I'm not seeing anyone moving to the microphones. Oh, I'm sorry.

MR. MACKEIL: Okay, great job to the panelists. A special shout-out to Pat. So I'm Scot Mackeil. You know, I work in a 1,200-bed teaching hospital. You know, I work at the point of care in support of doctors and nurses and respond to urgent and emerging technology service calls. In support of this mission, I depend on OEMs to be collaborative. I prefer to service my caregivers with the safest, most effective, and expedient manner possible. To do that, my collaborative partners are OEMs that have provided me with comprehensive factory service manuals, sell me parts, training, and provide tech support. I also depend on a number of ISOs to augment my practice, companies like MedEquip, Acertara, Conquest, EM Products, General Anesthetics, etc.

I also depend on my industry partners like AAMI, ACCE, and the Anesthesia Patient Safety Foundation. In some cases, my job to serve caregivers is made more difficult by OEMs who do not provide service manuals or who provide a document labeled as a service manual that does not meet even minimal requirements, or won't sell me even Level 1 repair

parts or collaborate with me in my mission to serve the clinicians, supporting their technology needs. At the table I see a number of regulatory affairs professionals from the industry, I see a number of regulators from the FDA, and I see equipment servicers. In a collaborative community, our FDA regulators could consider the needs of servicers for things like complete, comprehensive service manuals, diagnostic software, and parts access and training, etc., and then give the regulatory affairs professionals the things that they need most, like a clear, definitive regulation of what a service manual is and what should be in it and clear regulation on repair and replacement parts.

You know, it's so important for those of us who serve at the point of care to have what we need to do our job quickly, efficiently, safely, and effectively. And all of you in the room are an important part of what I do every day, so the effectiveness and success of the collaborative communities going forward is really, really important, and I hope you all do a great job, and I hope we all love the result as everything comes together as we move forward.

Thank you so much.

DR. WANG: Hello, my name is Binseng Wang. I'm here representing the American College of Clinical Engineering; however, I want to make a suggestion here that is not in the name of the college but in my personal name. As I mentioned before, I feel myself as a patient here because of my age, obviously, and I would like to suggest one particular topic for collaboration among everybody here, because I think it was not mentioned by all the panelists before, but it was mentioned yesterday, and it was mentioned yesterday something said, somebody said like this, if you go to the airport you'll see something on the wall that says if you see something, say something.

The reason I'm saying this is because I believe the majority of the people here and in previous workshops are not the ones causing problems out there. The people who come to

these meetings are really representing good companies, good professionals, people who want to do good. They may have particular interests to protect, but at the end of the day, very few of them are trying to intentionally do something bad. Unfortunately, we have a few bad apples out there, we have all to recognize that, and these few bad apples are the ones who actually are corrupting the whole barrel. So we need to remind people that we need to point out these people and as Mr. Shuren said, we need to spread the misery around, so we need to spread the misery to them as well. And, more importantly, to the FDA itself, I would like to ask Mr. Shuren to give a little more resources to your branch called Alleged Regulatory Misconduct Branch because I have heard that someone filing a complaint with that branch 4 years ago and still has not been able to receive a report filed through the Freedom of Information Act. Evidently, it's not because they are not working, but they most likely probably have a lack of resources to pursue all the allegations they receive.

What I'm trying to say, in other words, is that all the reports that were presented at the last workshop and deemed actually are remanufacturing exercises by the FDA, some of them, I think, at most, might be they're not just really dumb mistakes made by service companies or service individuals that became remanufacturing exercises in terms of just servicing. These people, these companies need to be pointed out to the FDA, and the FDA needs to take proper actions to get these people out of the marketplace.

So I think we really don't have a huge problem to solve from the companies that are trying to do well, but we have a few bad apples out there, and we really need to basically point out and eliminate those bad apples; otherwise, we are wasting a lot of resources. Just look at the room here, the number of people, resources, intelligence here, excluding myself obviously, that are trying to solve a problem that does not really exist in terms of evidence. However, there are a few problems out there that we cannot even know if they exist, and

let's try to address those problems instead of trying to put misery, spread misery around.

Thank you.

DR. SILVERSTEIN: We have about 90 seconds.

MR. NOWAK: Great, I'll make it quick. Christopher Nowak, Universal Health Services. We represent a for-profit health system, and just a suggestion that we have. Maybe end users or hospitals will also be represented the next time on a panel such as this. The thing that I want to speak to this morning, though, is to expound upon Rob Jensen's point from a collaborative perspective. I'm the Board Chairman of the AAMI Credentials Institute. That is a certifying organization for professionals, technological professionals. Whether you work for a company, a hospital, a third party, we certify all of those folks. While your staff, you may run them through a training program so that they can function and operate on your equipment and fix it properly, they are not competent to work in hospitals, the environment of a hospital.

The certification programs that AAMI has in place is a very broad examination, and it expands upon those competencies that are required to work in a health organization. So that is very collaborative; it's very neutral. AAMI is a non-hostile environment. We certainly would encourage to send your staff, get your staff certified in -- whether it's the CBET certification, radiology, healthcare technology management.

Thanks.

DR. SILVERSTEIN: Thank you.

So I'd just like to briefly summarize what we've heard during our sort of update. So just so the public is aware, there have been two efforts that were discussed at this table. One of those efforts involved many of the organizations who are also sitting here, and then there was also recently a meeting in Chicago to start talking about efforts to collaborate. In terms of areas most amenable to collaborate, I heard a lot about training, quality

management principles, cybersecurity, and evidence generation. And I heard multiple suggestions on sort of the terms of collaboration being it should be public, it should be based on trust, end users should be included in any collaborative effort, and in the end we should have our number one goal being protecting patients.

So, with that, we have a 15-minute break. It's now 9:15. We'll reconvene at 9:30. Thank you.

(Off the record at 9:15 a.m.)

(On the record at 9:33 a.m.)

DR. SILVERSTEIN: I'd like to invite all panelists who haven't made their way to their seats to find their seats. Thank you. Okay, welcome back. So over the next hour we're going to be discussing opportunities, barriers, and goals of collaboration, and I kind of wanted to go over Jeff's four goals for the day, just to make sure that we're making progress. So Number 1 is to identify areas where we all agree that collaboration would be helpful or that collaboration is important. Number 2, that there's a shared interest to identify this collaboration and implement it. Number 3, identify entities to participate and Number 4, establish time frames.

So I'd like to take a deeper dive right now on areas that we agree are needed or are important. We talked a lot about training so far. I think at least six people mentioned training. I'm just kind of wondering what kind of cross-pollination is happening right now between OEMs, ISOs, and biomeds as well, just in terms of talking about training and sort of establishing a core basis by which anyone's doing these activities, whether it be a certification or not.

So I mean, Rob, I don't know if you want to talk about certification first and we can, you know, sort of branch off into training a little bit more from there.

MR. JENSEN: Okay. So we have three certifications, as was mentioned, for biomeds.

I think the important thing here from a training perspective is we really don't, as I think Gary mentioned earlier, we don't have sort of a progression of someone from, say, an electrical safety person in a hospital that just either graduated from high school or may be in their second year of college all the way up to a clinical engineer who could very well be the CTO of a facility or a whole system. That particular sort of path of progression, at this point, really doesn't exist. I might suggest that that would be -- if we could come to some sort of agreement on that, at least we would be able to kind of compare where each organization's training fits, and it kind of goes to one of the causes of what's of concern, which is, you know, OEMs and remanufacturers, they want people that are qualified working on their equipment. But when there's not really a -- I'll call it a standard, not a technical standard and there's not really a standard in terms of what's agreed to for training, then it's really impossible to kind of come to that and have someone's credentials mean something working for one company or one hospital system and have it mean the same thing when they go across town and work at another.

DR. SILVERSTEIN: Okay. And so I think I'm going to go to Diane next, and I'm just wondering, you know, is this something -- you know, in terms of collaborating on participating in other just broader training efforts, is this something that interests your organization? What do you think that collaboration might look like?

MS. JOHNSON: I think it would be interesting to have an opportunity to discuss how -- you know, we develop our training very specifically for a product, and it can be quite intensive, but how do you kind of set -- make that transferable across a skill set as opposed to, you know, the specifics for the product? You would still need to know the specifics of the product, but I think maybe there's an opportunity to collaborate around the minimum skill sets for -- and as you said, leveling, not -- level setting in terms of how do you move it across hospitals, I think that that would be an interesting discussion.

MS. FEDERICI: Can I jump in here, Josh? I mean, I think there's always going to be a need for certain product-specific training. I know I've heard from some of our members that their training, as Diane just reported, is extremely intense. But I think there could be certification both kind of at the product level for certain products, particularly those that are serviced a lot, and then certain categories that ISOs may focus on. But then there's also higher-level certification that I think would be helpful on quality system principles, etc. So I think there's kind of two layers of certification, but I do want to stress that I think that there's going to be a need for certain products to have company led training because of the complexity of those particular devices.

