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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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Hilton Washington DC North
620 Perry Parkway
Gaithersburg, MD 20877

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M E E T I N G

(8:03 a.m.)

DR. SILVERSTEIN: Good morning. My name is Josh Silverstein. I'm a regulatory advisor in the Office of Device Evaluation. I'm going to let Dr. Maisel formally welcome everyone in a few minutes, I just want to go through a few housekeeping items.

If anyone is curious about the restroom, it's out the doors, to the left. There is coffee and water over here.

Everyone should have an agenda in their workshop folder. There are also some workshop materials in there. So as you can see from the agenda, we do have breaks and lunch. There's a restaurant here at the hotel. There's also a Panera, Chipotle, Boston Market, and a Sardi's close by, among other places.

So if you have any questions and you'd like to find someone from FDA, we have a white ribbon on our name badges.

And so with that, I'd like to have Dr. Maisel welcome you to this public workshop. Dr. Maisel is the Director of the Office of Device Evaluation, the Acting Director of the Office of Compliance, and the Center for Devices and Radiological Health's Chief Medical Officer.

DR. MAISEL: Good morning. Let me add my welcome. Thank you for joining us today for this workshop on what we think is a very important topic, and I hope you think it's a very important topic, on distinguishing servicing and remanufacturing activities.

You know, several years ago CDRH revised our vision statement such that it reads that patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world, and it's no coincidence that we put the word "patient" first in our vision statement. And we're happy that we've seen a significant increase in the number of novel devices that have come to the U.S. market each year, and importantly, these novel devices aren't simply "me too" devices. They really and truly have

an impact on patient lives. We've seen devices that can help paraplegic patients to walk, that help blind patients to see, that can help deaf patients to hear. We've seen devices that infuse insulin for diabetic patients and adjust the dose automatically, that can automatically notify parents of a pediatric diabetic patient's -- that their child's glucose level is too high or too low. There have been diagnostic tests that can help diagnose cancer earlier or can help identify which treatments are best for these patients.

And so we've seen these incredible advances in technology, in materials, in digital health, in artificial intelligence and the list literally goes on and on. And while it's hard to overstate the importance of getting these novel technologies to patients in a timely fashion, our vision statement isn't just about getting these devices to patients; it's about making sure that once they get to patients, that they remain high quality, safe, and effective.

Last month we announced an important new goal, ensuring that FDA is consistently first among the world's regulatory agencies to identify and act upon safety signals related to medical devices. And for reusable devices such as radiological equipment, infusion pumps, and endoscopes, the performance of professional and quality servicing and maintenance really plays an important role in the continued safety and effectiveness of devices.

We know that independent service organizations, hospital facilities, and original equipment manufacturers perform excellent servicing and maintenance. We've seen and been to many facilities that do this.

But we also know that there are other aspects of medical device servicing for which we can work together and do better. One of those areas pertains to clarifying the difference between servicing and remanufacturing. FDA makes an important distinction between these activities because remanufacturing can have a significant impact on the safety and effectiveness of a device, and accordingly, the regulatory requirements for these activities are different.

Some entities, we've seen significantly modified devices. For example, we've seen entities that override certain safety features on a device, and these activities are not servicing; these are remanufacturing activities. And based on the examples and comments that have been provided to the Agency over the last 2 years through our public docket, through discussions and through our workshop, it's clear that there's some confusion about the distinction between these two activities.

So the first day of our workshop, therefore, focuses on clarifying this distinction, and we really seek your help and your input on our proposed approach. You'll hear much more about this, obviously, this morning and throughout the day. And while today's topic will primarily focus on clarifying the difference between servicing and remanufacturing, the servicing report that we released earlier this year also highlighted several other areas of importance.

The adoption of quality management principles by servicers can help identify, prevent, track, and monitor safety hazards and reduce risks, and we intend to work with the servicing community to identify the essential elements of a voluntary medical device servicing quality framework. Hopefully, the importance of a quality framework will be evident to you today as we talk about taking and organizing a consistent approach to distinguishing servicing and remanufacturing activities, as we talk about employing a risk-based approach and ensuring proper documentation.

Our servicing report also highlighted the importance of effective cybersecurity practices. On the one hand, original equipment manufacturers need to secure their devices and protect them from unauthorized access, but on the other hand, they need to design them so that servicers can have secure access to the device and perform the activities that are necessary in order to maintain the products in the field. We know that cyber vulnerabilities are a modern-day reality, and services are positioned to perform an

important role in assuring that devices receive the necessary product updates to protect them from malware and other unauthorized intrusions. Some of today's examples involve modifications to software, and we have proposed certain activities that may or may not qualify as servicing or remanufacturing, and we look forward to hearing your thoughts about whether the proposed list got it right.