MR. FRANCOEUR: Hey, Josh, so from -- I guess I would like to share the fact that at least reality from our world is, is that there's varying levels of opportunity, if you will. From an OEM perspective, if you're an in-house technician -- and that means that you work directly for the hospital, that's what I mean by in-house -- the OEMs often make it available for training, and it's primarily because there's actually a standard that says they're supposed to do that. And so they would rather not, but in fact, they do. If you're an ISO, other than working in a hospital, so ISO can mean many things to many different people, if you're an ISO, other than working in a hospital, often you're not allowed to go to that training. They won't allow you to do that.

I'm fine we didn't agree that there's maybe different levels in terms of training. You know, it could be that there's the preventive maintenance-level training, there's some level of corrective maintenance, and then maybe there's a higher level yet of corrective maintenance that would need to be done. And I think, as an OEM, you have that obligation and right to determine what that should be. But I think where the inconsistency is, is where the availability is.

What I would say is, is that where some organizations are becoming more

progressive is in terms of recognizing that when it comes -time for replacement of a device, they want a favorable opinion from the end user in terms of how that device has been working throughout the history, the life cycle of that device. Then the manufacturer recognizes that it really doesn't matter who services it; it's really all making sure it gets serviced properly in a timely manner, so they're making education opportunities more available, and I would say that, you know, I support that and help that where I can, but I think it's around the inequities of opportunities is maybe something that needs to be discussed.

MS. RACIC: Yeah, if I can just add just a little bit more color to that, too. I know I've talked about this in my opening statement, and Diane just reminded me again. So at Medtronic certainly, training is done on individuals that are trained for specific product lines, and they don't go beyond the specific product line. Just to give you an example, and this may be one of the worst-case scenarios, but for some of our large capital equipment, training can take up to 18 months, and then recertification is required every 2 years or so.

So, again, they start with kind of a patient and service provider safety as a focus; they go over the theory of operation of that entire device because a lot of times you'll walk in thinking that it's one problem and then end up, you know, trying to fix another problem that's kind of been discovered along the way. System schematics are also kind of broad into the light of this training. Calibration and testing procedures, so this is all a lot of proprietary information that's being discussed. And then also they focus on the clinical application and the operation of the equipment, and there's a course that they're required to take that's called beyond servicing of the equipment. So they really are required to understand about the clinical application of that device and how it can directly affect the patient.

Thank you.

DR. SILVERSTEIN: So maybe Scott or Dave could kind of talk about sort of -- I think

we're getting a little bit further down than I'd like to, and we're getting into device-specific training, and I think what we kind of all agreed to at the beginning is that training is really important, and we're here also to talk about collaboration. And so we understand that there are some issues with device-specific information, whether it be a trade secret or confidential commercial information, but you know, just trying to think about the core tenets of training that everyone agrees upon, I think that's what we'd really like to advance forward. And so, you know, just a brief idea from you about the training that you provide to your folks that maybe service a wide slew of products.

MR. TREVINO: Sure. So I'll answer and then hand it over to Dave, and he can share his thoughts as well. There's certainly certification and that's part of -- you know, there's a job description which includes competency requirements, and that includes training as well as experience. You know, there's a difference between certification and competency. One complements the other, but that doesn't necessarily mean you're competent if you're certified. So I think there's a complexity here with making sure your folks have the competency to do the job that they do.

So the way we approach it is exactly that, based on the job type. It determines what level of competency they have that may include a combination of certifications and training as well as experience. And I think that's an important component to this as well, as many in industry would speak to. Experience goes a long way, and you learn through that experience in a number of cases.

I do believe there's opportunity to improve, and I think Dave Francoeur mentioned earlier, and I think this is a point that's very important, which is access to training. I mentioned yesterday, I used the term service materials, which includes training, the things that are necessary. I think that's something where, you know, the Alliance would certainly support and is interested in discussing as a collaborative community how that access to that

can be provided in a way that's more open than it is today and truly collaborative. So I would say that's, you know, that's a significant opportunity, and I'd like to see that pursued as a subset of the training.

DR. SILVERSTEIN: So, Dave, I'm actually going to ask you a targeted question based on what Scott said. So I wonder, I'm not familiar with most -- I'm guessing by your company's name that most of your folks are not in-house. And so do you have any agreements with OEMs to get some of their more specific training, and if so, could you just kind of walk us through it, sort of the pros and cons of that, or we'd just kind of like to get to how do we get access to training that folks need to service products.

MR. ANBARI: The answer is no.

DR. SILVERSTEIN: Okay. And so --

MR. ANBARI: I'm sorry, I was being funny.

DR. SILVERSTEIN: Oh.

MR. ANBARI: In our particular segment of the industry, really, other than a couple of stainless steel instrument manufacturers that we work pretty closely with as their authorized repair provider, there is no real sharing of training, parts, materials with manufacturers. It's really on us to be able to source the training, to do the engineering, to be able to perform the repairs. And then that's really true, for the most part, in all of the surgical segment. Having said that, you know, when we talk about training people, industry-wide it's a real struggle because for us it is both the textbook element of it but it's also it is a trade skill, there's just no other way of putting it, and we really industry-wide have adopted very much an apprenticeship-based training program.

So speaking both for my company and the other companies that are represented by AMDSO, we've built our -- at this stage, the training programs that we espouse, we've got a handful of principles on them, but we don't get into the details of the program, and those

principles include things like it has to be a documented structured approach. It can't just be we put Joe and Sally together and Joe trains Sally. It has to be a structured formal approach. It has to be based on proven skills mastery. So we've introduced the concept of master technicians in each one of the different types of equipment, and there are -- there's a formal both paper-based exam and formal demonstration of repair technique that we use to certify people. Once they're certified, they go through a recertification process on an annual basis. We don't just trust that that works. We've also established an audit process both for the people based in the field, which for the record is about half our total staffing, and the people that are based in our repair depots. So it's what level of competence you have for what the job is and recertification on an annual basis, retraining on an annual basis, but also a verification process, and it's very much differentiated by the type of equipment. But at the end of the day, it is absolutely a skills-based, proven demonstration of the skills to master craftspeople to do it.

DR. SILVERSTEIN: I'm sorry, we're actually going to take public comment towards the end. Thank you very much.

Robert, did you just -- we'd like to wrap up training, but could you keep maybe to 30 seconds or less?

MR. PHILLIPS: I'll give it a try. So I think we are, you know, fairly mature manufacturers and servicing organizations in this room, and I think the concept of training is probably well characterized within our activities, and I wonder what we can do as a collaborative community to address those people that aren't in the room. So, you know, when we look at training from a manufacturer perspective, a lot of times it's either internal or it's bundled with the sale of our devices. We would look at training associated with certifications.

You know, that may be burdensome for some people, from a time perspective or a

financial perspective if that's not reimbursed by their employer. Is there a training opportunity that is sort of low-hanging fruit around the theory and principles of the devices that doesn't get into competitive concerns that can be public knowledge and shared? And I think from a manufacturer and a servicer's perspective, that's something Siemens Healthineers would be happy to support by providing our technical knowledge, our research and development engineers to support that generation of that work product.

DR. SILVERSTEIN: Yeah, I think you provided an excellent summary, and I also think it's a really good segue into our next topic, which is quality management. And, Robert, I actually planned on calling you next because I think you have an interesting perspective because you service other entities' products. And so just thinking about how -- wearing both of your hats as an OEM and a servicer, you know, how do you think about quality management and, you know, thinking about how quality management principles could be applied to this community? Can you provide a few thoughts about that and sort of identify what you think might be next steps in terms of collaboration?

MR. PHILLIPS: You know, that's an interesting question, I think, because when you look at what we do as a manufacturer, as a servicer or even as a third-party servicer of other manufacturers' equipment, for us, we don't try to develop three different systems to handle those three different activities. We've got one system that handles it all, and we look at what is the most heavily regulated, you know, the system that has the most requirements associated with it, and that's as a manufacturer performing the servicing activities. So many of the things that we talked about here today are things that are deeply ingrained in our DNA, whether we're servicing devices that we manufacture or we're servicing devices that other people manufacture.

And so, for us, I think it's a little bit difficult to say how would you set up the street of consistence because for us it's always one system and we always have one set of

requirements, regardless of the servicing activity that we're performing and regardless of the reportability requirements of the regulatory venue in which we're doing that activity. As far as collaboration, I think that we could parse out those different stakeholders and say what are the requirements for each of those, or we could define essentially a minimum level of requirements that would be applicable to all. Not necessarily the manufacturer's requirements but really looking at maybe what does it require for third-party servicing where you're not the manufacturer, and how do you actually perform effective servicing of those devices?

DR. SILVERSTEIN: I actually think that's a great segue to Gary. I mean, you were talking about 13485 earlier, and so I'd like to hear sort of who's been involved in that process, and I wonder if other folks at this table would be interested in participating in that.

MR. FANSLER: Yeah. So, currently, our 13485 workgroup is primarily for our members, although we've had discussions in trying to figure out how we could make that a collaborative session conversation amongst anybody who would like to join.

One of the things that we're identifying is that auditors all have different personalities, just like each company has different personalities, and so if we can understand, when it comes to servicing, how we best align with the quality management systems that we have in place and specifically ISO certification, then it helps all of us to progress further in our not only implementation of that certification and those procedures in there, but also in dealing with the auditors that are coming to make sure that we're following those.

DR. SILVERSTEIN: I was wondering, Pat, is that something that you would be interested in participating? You know, I understand you're both a member of AdvaMed and MITA under Philips and so --

MR. BAIRD: I am, yes, absolutely also a member of AAMI and a member of MDMA --

I've got to be everywhere. So I absolutely love and have had conversations with many people about the applicability of 13485 and how 13845 doesn't apply, you know, both sides of the argument. So I'm absolutely interested in chasing that. One thing that I think was mentioned in passing before that I want to make sure that we don't lose track of, in the medical device world we have some concepts called essential principles. And I think, David, you were actually talking about looking at your training and your training adheres to certain basic tenets of what makes for good training. So I'm not saying we need a committee to form and take a year to decide what good training is. I'm saying, hey, can we have 30 minutes with some folks to develop some training, come up with what does good training look like, and that's a bar that we can take and set, moving forward for some of it, because for a lot of these things I mentioned yesterday, I worry about risk management theater, I worry about training, right, which really is "There, look, I participated in an afternoon webinar, and Jack, I'm done." No, this has got to be real for it to make a difference. I must have hit a nerve because, Josh, you're writing furiously. That's good.

DR. JACQUES: So, Josh, I'd like to weigh in as well because I think amongst this group, as one of the participants pointed out, there is no in-hospital based participant, and so as a representative for ACCE, I'd like to say, you know, we do need to take into account those in-house requirements as well, which generally come from CMS. And I think I'd like to see some alignment with the quality management system with some of the CMS regulations so, again, we're not adding additional regulations to those in-house parties as well. You know, I think they align relatively nicely, but I just don't want to leave them out of the conversation.

MR. ANBARI: Just to pile on to that comment real quickly. You know, I think one of the things that is important to keep in mind is that everything that we do with provider organizations is directly subject to their CMS, Joint Commission, and other state regulatory

oversight, and we have worked very diligently to redesign a lot of our processes to evolve with the increasing requirements that they see from CMS, Joint Commission, and state regulatory authorities, whether it be on individual inspections and audits or whether it be from a compliance perspective. So while, yes, it's true, there's no direct provider sitting here today representing the provider perspective, I like to think that's the only perspective that we really bring to the table. Yeah, we have our commercial interests and our interests in quality, but it's also with a keen focus on the provider.

MR. BAIRD: And if I could add on to that. You triggered a thought, which was among the AAMI working group, if we're taking a look at 13485 and the QSRs and saying, you know, there's a lot of overlap between the two, I think it would be very interesting to take a look at the CMS requirements and the Joint Commission requirements and see how much of 13485 overlaps with that because good processes are usually good processes regardless of who breaks them.

MR. FRANCOEUR: So, yes, and I guess, in addition to a concern -- not a concern, but a thought process in terms of making sure that we don't duplicate efforts and drop things through the ball, right? So I mean that's the biggest thing. We're all regulated in one form or fashion, right, and we're all doing a lot of the things already today in terms of documentation and other things. So as long as we're taking into -- I think guiding principles would be phenomenal in terms of giving us guardrails. My only caution would be, again, that we're not duplicating efforts, we're not dropping things through the ball, and we're not making things so stringent that it becomes prohibitive for us to be successful in any form, whether that's in-house, third parties, or OEMs quite frankly. So as long as it's all being considered and it's looked at, I think that would be phenomenal.

DR. MAISEL: This is Bill.

You know, I think this point was made earlier by one of our public speakers. Often

we end up in rooms like this not because of the good players but because of people who need help in meeting certain expectations. And so I wonder, as we talk about quality management and 13485, that's a big lift for a servicer who may not have a quality system, and I wonder if there are components or subparts of quality management that this group thinks would be a good starting point. So instead of, you know, checking the box, oh, okay, let's collaborate on quality management, let's collaborate on documentation or some other piece, so it would be interesting to hear what folks think of the lowest hanging fruit within the quality management space.

MR. FRANCOEUR: So in some respects, if we put guiding principles -- and I'm really being careful in terminology because I don't want to define anything specifically, right? But in terms of setting guardrails around guiding principles, I think by virtue of putting those together, it would start to weed out the people that weren't making the grade, if you will, right? So if we put guiding principles around documentation or on vendor management or on part quality, all of the aspects associated with the things that the community feels are the important factors for which to earmark or benchmark a certain entity, then that would more or less sift out, from my perspective, the ones that couldn't cut the grade.

But the concern that I've got is, is that everything that we've talked about is there's not -- one answer isn't going to solve it, right, whether we talk about the training aspect or we talk about QMS. No one thing is going to do it because there are people that are going to be into this business that are going to command it from a whole different perspective than just out of high school. There's people that are going to work for an OEM for 20 years and want to start their own business. At that point they have a major skill set associated with the product that they're going to offer. They want to continue that education. So there's different aspects of this thing, and we're going to have to make sure that it's not just one solution; it's going to have to be across the gamut, and that's why I'm in favor of

guiding principles associated with setting up guardrails and not being too proscriptive.

MR. ANBARI: I think one of the challenges is -- because we've looked at exactly what you spoke of, which is if there's something that's better than nothing, what does that something look like for companies that don't have the quality systems that we really would like to see them have as part of our organization. And I think what we've concluded is there are portions of it that have to be interpreted to servicers, but you can't have a quality system -- you can't pull out portions of it and still call it a quality system, you know, whether it be staff qualifications, work processes, parts sourcing, design specification, maintenance, and the documentation and reporting that goes around with it.

It is very difficult to assure the outcomes when you remove a component of that system, and for that reason we've tended to -- we have rejected that notion and have said, no, it has to be a complete system, but it has to be a system that's been interpreted and adjusted to reflect the servicing role. And it's a hardcore answer, but we have really, really struggled with that. Our quality workgroup on that, you know, we've got a team of people that are the quality leaders in each one of the organizations, member organizations, and that's been a big point of debate, and that's sort of the conclusion that we've rested on. You can't pull one of the legs out from underneath the table and expect it to stand.

MR. TREVINO: Maybe if I could add just a couple comments on this. I think that Dr. Maisel's question is spot on, and that's part of one of the things we try to tease out, which is what principles of, you know, a quality management system might be an opportunity for focus and discussion as a collaborative community.

What I'll add, and I think this is an area that might start to address this, is the AAMI EQ56 standard was recently assessed versus some ISO standards, and I was part of that process, as well as a number of others in the community, and what we did is we looked at true quality management system and looked at the current state of the EQ56, which is the

healthcare technology management standard which covers a number of different aspects of quality management system and had some gaps. And so we made a proposal to update that standard because of those gaps, to add things like cybersecurity, change control, address risk management.

And what I'd suggest is that we evaluate that and look at that to say is that a good step in the right direction. I believe that it is. I think it addresses a number of the things around quality management principles, and I think that was the intent in assessing that work to move it forward, you know. And I'm participating in that group, and I wanted to put that out there and share that that activity is occurring, and for those that may not be aware, I would welcome any comments from the rest of the panel on that.

MR. WEEMS: I think another element of this that might be useful is something that's been, I think, alluded to a couple of times, and I think, Pat, earlier today, you know, you said that there is a lot of utility, from a business perspective, in having a quality management system; there's a lot of good business practices in there. And so I think that there might be some need for education around the purpose and use of a quality management system, making it less scary maybe. And I think there's probably some opportunity for a collaborative community to undertake that, given that all the manufacturers in this room already have a QMS and many of the ISOs have one, have recently adopted one or are in the process of adopting one.

I think another element of some education, and that needs to be part of the discussion, is around the idea of scalability where you can have the same elements in the quality management system, but for a 4-person company, that will look a lot different than a 40,000-person company, but the same objectives will be met if properly implemented.

I think another part of the discussion is, and I think this has been mentioned a couple of times, is that there are a number of different quality management systems out there

which are specific to different activities, and I think that if we can have a robust discussion around what that system might look like particularized to servicing, and I think that was alluded to earlier, that would be a useful discussion to have, particularly within the context of scalability for the size and scope of the organization in question.

DR. SHUREN: And I would just add, you know, we went down a similar approach more recently with software as a medical device around quality systems as we are seeing more and more of the consumer product developers move into the healthcare space. And part of that exercise, which we started at an international level, in fact, was to say how do we better tailor quality systems to software, and then secondly, the communication side, how do we translate what we're talking about from an FDA perspective to this other industry which is not used to using our terminology? And that crosswalk alone was invaluable because what we found is, from many of the companies who were doing a very good job in software design and validation, many of those activities were not foreign to them but the language was more of a barrier.

DR. SILVERSTEIN: Not seeing anyone else who wanted to say something, so thank you very much. I think we made some good progress here and that everyone, in theory, thinks that quality management is important, but the specifics of that really need to be worked out. And I saw a lot -- I'm seeing a lot of heads nodding, and so we're hoping that any collaborative efforts can kind of reach some consensus about which principles coming from different -- whether it be 13485 or other quality management systems or principles, how those could be applied to this space.