Although we note in our report that the available objective evidence is not sufficient to conclude whether or not there's a widespread public health concern related to medical device servicing, we do believe that the creation of an environment of learning and continual improvement is of central importance for medical device servicing and for the industry to deliver high-quality, safe, and effective service.

Today we'll work together through examples to pressure test the draft proposal for how to distinguish servicing from remanufacturing. Tomorrow, during the half-day session, we'll focus on establishing a collaborative effort to address some of the other challenges that I've mentioned.

In concluding, I'd like to leave you with one final thought. I'm confident that not a single person in this room and not a single person listening via webcast wants anything other than our patients to have access to well-serviced devices. I'm very confident we all feel the same way about that. We set up this workshop to be interactive and to foster a collaborative spirit. We hope that you'll participate in good faith, that you'll be open-minded, that you'll share your perspective, and that you'll listen carefully to the perspective of the other attendees. And we're very grateful that you're here today to help us work through these challenges, and once again, on behalf of FDA, welcome.

DR. SILVERSTEIN: Okay. And I just have one other housekeeping remark. We just wanted to welcome a few members of the media today and just remind people that this is a public meeting.

So I'd like to introduce our first presentation for the day. So Laurel Burk is a biomedical engineer in the Office of In Vitro Diagnostics and Radiological Health, and she's going to be providing just a brief synopsis of our history, the purpose of our workshop, overview of the white paper, future guidance. So, Laurel, please.

DR. BURK: Thank you for the introduction, Josh. I'm Laurel Burk, and welcome to this public workshop on Medical Device Servicing and Remanufacturing Activities.

I'll give you a second to look at our disclaimer. Essentially, this presentation is meant to introduce some topics for discussion and to queue up our workshop for the day. It's not intended to represent guidance or policy.

Here's an overview of the presentation. We'll introduce the goals of this workshop, briefly touch on the recent regulatory history of servicing and how this relates to today's discussion; then we'll do a brief overview of the white paper that was released prior to today's workshop. I hope you've had a chance to look at it; you have a copy of it in your folder. The white paper's contents are a launching-off point for our panel discussions and our breakout sessions today, and then I'll run through the agenda.

Today our primary goal is to enter into a public discussion on the differences between servicing activities and remanufacturing activities for medical devices. What we discuss here today will better inform FDA's future draft guidance on the topic.

As we discuss servicing and remanufacturing of medical devices, please keep in mind we're talking about all different kinds of medical devices, not just the ones that you are most intimately familiar with. These are higher and lower risk devices, physical devices, software devices, covering the entire spectrum of devices.

We'll use the recently published white paper to facilitate the discussion. The white paper introduces an approach that FDA is considering proposing in draft guidance. The white paper lists several examples of medical devices and actions that are taken on those

devices. We'll be using those examples in our breakout sessions to discuss the approaches discussed in the white paper. And then, while we're here, we'll discuss opportunities for collaboration among servicing and remanufacturing stakeholders and FDA.

As we start, let's reintroduce some key terms to keep in mind throughout our discussions. These terms and definitions refer to actions taken, not the entities who are performing them.

So, first, remanufacture. This definition comes from the C.F.R.: Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications or intended use. Keep that distinction in mind as we talk about the rest of these terms.

Service: Repair and/or preventative or routine maintenance of one or more parts in a finished device for purposes of returning it to safety and performance specs established by the OEM to meet its original intended use. It excludes activities that change the intended use of the device or change the safety or performance specs.

Recondition, refurbish, or rebuild: Restores a medical device to the OEM's original specs or to be "like new." The device may be brought to current specs if the changes made to the device do not significantly change the finished device's performance or safety specifications or intended use. These include repair of components, installation of software or hardware updates that don't change the intended use, and replacement of worn parts.

And repair: A type of servicing that returns a component to original specifications, including replacing non-working components or parts outside of routine or periodic upkeep for the current owner.

One thing to emphasize from these definitions is that all of these actions, other than remanufacturing, do not make significant changes to the medical device. For example, a replacement of like-for-like parts would not be considered a significant change; they do not

significantly change the device's performance, safety specifications, or intended use.

Now I'll briefly go over the recent regulatory history of servicing. Many of you were here in 2016 when we held a public workshop to discuss the history, working definitions, and terms and comments on servicing that were submitted to the public docket that was open, and you submitted comments. In 2017, FDARA Section 710 was enacted, and the Agency released a report earlier this year on device servicing. This was published on our website. I hope you had a chance to read it. And then we announced that there would be a draft guidance on our A-List for this fiscal year, 2019, on the topics we're discussing here today.