So one of the other important topics that we raised back in 2016 that was discussed a lot at the workshop were access to parts or availability of parts as well. And so I'm just curious. In terms of how -- we'll start off with an ISO, I think, because, you know, in terms of the availability of parts, does anyone have existing agreements with some OEMs who are

more willing to provide sort of a contract or not? And so maybe, Diana, we could start with you because I haven't heard you speak in a while. Are you familiar with any of your members having detailed agreements for parts?

MS. UPTON: I don't know how many of them have formal agreements. I know that there are people that have problems getting access to parts. There are other companies that don't have the problem. I agree with a proper QMS system, that there should be some established condition whereby parts are not the end of the universe to get for quality people. And we at IAMERS encourage everyone to be 13485 if they touch the equipment, and we have a best practices and, you know, parts are a problem, there's no question. Everybody doesn't have the same access to parts, and there are people that are -- quality companies and are being denied access, and we'd like to work through that process.

DR. SILVERSTEIN: And so I'd like to know a little bit more about how we can make sure that the access to parts, this effort moves forward because we know that servicing is happening, and again, our number one goal here is assuring that patients have access to high-quality, safe, and effective devices. And so how do we move this effort forward in a collaborative manner? I'm voluntwisting an OEM to help me out a little bit here, and I can call on someone specifically, if they'd like.

MR. FRANCOEUR: Josh, maybe I can offer, again, a little bit different perspective in terms of, again, it's striated in terms of availability. You know, when a new device comes out, for the first couple of years access is virtually nonexistent because it's new technology; there's not a lot of them on the market, and it just doesn't happen. Typically, it's 3 years. After 3 years access starts to open up a little bit. Pieces of equipment get on the secondary market, they're torn apart for -- broken down for pieces and parts, and so it becomes a little more accessible. Again, there's a delineation between an in-house program versus a non-in-house program. If you're an in-house in some fashion or form, they're regulated and

mandated to sell those parts. If you're not, then not necessarily. Again, I use the term very matter-of-factly, I'm doing it intentionally, in terms of the more progressive OEMs have relationships with the ISOs and in-house programs with the idea that it's really around making sure that the device is running the way it needs to be and it's around making sure that the client is satisfied with the device versus just making it so that it's -- they're the only ones that can do it. I would just simply say again, it's around availability, and then so what ends up happening is, and I think this is important, if there's a secondary market for parts, then we just need to ensure that those are quality parts and that those are being handled and used in the right manner and frame. So I would look to see how we would facilitate taking that to that level, and I would just bring that up.

MR. ANBARI: So, you know, the sad reality in our world is that it's really on the companies that do what we do to be able to source parts independently, and that sourcing process results in parts coming from some of the same manufacturers as make components for the manufacturers. In a lot of cases we're able to figure out where those parts come from and source them thus. There's also a very robust market for precision-engineered parts that are exact matches and form-fit function and biocompatibility material composition for manufacturer parts. So, you know, a marketplace is there for us to be able to source the parts, and certainly we have begun -- we're in the infancy of being able to collaborate with others in the industry, other independent companies, to be able to commonly source some of those components and commonly source some of those parts that were not -- were done in efforts.

You know, as much as it's a competitive threat to the manufacturer parts distribution and repair operations, it's also a competitive threat internally amongst ourselves. So we're trying to, you know, build those bonds of trust to say, hey, look, you know, a quality part is strategic to both of us, so let's make sure that we're not spending

more than we need to and taking more time than we need to get there. But certainly being able to get greater access to manufacturer specifications and components -- I mean, access to quality parts isn't a problem for us. It certainly takes longer and costs us more money to do it, but you know, the broader issue is there's no safety or quality management issue with respect to it. We put all those components through a comprehensive vetting process that's part of our quality management program.

DR. SILVERSTEIN: Okay, so I think we've talked enough about parts to move forward to the next topic. And so evidence generation was mentioned in our May 2018 report as being a really important deliverable, and you know, I'll refer the public back to our report about whether -- the objective evidence that we found in this space, but I know that a few people yesterday mentioned evidence generation. And so just in terms of information sharing of when a problem is noticed, maybe Diane, I'm just wondering, do you ever hear issues from the field, whether maybe it's an in-house or even an ISO who is doing service on one of your products, and do they share complaints with you at all or something else that they notice?

MS. JOHNSON: Well, if there's some sort of an issue with the hospital, the hospital will usually report it to us like they would any other complaint. When we have seen instances when we get the device back and we go to do the failure investigation, we note the presence of parts that were not ours, and that seems to be where there could be better communication because we have a hard time, at that point, figuring out where the part came from specifically. Yeah, we know it came from -- what hospital the device was returned from, but we don't know who did the interim repair of the product, you know, unlike reprocessed where there would be some marking and it would go back to whoever reprocessed it as the new manufacturer. We don't necessarily -- in fact, we don't know almost ever who actually did the repair, if it was done outside the hospital.

DR. SILVERSTEIN: And so, yeah, I mean, I think I'm going to put the documentation piece aside because I think that dovetails a little bit better with quality management. But I think in terms of just sharing information and gathering more evidence, I wonder if I could say, Dave -- and then, Sam, I'd also like to hear your thoughts about it as well --- you know, what kind of objective evidence can we start gathering, and how do you think that you can contribute to this issue? We'll let Sam go first.

DR. JACQUES: So I think there's a need for evidence on a couple of different levels, and I think we heard -- in a couple of different aspects, right? So, from a CMS/hospital perspective, I think, you know, one of the struggles of -- either in-house programs or third parties are looking at is the new AEM requirements. And so, currently, a lot of hospitals or ISOs are really looking at their own data, trying to justify or assess their AEM programs, and it's a very hard struggle, especially for very small hospitals, to generate enough evidence, right, to justify a different servicing than what the manufacturer recommends.

And so if I had to advocate for one type of evidence collection, it would be a pooling of data across entities related to AEM. And that evidence, it gets very complicated because obviously we all document stuff differently, and we all kind of have a different level of detail when we document, and so some conversation around what is the minimum level, right, we need to go ahead and document to look at servicing and to justify what type of servicing we're doing to different equipment would be the one aspect that I would really advocate for a cross-functional group to go ahead and look at.

MR. FRANCOEUR: Yes, that would be great, and I completely agree with it. The opportunity, from my perspective, is -- and I said this earlier, in terms of why we stayed in the ISO world as long as I have, it's because there's -- in numbers, there's more opportunity. So, you know, as an OEM, you raise a point, and it sounds like you guys do not necessarily get the information, but the information is absolutely available. We are mandated by CMS

to make sure that we document everything that we do, so the information is there. We just haven't, for whatever reason, chosen to share it with each other, and I think it's a big mistake.

And whether we're talking about AEM, which again, to your point, if I'm a small five, six-man shop, person shop, you know, I may not have the opportunity to be able to be as detailed or as accurate as I should be. If we were to take the entire industry and create an AEM that was industry accepted, that everybody added into, then I think that would be hugely valuable. Have the OEMs involved, have the non-OEMs involved, get us all at the table at the same time, and I think there would be big value and merit, and then it wouldn't need discussion around whether or not there was -- you know, it's acceptable or not acceptable.

I think sharing of information is absolutely important. I just refer to a story back several years ago when I was in an in-house program. We had to pull a suction motor that worked fine on the shelf. When that was put on a bed to be transported, it would quit working. It was only through evaluating and repeat failure analysis that we realized that the circuit board didn't have anything to hold it down, so we put a small little piece between the top and the circuit board to keep it there, and it prevented it from happening. Working with the manufacturer, we solved the problem together on a national level, locally, and I think that's the type of relationship that needs to happen on an everyday basis.

DR. SILVERSTEIN: Okay, thank you. I think that's really helpful to know. I mean, I think I saw Diane nodding her head to what Dave said, and so I think it's really interesting to just talk about, you know, minimum information that would be documented as part of servicing. So I wanted to go to our next topic, which is --

DR. MAISEL: Josh --

DR. SILVERSTEIN: I'm sorry.

DR. MAISEL: -- can I just interrupt for a second?

DR. SILVERSTEIN: Yes.

DR. MAISEL: So before we move on from evidence development, you know, we've heard from OEMs that, you know, they have knowledge and information regarding servicing that has occurred, and sometimes that is performed very well, sometimes it's performed less well. We've heard from ISOs that they have lots of information about what's going on in the field, probably, you know, sometimes a different perspective because they may service a number of different products and so they have a different look at what's happening. We know frontline hospital staff have different information.

Is there an agreement that having access to this type of information would be beneficial? I mean, you know, sitting from our perspective, it seems like that would benefit everyone. It would benefit the OEMs to know what's going on in the field; it would benefit the ISOs to know what servicing isn't being performed well so they can train their staff; it would benefit the hospitals. So is that an area where -- and I understand there would need to be ground rules, and we're not looking to necessarily, you know -- we understand that there's important information that may need to be protected from each of those entities. I see a lot of shaking heads, but maybe folks could comment on that.