So we refer you to the full published FDARA Section 710 report for a full background on medical device servicing, regulatory history, a summary of the public workshop and the input that we received, and also a summary of the evidence that the Agency considered in forming its conclusions.

And I thank Dr. Maisel for summarizing a lot of our conclusions. I'll repeat them very briefly again today.

The currently available objective evidence isn't sufficient to conclude whether or not there is a widespread public health concern related to servicing that would require additional requirements.

The objective evidence indicates that many entities provide very high-quality, safe, and effective servicing of medical devices.

But more pertinent to today's discussion, a majority of the comments, complaints, and adverse event reports that we received alleging inadequate servicing actually appeared to pertain to remanufacturing.

And in the report, the Agency expressed an intention to pursue the following activities:

- Promote the adoption of quality management principles;
- Clarify the difference between servicing and remanufacturing;
- Strengthen cybersecurity practices; and
- Foster evidence development to assess the quality, safety, and effectiveness of medical device servicing.

Today's workshop and the white paper that was released in advance of this workshop are intended to support that second action.

As mentioned, we released a white paper on servicing and remanufacturing activities a few weeks ago, and you have a copy of it here today. I hope you have had an opportunity to reflect on it and think about the contents because that will guide our conversation.

The white paper is not draft or final guidance. It isn't intended to propose or implement changes in policy. It contains the Agency's initial thoughts on our guiding principles, a flowchart to guide decision making if an activity is servicing or remanufacturing; it contains a discussion of a complementary approach for software, considerations for labeling, and device-specific examples.

This white paper is intended to facilitate public comment and discussion at this workshop.

I'll spend some time discussing the five guiding principles discussed in the white paper, which are FDA's initial thoughts which we are considering to help determine whether activities are servicing or remanufacturing.

1. Servicing does not significantly change the safety or performance specifications of a device.
    - Activities that significantly change the performance or safety specifications, or the intended use of the device, fall into the definition of remanufacturing that was introduced a few slides back.

- And even if an activity isn't intended to make a change to safety or performance, that activity should be first evaluated to determine whether it, in fact, does.

2. Evaluate whether any changes to a device require a new 510(k).
    - Regardless of whether an activity is servicing or remanufacturing, any changes should be considered pursuant to 21 C.F.R. 807.81(a)(3), and also the FDA guidance documents, Deciding when to Submit a 510(k) for Changes to an Existing Device and Deciding when to Submit a 510(k) for a Software Change to an Existing Device.
3. Assess component, part, and material dimensional and performance specifications.
    - This assessment will inform whether the action being taken is servicing or remanufacturing. Evaluations can be made as compared to OEM parts, materials, or specifications determined through testing.
    - And any deviations from the original specs may require closer evaluation because they could result in significant changes to performance.
4. Employ a risk-based approach.
    - FDA is considering recommending a risk-based approach similar to ISO 14971 using concepts like risk estimation, risk control, assessment of hazards, etc., which we believe could be applied to servicing and remanufacturing activities.
5. Adequately document all decision making.
    - We're considering recommending that entities document the rationale behind your determination of whether something is servicing or remanufacturing.
    - And effective documentation can facilitate sound decision making and help

justify the decision that you made.

We will discuss these guiding principles again in more detail at the end of the day in a panel discussion. But for now, please keep these guiding principles in mind and use them as appropriate throughout the day.

I'll breeze through the rest of the white paper contents because, throughout the rest of the day, we'll be having breakout sessions dedicated to these.

Activities generally not considered servicing are mentioned in the white paper. There's an introduction of the flowchart, a discussion of changes involving software, and device-specific examples:

Staged to test validity of the guiding principles and distinction approaches.

The examples include activities performed on infusion pumps, endoscopes, MRI, ultrasound monitors, non-device specific articles, and software.

And each of your tables will be assigned one of these to think about primarily in the examples, but we encourage your input on all of the examples.

And then, finally, labeling considerations and protection of trade secrets and confidential commercial information.

So, finally, here's our agenda for today. After I'm done speaking with you, Josh will introduce the flowchart presented in the white paper and queue up our first breakout session. After lunch, there will be another breakout session topic on access to labeling and servicing information. And, finally, there will be a panel discussion on the guiding principles introduced in the white paper.

And then for tomorrow, when you come back for more, we'll pick up with an introduction and remarks from Dr. Jeff Shuren and transition into a discussion of our larger collaborative goals in the medical device servicing space.

On Day 2, when we discuss opportunities for collaboration among servicing and

remanufacturing stakeholders, we believe that this collaboration will benefit the safety and health of patients, which is paramount. Collaboration will extend beyond the topics that we're discussing here on Day 1 of this workshop.