MS. FEDERICI: Yeah. So let me backtrack and address something that was raised yesterday and that was --

DR. MAISEL: It's hard to hear you.

MS. FEDERICI: Let me backtrack and address something that was raised yesterday, and that was this notion that our companies are not interested in hearing about adverse events with their devices. As I mentioned when I started, when I introduced myself, I manage a very active working group with a lot of companies, and we talk about this quite a bit, and not a single company has ever said, in all those many calls, that they are not

interested in getting information on their devices. So, you know, Diane mentioned at the top of this panel that trending on devices is critically important for OEMs to understand how their devices are performing, and it's important to the total product life cycle. So I think we would be very supportive of figuring out a way that we could better communicate information between third-party servicers and OEMs because my members are extremely interested in understanding this information.

MR. FRANCOEUR: I don't see how we can't do it, to be candid. I mean, if it's truly around safety and quality, the only way we're going to actually know whether or not we're making a difference or have an impact is to get all of the information. If the OEMs have a percentage of information and they're dealing with it in their end, and the non-OEMs have a percentage of information and they're trying to deal with it individually, not collectively, then we're not getting the benefit of the buck, and I know it needs to happen.

I don't think, candidly, from my perspective, I don't think there's many secrets in terms of a repair work order around what we did, where we got the part from. You know, I don't think those are real secrets, to be candid. I don't think there's any reason why we shouldn't share that and why we can't. And the only thing I would say is -- and I said this back in '16 -- there's no reason why we can't share it with you. Conversely, it would be nice if some of our large organizations that have the ability to do data analytics, to get some of that ourselves because we actually might be able to give a different perspective and share information as well. So I would just say it needs to be both directions.

MR. KERWIN: Josh, could I just offer a concern? I think that many third parties who saw the XR-29 standard inserted as part of the Affordable Care Act, I can remember receiving calls from our members about how there was a sharing of information, not about whether the dose optimizer was compatible, but about whether or not this was an opportunity for a pitch for new business, for somebody to come in and say some remarks

about the quality of service to the owner of the device. And so the level playing things are pretty much of concern because some of this information, while we would wish to have a free exchange, is being used for competitive purposes, and we have to keep mindful of that.

DR. SILVERSTEIN: Okay. So I think information sharing is something that we saw a lot of nodding heads, so we're going to assume that that's an area for collaboration. I think one of our next, and it will probably end up being our final topics because we only have a few minutes left for this particular session, is cybersecurity. And so I know, I know that cybersecurity is a very important issue, and so rather than trying to focus on all of the problems that we might face or challenges that we have in cybersecurity, how are all of the stakeholders at this table collaborating with each other currently to either identify or help fix cybersecurity issues?

MR. TREVINO: What I'll add here is what we find to be the best situation, and I'll use an example, is collaborating closely with the OEM, and I think this is a nice crossover to the previous topic with regard to information sharing. One of the needs in industry, and I think many of you are well aware of this, is to understand the threat and risk profile for devices, and that's truly information sharing to understand patch management across all the massive number of permutations of rev and device and model types. And what we find is the open collaboration with our OEM partners, certainly there's, you know, an entire universe of, you know, participation and levels of collaboration there, but what we find best is where we work closely with an OEM to strategize on that as independent service providers.

Oftentimes what we're trying to do is, of course, update the device and add patches for cyber. One of the challenges, as folks may be well aware, is most cyber events do not rise to the level of risk that require action, so it's therefore the choice of the OEM to take action, and actions can vary from end of life in a device, not supporting and providing a

patch for a well-known threat that's been out there for more than a year and a half or providing patches, and what we find is, working closely with the OEM, is really where the opportunity lies, and I think it's mutually beneficial in those relationships because we're able to address those situations. And our customers are frankly asking why can't I add this patch to an OS that's been out for a long time? Well, it needs to be validated by the OEM, and I think what I'd like to add is we find that a terrific opportunity to collaborate and really solve the end-user's, the patient's, the provider's challenge there, and it really comes down to information sharing. And there's efforts in industry to address this problem, there's efforts individually by folks to do it, and I think this is a significant opportunity within cybersecurity to both share information and address a profiling problem that's only going to be exacerbated by the proliferation of more cyber threats.

DR. MAISEL: This is Bill.

So, you know, we heard yesterday and certainly are aware of concerns more, I think, among the servicers about OEMs securing their devices and making it difficult to service. On the other hand, servicers are obviously in a great position to help strengthen the cybersecurity of devices and make sure that the patches are being put in place in a timely fashion. And certainly the Agency, I think, views all of the people around the table and those stakeholders that aren't represented as being critical to strengthening the cyber infrastructure for medical devices.

And so putting aside maybe some of the more contentious aspects of the cybersecurity but focusing on the benefit that we can do for strengthening the infrastructure, which I think we would all benefit from, do we see -- do you see places within the cyber space that would be amenable to collaboration and working together? So, for example, you know, maybe it's streamlining the deployment of patches to the field, you know, so an OEM has a patch and they have, you know, potentially access to people who

are going to be touching their devices, and it might very much help the OEMs; it would help the patients. So, you know, I'm not here to force collaboration in areas that the group doesn't feel are ripe for collaboration, but can you imagine areas in the cyber space that could be amenable to working together? I see some skeptical looks and some nodding heads.

DR. JACQUES: So I would recommend really, again, back to Scott's conversation, you know, having some collaboration related to just communication. I think learning from how-to's and options, I think, around some of the cybersecurity allows us to discuss some different mitigation techniques. So perhaps patching is a technique, perhaps, you know, segmenting a network is a different technique, I think understanding collaboratively across the entire ecosystem how we can secure things in various ways because I don't believe that the one answer is going to fit for every entity across the ecosystem.

And so I don't necessarily need to be competitive around how we do that. I think we can really collaborate about options and what works best where so that we have something to take back to our cyber teams to say, well, perhaps, you know, this patch isn't going to be available for 90 days; should I take it off my network or should I create this workaround from a workflow perspective to continue, right, that quality and safety and be able to provide that service while not reducing the cybersecurity kind of defense that we have in place?

MR. FRANCOEUR: I've been accused often of being oversimplistic. I just make things -- this is a challenge for me from a perspective of how can this not be something that just gets taken care of? It's around safety, and it's around quality. It's not about a revenue thing. It's about just making sure that the devices and the exposure to the organization are mitigated absolutely as much as possible, and why can't we work together to make sure that that happens. I'm not looking for anything outside of that, other than if the OEM has

the ability to help us mitigate, reduce, eliminate that exposure, why wouldn't we do that in any way, shape, or form that we possibly can? I know I oversimplify things, but that's my perspective.

MR. JENSEN: I might add that if there is a collaborative put together around this topic, there are embedded operating systems that could advance OEM and remanufacturing security on the devices that would mitigate even an awful lot of things that you have to do afterwards. That's kind of a longer-term thing, and it would require companies to put some of their really talented technical people at the table. So it's just a thought.

MR. WEEMS: In terms of opportunities for collaboration on this issue, I think I'll mention again something which is adjacent with this, which is the MDS^2 standard which MITA/NEMA owns and is currently revising. And for those of you who don't know the standard, it's a voluntary standard, but it presents an opportunity for communication between the manufacturer and the customer around the security features of the device, and we're doing this as an American national standard. A multi-stakeholder group collaborative is working to revise the standard, and so I think it would be a good opportunity for folks who want to be involved in that process to get themselves involved.

DR. MAISEL: Peter, you just mentioned that it focuses on the OEM and the end customer. Sometimes there's someone in between. And so is your standard -- or is MITA open to having conversations about what the role of those intermediary parties are?

MR. WEEMS: You know, like all of our work on American National Standards, it's open to all affected or interested stakeholders.

DR. SHUREN: Can I ask sort of a related question? Maybe it goes to the OEMs. You know, for both cybersecurity and training, there is a certain level of, yes, there's things that can be shared that does not get into issues around IP, and then there are those circumstances where they do, and that comes down to a matter of trust in the entity that's

providing the servicing. Are there certain things from your perspective that, you know, this is what we look for, this was there, or we established it through a following mechanism, we have that trust in that servicer? Because if we can establish that, those expectations and how you assure it, then there's that point for sharing what becomes the truly critical information around, you know, crossing that line into confidential commercial or trade secrets, to be able to address some issues regarding both training and cybersecurity.

MR. FRANCOEUR: Yes. My perspective is -- sorry, my perspective is that, yes, that we should be -- that's what partnerships should be about, the collaborative community should be about. It's us coming to the table and trying to figure out what would be acceptable. I mean, as I sit here and think about the cybersecurity, I mean, the last thing I would think anybody would want would be that it was their device that caused, you know, the problem in the hospital cybersecurity issue.

So I would think they'd want to mitigate that as absolutely fast as they possibly can and in whatever method that needs to happen. I would think that would happen, and I do believe that we could achieve that by creating the partnerships, creating the boundaries, determining what would be acceptable or not acceptable and figuring out how do we work together to achieve the greater goal, which is quality and safety.

MR. PHILLIPS: Yeah, Jeff. I would agree. I think, yes, there's an opportunity, and I think it warrants more discussion about what that would look like and what type of protections on both sides of the fence could occur. I don't have an answer for you right now on how that would look, but I think there's an opportunity to, you know, open that discussion because it's not always just the OEM and the product owner, which is really where we sell the device and a lot of times where we bundle our training, but it's also the intermediaries in between, and we have relationships with those as well. And, you know, be it training for them and providing access to training materials and keys, you know, that

also occurs. So I think there's an opportunity kind of to parse that out and decide what more we can do.

DR. SILVERSTEIN: Okay, so I'd like to summarize our session.

And so just in terms of identifying areas for collaboration, we talked about training. We have a lot of details to work out about what that collaboration around training or core competencies might look like.

Two, quality management, sort of a translation into what this means in the servicing environment and how it can be applied.

And we have a few different examples of information sharing. And so evidence generation is one particular example where information sharing between all of the entities could really benefit the public health, and the other aspect of that is cybersecurity, so a good -- you know, good lines of communication and information sharing to make sure that there's opportunities for collaboration in strengthening cybersecurity.

And just for our last point, you know, establishing trust and how we're going to do that, I think, was going to be really important.

So for now we have -- we're going to adjourn, and we have a 30-minute break, but I'd like for the panelists to try to be back here by 11:00, so that will be 25 minutes from now, and we'll reconvene right at 30 minutes.

Thank you.

(Off the record at 10:36 a.m.)

(On the record at 11:09 a.m.)

DR. SILVERSTEIN: Okay, thank you, everyone. So welcome back to our last session of the day and for our workshop, and we're going to be discussing about proposed next steps. So just to reiterate the four goals of our day, are there areas that we all agree upon that collaboration would be helpful or would be important for collaboration? We talked a lot

about training, quality management principles, evidence generation, and cybersecurity, and specifically, for those last two, information sharing was really important. In general, we've heard so far that there is sort of an interest from the entities at this table that these would be good opportunities for a collaborative forum.

And so I'd like to focus on our next goal, which is to identify entities to participate, so who have we missed? And we've already started to talk about hospital providers not being at the table. You know, I'd like to open it up for the panel to identify additional entities that we'd like to consider in this collaborative effort.

MS. FEDERICI: Josh, I think the Joint Commission and CMS are important participants in some of these activities because they're the ones setting the -- you know, the Joint Commission has set the standard, and then CMS essentially just adopts whatever the Joint Commission has established. So if I had to pick one, I'd focus on the Joint Commission.

DR. JACQUES: To be inclusive, I think, right, DMC is also a regulatory body that we should be including, but I'd also like to add some of the safety organizations, so ECRI or IHI, that have some of the safety perspectives from it would be very helpful.

MR. PHILLIPS: Josh, I think you also hit the hospitals, but you know, certainly the larger hospital chains and environments but maybe also the VPOs that are helping select servicing organizations for their members, the smaller rural hospitals.

MR. FRANCOEUR: I know we said hospitals, but I'd like it from two perspectives, right? So hospital representation from a hands-on perspective as well as the administration piece of it, so it's two aspects of that here.

MS. RACIC: Josh, I think, from an industry perspective, certainly it's important to have, you know, the big players at the table, but also we don't want to underestimate the importance of the smaller manufacturers, and the same goes for servicers, you know. I

appreciate the associations, but I think the individual smaller servicers have a role in this, too, and I think those are the individuals that -- I know the FDA has acknowledged, too, it's not easy to track down. There's a lot of them, I think we mentioned that earlier. Someone brought up the point that the companies that are in the room here today are not the problem. I think we are after building a little bit more of a collaborative effort with those that are, you know, not here.

DR. JACQUES: And I would like to add, just from a cybersecurity perspective, if we can include NIST and some of the cybersecurity groups that the government has started forming so that we don't misalign efforts with some of the things that they're working on.

MR. FRANCOEUR: Yeah, I was just going to say the same thing. Let's go outside of our industry, right. From a cybersecurity perspective, let's get outside of healthcare, and it's always -- and I would say maybe even aviation in terms of QMS, right, let's get -- they meet people from outside of our industry that have much more experience than this that can bring value that we might want to consider and glean from.

MR. PHILLIPS: I think, on the cybersecurity front, we could also have maybe an ISO, you know, like an ICS-CERT in addition to NIST.

MS. UPTON: Perhaps some of the smaller service groups like NIR that are 17 smaller ISOs that are forming groups.

DR. SILVERSTEIN: Anyone else?

(No response.)

DR. SILVERSTEIN: Okay, so we have a fairly large list of people that we know we need to interact with and so --

MR. FRANCOEUR: Hey, Josh, real quick. What about -- how about -- I'm sorry, what about training, parts companies, you know, those type of people, right? So from their perspective, right, the people that, you know, do just parts only or, you know, companies

that do just training only, I think they would be a great suggestion.

MR. BOALS: Josh, you need to include the federal healthcare marketplace also in the discussion. The VA, DoD, Indian Health Service, Public Health Service, NIH have a significant input in it, play in this market. And as you're looking for the small vendors, ECRI used to have an index of all the small repair companies.

MR. FRANCOEUR: So I was just thinking, too, maybe test equipment, right? The manufacturers of test equipment, maybe they should be there in terms of ensuring that they're aligned with what it is that we're trying to do.

DR. SILVERSTEIN: Okay, great. And so I'd like to start getting into Number 4, which are time frames, and so we'd start -- the discussion started before this meeting, and we'd like to continue them after, and so part of this is trying to figure out what the next meeting might look like. And so, you know, would there be a convener, not for a collaborative community but someone who'd be willing to convene another meeting to continue this discussion? And I'm looking around the table.

MR. FRANCOEUR: Sorry, go ahead.

MR. JENSEN: We'll do that.

DR. SILVERSTEIN: Okay.

MS. UPTON: And as mentioned, we're happy to host at the next IAMERS meeting.

MR. FRANCOEUR: And just, I mean, the coalition, I mean, I'm hoping that we're going to get another opportunity to talk about, but the coalition already exists and, you know, would be happy to take that and take it to the next level and have every intention of doing so.

DR. SILVERSTEIN: Okay, that's great. And so I think, in terms of our idea of doing this, I think the first quarter of the new year is sort of a time frame, you know, we'd like. There's lot of renewed interest on this issue coming from some of the recent meetings and

collaborative efforts, and we'd like to continue that momentum. And so, you know, I don't think it necessarily has to be done in person. I think if there was a teleconference option, that would be really great.

MR. JENSEN: Right, we have the capability to do both, just like we're doing here today.

DR. SILVERSTEIN: Okay.

MR. JENSEN: We can do both.

DR. MAISEL: So things are moving really fast here at the table, so let me just make sure I understand what just happened and make sure everyone is on board. So I heard a very generous offer from Rob Jensen of AAMI to convene a next meeting; did I hear that correctly?

MR. JENSEN: Yes, sir.

DR. MAISEL: And so before we just jump on board, I do want to make sure others have -- you know, that was a nice offer. Is that an offer that is acceptable to the group, and are people comfortable with that, or do we think we should have some more conversation or discussion about that venue?

MS. UPTON: It would certainly be acceptable to IAMERS, subject to the date selected, as we have to go to the European Congress of Radiology in late February/early March, and I would certainly say that if it's something that was done at the IAMERS meeting, if you would be so good as to chair it, we'd be grateful.

DR. MAISEL: And let me just set maybe a ground rule or two around what we are talking about. We are talking about a physical space where we could meet that is different than, you know, moderating the meeting, setting the agenda. So let's just be talking about the physical space or the arrangement of a teleconference.

And so, Peter, did you have a comment?

MR. WEEMS: That's in line with what I was going to say. I think, you know, it's very generous and also very convenient for me to go to AAMI for a meeting, but you know, I think that as I've discussed with, you know, some of the other organizations around this table, that it's going to be important that, you know, whatever does move forward, if something does move forward, that it be jointly either by a mutual party or by a coalition of diverse stakeholders so that no one stakeholder or set of stakeholders has ownership of it.

DR. SHUREN: Yeah. And maybe then put on the table, too, for that meeting, since we are continuing a dialogue, that that would be a topic of discussion at that next meeting, you know, who might serve as or entities who serve as the convener on an ongoing basis. And we haven't even asked the threshold question because there's actually interest in doing that, right, getting a more collaborative effort under way, and maybe that would be the next question, and then we could talk about what that next meeting would look like and what we would want to achieve walking out of that meeting.

MR. JENSEN: I guess my request would be to Peter's point. Perhaps this particular group here, and maybe the gentleman that was representing the feds in terms of their health, could be the group that assembles the agenda, if you will, kind of a team effort, virtual, or somebody else can do it completely. I don't want to considerably stub my toes here.

DR. MAISEL: Yeah, I think we're trying to do one step at a time, which was a venue, and you've made a generous offer, and I haven't heard anyone who particularly objects, and so I think that is great. I think we've heard a list of who should be at the -- you know, some ideas about who should be at the meeting. And so I don't know that we're going to solve it here at the table today as to who should -- you know, which organizations should be represented, but we certainly appreciate the need to include a broader stakeholder community than what we have around the table here today, and I think there would need

to be discussions about agendas and, you know, format at a meeting and all of that.

DR. SILVERSTEIN: Did anyone else want to chime in? I mean, I wanted to provide the panel with an opportunity to just make sure that all of their voices are heard just in terms of scheduling another meeting and not necessarily anyone acting as a convener for the collaboration. So I mean, Diane, is that something -- I'd like to give the entire panel the opportunity to say something if they'd like.

MS. JOHNSON: So can you repeat the question?

DR. SILVERSTEIN: So what was posed just now was that, you know, AAMI is willing to --

MS. JOHNSON: Um-hum.

DR. SILVERSTEIN: -- schedule the next meeting to be in person and/or remote, and so what we'd like to do is continue this discussion and with the appreciation that this is a multi-stakeholder effort and AAMI is sort of just playing the host for the next meeting, not for the entire collaborative effort, and I think that's something that we would like to do either as a neutral convener or having some rotational ability. And so, I mean, is that something, a concept that sounds like you'd be willing to do?

MS. JOHNSON: Yes.

DR. SILVERSTEIN: Okay. And Gary?

MR. FANSLER: Okay.

DR. SILVERSTEIN: Pat?

MR. BAIRD: That was actually my expectation from the output from this meeting and today's work, yeah, so absolutely.

MR. KERWIN: As Diana said, we agree. We think AAMI would be great to convene this.

MR. PHILLIPS: You know, I agree as well. I think everything, and maybe you're going

to get to this next, Josh, is defining what those areas of shared interest are that we could create or define the agenda for the next meeting.

MR. ANBARI: So I mean, who doesn't like a meeting, right?

(Laughter.)

MR. ANBARI: I mean, we certainly would be on board with that. I think, you know, in looking at how to take this from a lot of talk to some action that can progress things, I think there's a handful of hurdles, aside from convening authority and logistics, that we'll have to take a hard look at, not the least of which is, you know, there's a lot of different organizational types in the room, right, you know, from manufacturers to independent service organizations to part suppliers to training suppliers. I think there's got to be a diversity there. I think you've got a wide range of equipment types as well represented, and they certainly represent different levels of risk, different levels of safety concern, and different levels of servicing requirements that you've got to take into account.

And then, finally, I think there's just different disciplines within the overall quality and safety management world that you have to look at, and I think, you know, perhaps the best bet is to say to ourselves, okay, we've knocked these ideas around extensively, and I guess maybe this is what you're suggesting or hinting at with this next meeting, would be to say, okay, now how do we break this into some reasonable work streams that, you know, people can attack and go get busy with? And I'm not sure -- you know, from our trade association perspective, we're a hundred percent on board with being a part of that effort.

MS. FEDERICI: So I have, I think, a related comment or a similar comment. I mean, there's a lot of people, OEMs, at the table who just happen to get selected to be at the table, but there's a lot of OEMs in the room who have not been given the opportunity to speak. I have people in my workgroup who aren't here. So I think any collaborative community has to have the availability for industry as a whole to participate, not just a few

select individuals, and that's nothing against anyone around the table; they're all, you know, great, wonderful members.

So I would suggest that we have the opportunity to designate a representative that could represent at the meeting and then go back to their respective community and obtain, you know, input and feedback to the larger group. I think this is maybe where we're going, David. I think you need to start smaller rather than larger, identify an area that is susceptible to success, and if we are successful in that, then move to the next one. It's frequently helpful to have some successes under your belt before you try and eat the whole pie. So just some thoughts.

DR. MAISEL: So this is Bill.

So I think those are great thoughts, and I'm sorry if this wasn't clear from the outset, but that is exactly what happened at this meeting, as you know. AdvaMed and MDMA and MITA were asked to identify members that could represent their industries because we obviously can't have 10,000 manufacturers around the table. And so for each of the respective stakeholder groups, that is how we identified this group. FDA did not pick the selected individuals who are up here today.

MR. TREVINO: AQMDS is on board, and I'd love to see the new AAMI facilities.

MS. RACIC: And yes. Yeah, thank you.

MR. JENSEN: Josh, can I add one thing? So I was a little short on the uptake on your first ask on who else should be invited. I would like to ask the FDA to consider inviting their federally funded research and development center, MITRE Corporation. And a full disclosure, I used to be the vertical healthcare VP there. The FFRDC is for HHS, NIST, VA, and DoD. So the representation in terms of at least medical knowledge is very deep, and the abilities of that team are very deep in terms of research and other resources that could be brought to bear on some of these issues. So I'd encourage the FDA to think that over, if

there's some things that we can learn there. And their aviation, as Dave mentioned, their aviation safety information analysis system gathers a lot of the same sorts of safety data that we talk about in the medical community, and that kind of approach and code and methodology is really all owned by the government, so there may be some leverage there as well. Just a suggestion.

MS. JOHNSON: And perhaps you could focus the cybersecurity folks around like the Sector Coordinating Councils. I mean, that should be pulling everybody in. That might be an efficient way to cover it.

DR. MAISEL: So one of the ideas that Tara put forward, which I think many organizations have done, you know, standards development organizations, other collaborative efforts, you know, there is a core group that sort of becomes the steering committee, and then there are potentially subgroups or work streams that can work on the individual areas. Obviously, the person -- you know, the same people working on education and training aren't going to be the cybersecurity folks, and we want to make sure we have the right expertise around the table.

And so I guess a question for -- as we move forward, I'd be interested in your thoughts. It seems like -- I mean, there are two options, right? We could get -- you know, focus more on that core group piece and talk about what it is we're trying to accomplish, or we could try to identify, you know, do that and identify potentially one of the first work streams where we might want to bring in some subject matter expertise to focus and spend some time starting to tackle one of the areas that we've identified. So what are the thoughts about what that next meeting might look like or as we start to move on to next steps?

DR. JACQUES: I think it's a wonderful plan, right, from a steering team workgroup perspective, to really focus on who needs to shape the agenda, right, the very cross-

functional team to a lot of the conversations that we've had, but also a well diverse team that allows input, right, from various stakeholders, right, with maybe one or two memberships. So I agree, you know, focusing on a steering team first would be wonderful, and then off that steering team, right, some subgroups with some really deep and wide expertise on the particular work stream, I think, would be a wonderful next step.

MR. PHILLIPS: Bill, I think there are two different options. One is we can take the next forum to look at our list of shared interests and flesh those out further and make sure that the broader community that we just identified is actually in agreement that those are shared interests or the next forum could be to take a deeper dive. My only concern with taking a deeper dive is that, number one, we have the right stakeholders in the room and, number two, we don't take a deeper dive around an Everest. And so really our first efforts should not be the toughest hill to climb; it should be trying to find a quick win or a success to build upon for the community itself.

MR. WEEMS: Yeah, I think that, you know, in line with that comment and with others, you know, it would be useful at some point to, you know, maybe divide out into categories what the different interests are, and I think that might be a useful activity for the next or -- you know, the meeting after that to pick out whatever the three or four or five or six, you know, categories of interest would be and get some consensus around that so that when we do start moving into work streams, whenever that is, we already have some sense of the direction we're going, the kinds of people that we would need to feed into that work stream and what an objective might be.

DR. SILVERSTEIN: Anyone else? The panel is being a little quiet on this particular topic. I would like to give the rest of the panel an opportunity to chime in if that format makes sense to them.

MR. TREVINO: What I'll say is it makes sense, I think that's the right first step, is to

understand and organize a steering committee. I think breaking into the identified subcommittees is fairly obvious and straightforward, but I think the tactical structural nature, operating mechanism and procedure, decision making, representation, all those things I think are important to start with, and then the real work can begin.

DR. JACQUES: I would probably add to that list some ground rules, right, some basic guiding principles, right, because as all of us come together in a collaborative community, we want to assure that, right, we're all in it for the right reasons and so -- but I like your list.

MS. RACIC: Yeah, I think one of the questions maybe for the FDA, we know that the FDA is striving for kind of encouraging more of these collaborative communities in other areas, too, and I'm wondering if those ground rules are already established, if there's any lessons learned from the other communities that we can add to this.

DR. SILVERSTEIN: Yeah, we do have a toolkit available, and we'll make sure that when we do start, you know, more substantive discussions, the ground rules are very clear to everybody. So everybody's got a perspective on the ground rules, and I think that those ground rules should also be mutually agreed upon by all the stakeholders that are going to be at the table as well. So I don't think that's something that necessarily we would be doing, but I think we would be happy to participate in that part. So we have some time for public comment, and so what we'd like the public comment to discuss --

MS. FEDERICI: Joshua, before we do that --

DR. SILVERSTEIN: Sure.

MS. FEDERICI: -- I just want to make -- I want people to understand, you know, AdvaMed is structured. You know, we're a large organization, and we have lots of different working groups with different expertise. We have an entirely separate group that works on cybersecurity issues. They're not socialized to any of these issues necessarily, so there's going to be time and effort on the part of our working group to socialize that group that has

the lead on cybersecurity to the issues that we're talking about here. So I would encourage that to be a later discussion to enable that discussion to occur within industry and AdvaMed.

MR. WEEMS: Josh, one other thing. Maybe you were alluding to this, but I think it might be instructive at the next meeting for you or somebody from your team to maybe give a presentation on the collaborative community toolkit. You've alluded to its availability, but I think that hearing from you all a little bit about it might be instructive.

DR. SILVERSTEIN: Thank you.

Okay, so we do have time for public comment, and so what we'd like to hear about specifically are the topics that we've been discussing and so, you know, just again, if there's another area that you would think is most amenable to collaboration or important stakeholders that should be involved in this effort.

Thank you.

MR. MACKEIL: Okay, thank you again. And once again, you know, I feel like I've been thrown into the pit of misery right along with you, so we're accomplishing that goal here. To tie in some of the topics that we spoke here, evidence and QMS and participation, one of the key participants in HTM are the CMMS software vendors. You need QMS and you need evidence and you need reporting. A significant part of my day is typing work orders and documentation into a computer terminal, and that information, because it's very specific to the software that my facility uses, you know, goes to risk management, organizational decisions, and planning.

But to the best of my knowledge, that CMMS software doesn't have a common core which allows that data to be exported to regulators and industry for providing CDRH and the FDA with information about device failures and servicing. So I think CMMS software vendors and developers could be part of our discussion so that their products gives the

industry a common core of data exchange to answer a lot of these questions that we're all asking. And a common core of coding that those of us who work at the point of care with these devices, I know there's a standard being worked on for that, but it would be so important and so much more relevant, and I would be so much happier when I'm sitting there in front of the keyboard saying, I've got to get these work orders done before I can go home, if I knew not only was I contributing to my employer's knowledge of what I do but to the entire industry's perspective in what I do and to the greater safety of the patient population of the U.S. I think that would be -- so CMMS software vendors should really be a part of this discussion and the products that they sell to all of us that we use in our healthcare facilities and should have a common core to meet the needs of those of you who are sitting on these panels.

You spoke a little bit about training, many things to many people. I took that CBET exam in 1994 with a number 2 pencil, but in this day and age, hospital budgets to send biomeds to expensive training, you know, travel, etc., those budgets are getting pretty thin, so I think all of you in the industry who train biomeds and providers need to go look more at CBETs and distance learning. And, you know, we use a thing called HealthStream, and believe me, if I don't meet my HealthStream requirements, you know, I get a severe talking to. So I have to be up to date on all my CBETs and all my training, everything from bloodborne pathogens to radiation safety to MRI safety, and I think we could definitely do a lot better with that across the industry as a model.

Everyone needs to know about -- so for certification, you know, I took that CBET exam a long time ago. The FCC has a great model where you have levels, you know. A Level 1, you know, is all the basic knowledge you need to be safe to be a radio operator, etc., etc. I think we need a beam at one certification. And one of my duties is what I call vendor escort and support. When that OEM FSE happens to be a former biomed, we speak

the same language, we know all the -- we know the drill, we get it all done. Some FSEs I bring into my environment and I facilitate their work to do what they do, and they're sometimes like deer in the headlights. I honestly think there should be an FSE certification that one of our well-known certification agencies could provide so that all of the FSEs from the OEMs have a basic understanding of what they do and need to do to work in the environment. And I know Medtronic spoke about their extensive FSE training. So that would be something to do.

DR. SILVERSTEIN: Hey, Scot, I'm sorry to cut you off. I just wanted to allow other folks. We had some other people standing up, and I have -- we have a few more minutes to accept public comment, and I already see some folks --

MR. MACKEIL: All right.

DR. SILVERSTEIN: -- coming to --

MR. MACKEIL: Thank you. I was just about to say thank you.

DR. SILVERSTEIN: Oh, I'm sorry.

MR. MACKEIL: You were right on the same page with that.

DR. SILVERSTEIN: Yeah. No, thank you very much for your comments.

MR. MACKEIL: Absolutely.

DR. SILVERSTEIN: We really appreciate that.

MR. MACKEIL: You got it.

DR. SILVERSTEIN: Thank you.

So we have 5 minutes total, and I see multiple people, so please, you know, keep your comments within a minute. Thank you.

MR. BOALS: Frank Boals, Defense Health.

I want to thank you, Josh. You did a wonderful job coordinating the meeting, making sure everything ran. Bringing that to the concept of the future meeting, it is very important

to have a neutral facilitator to almost have a meeting. One needs to be willing to pay to have a neutral facilitator.

Thank you.

MR. CLUFF: Hello. Eric Cluff representing Abbott Laboratories.

I just wanted to thank you for your focus on quality. I really got the feeling that the panel generally aligned with that, and that is very encouraging. A couple of ideas that don't necessarily represent Abbott's perspective: One of those is that a common area of concern to focus on would be risk assessments, the idea of a risk-based approach. And, really quickly, I think there are other industries that use common FMEA language, failure modes, failure causes. I think if there were some development around that, that there would be a lot of value in that, especially for the smaller mom and pop shops that might be out there that could also take that as long as we make sure that IP is protected in all of that.

And then the second thing was just the thought of in conjunction with these types of meetings, if there might be an opportunity to just have like a solutions gathering area where you just throw people at it, and the only common ground rule is that if they start to yell, they can leave and anybody else can share things and work on specifics of solutions, because a lot of what we're talking about, really a solution does exist, and that kind of will get some traction pretty quickly, you know, at subsequent meetings.

Thank you.

MR. AGGIS: Hi, my name is Greg Aggis, and I'm with Stryker Corporation.

A couple of thoughts. One related to just the discussion around collaboration, I think it's very important. Our organization, we, like several of the other organizations up there, were involved with direct OEM repair. We also do some third-party repair through different divisions, and we sell parts for some of our equipment, etc., etc. But I think one of the hurdles to this collaboration is going to be identifying the remanufacturing because, in fact,

our organization, for certain divisions within our organization, remanufacturing would be considered a lot of what is considered just general repair and getting the general discussion. So I think without that definition of defining that, and particularly, I'm referring to devices that are sterile devices or high-level disinfected devices and the requirements that manufacturers are burdened with or not so burdened with, but meaning that we have to comply with that certain other organizations don't have to. I also understand that we've got biomedical engineering that's required to do certain things for the Joint Commission, CMS, etc., etc., and have their own hospital requirements. But, again, there's a group of organizations out there that have no responsibility other than having a business license to repair medical devices, and I think that's an important distinction as well.

From a manufacturer standpoint, we're concerned with the safety and efficacy for the patients. We're also concerned about IP and also about the general quality and name brand that is on the device when it's used in the hospital and the safety of that device. So I think there are some hurdles to collaboration that have to be overcome before we can get to that point.

The other thing is, is that we talk about training again because there's no regulation on a certain component of organizations out there that services equipment, if we go in and train a biomedical engineer. And this was brought up before, that biomedical engineer, I think it was mentioned, gets 20 years experience and then goes out and starts his own shop and now he's doing his own thing. Again, there's no requirements on that group of people to do anything related to registration or oversight, and then how do we get the information back as the OEM? So I think there are several hurdles that we've got to overcome before you actually get to collaboration.

Thank you.

DR. SILVERSTEIN: Thank you. We have one more minute. I'm not seeing anyone.

Okay, so I would just like to very briefly summarize this session. So we talked about identifying additional entities to participate in this effort. I'm not going to go through every single one that I heard, but I took very good notes, I promise you, but examples include the VA, CMS, the Joint Commission, providers, and smaller independent service organizations. So, with that, we're hoping to have sort of a steering committee developed that would meet in the first quarter. And so if anyone from the public is interested in helping join that steering committee, you can email me, and I'll make sure that I communicate with the rest of the folks at this table or others who are interested in this effort.

And so just to summarize the meeting in general, I'd like to remind everyone that FDA has an open docket related to the white paper that we discussed yesterday, and please submit your comments. But before that, I'd just like to take a step back, and Jeff, I just wasn't sure if you wanted to add anything about our collaborative efforts. Sorry, I jumped the gun on comments.

DR. SHUREN: I don't know. I just want to thank everyone who participated on the panel, everyone who attended here in the audience for the great comments on this topic. I think, as you can see, it's important to a lot of parties, including to the Agency, and we look forward to continuing the undertaking. Thank you.

DR. SILVERSTEIN: Okay. So, again, I would encourage public comment to our docket. That will be closing in about 6 weeks, at the end of January. Thank you very much for attending our public meeting on servicing and remanufacturing activities, and this adjourns the meeting. Thank you.

(Whereupon, at 11:47 a.m., the meeting was adjourned.)

C E R T I F I C A T E

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

PUBLIC WORKSHOP - MEDICAL DEVICE SERVICING AND REMANUFACTURING ACTIVITIES

December 11, 2018

Gaithersburg, 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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TOM BOWMAN

Official Reporter