FDA is aware of collaborative efforts in the medical device servicing and remanufacturing community, and we encourage participation and representation of all stakeholder groups in these efforts. FDA will also actively participate as a stakeholder in collaboration efforts.

So, with that, I'll hand the microphone back over to Josh. Thank you.

DR. SILVERSTEIN: Thanks, Laurel. So as I said earlier, my name is Josh Silverstein, and I'm a regulatory advisor in the Center for Devices and Radiological Health.

This presentation will act as an introduction to our first breakout of the day. I'll discuss the flowchart and complementary approach for software that are included in FDA's white paper. At the end of this presentation, we'll break out into our groups to discuss the examples in the context of the flowchart and our complementary approach for software.

Before we get started, I'd just like to disclaim that the information in these slides is for discussion purposes only and does not represent draft or final guidance. It's not intended to propose or implement policy changes regarding servicing and remanufacturing or the applicable statutory and regulatory requirements for entities conducting these activities.

So as a background for this session, FDA is considering proposing a flowchart as a visual aid to help entities distinguish servicing from remanufacturing. This flowchart is intended to be used in concert with the accompanying text and guiding principles. The flowchart is intended to guide entities, but it is not meant to capture all necessary considerations for an entity to distinguish servicing from remanufacturing. FDA is considering proposing a complementary approach for changes involving software that I'll

talk about as well.

So even before an entity would consider the flowchart, FDA is considering identifying certain activities as not servicing. These include:

- Changes to sterilization methods
- Changes to reprocessing instructions
- Changes to the control mechanism, operating principle, or energy type
- Significant changes to intended use, such as changing a single-use device to become reusable

These activities typically would represent remanufacturing, and further evaluation would not be necessary.

FDA would like stakeholders to consider whether they agree with this list or whether any activities should be added or removed to represent examples of changes that do not constitute servicing.

Everyone, in their workshop folder, has a copy of the white paper that is on the left side, and so the flowchart can be found in that white paper.

And we think about this flowchart as sort of being divided into the left and the right columns. So on the left side we see there being an objective decision about the activity that's being performed on the device, and the right side is the assessment of whether it significantly changes performance or safety specifications.

And now I'm going to individually go through each decision point on the flowchart.

So the first question is A1: Add, remove, or change a component/part/material which directly or indirectly contacts body tissues or fluid. This part of the flowchart helps consider biocompatibility of the device by focusing on patient-contacting component/part/materials. If there is an addition, removal, or change to a component/part/material that directly or indirectly contacts body tissue, or an entity is

uncertain, the answer should be yes to this question.

If the answer was no, entities would proceed to A2 on the flowchart. If the answer was yes because of a change to patient-contacting materials, including removal to expose a previously unexposed component, part, or material, a risk-based assessment should be conducted. Depending on the magnitude, a more thorough assessment or testing may be necessary. If there is a significant effect to biocompatibility, this change may be considered remanufacturing.

After assessing patient-contacting materials, the next step in the flowchart is to assess whether activities add or remove a component/part/material or change the dimensional or performance specifications of a component/part/material. In addition, removal or change to dimensional or performance specifications should have a yes answer to this question.

If the answer to A2 was no, entities would then proceed to A3. If the answer was yes, they would then assess whether the change significantly affects performance or safety specifications. For example, considerations include whether new components can withstand repeated reprocessing cycles or whether the added or changed part is within acceptable dimension or performance output specifications. If yes, the change would likely constitute remanufacturing.

So part 3 is, is there a new or increased risk, or is there a change in the performance or safety specifications? This includes consideration of individual and cumulative changes, and the extent of this assessment should consider the nature and extent of the activities performed on the device. If the answer is no, the change is likely servicing. If yes, then we assess whether the change significantly affects device performance or safety specifications. If new or increased risks were identified, entities should evaluate whether they significantly change the performance or safety specifications. For example, changes that bypass safety

features likely do affect safety and performance specifications. If the answer to this question is yes, then the changes would constitute remanufacturing.

In our white paper, FDA noted that the flowchart in Section 5 should not be applied to software. We instead are considering identifying certain activities that are generally considered to be servicing, and we think that the following common activities performed on software might be generally considered servicing, such as

- Implementing OEM-provided updates and upgrades;
- Running software diagnostics;
- Assessing for viruses, malware, and other cybersecurity-related issues;
- Reinstalling OEM software to restore original performance and safety specifications;
- Reverting software to a previous configuration;
- Installing cybersecurity updates that are authorized by the OEM; and
- Turning on or off connectivity issues such as Wi-Fi or Bluetooth connections, consistent with the OEM intended use.

So within our white paper there are several examples that we have for discussion, and there are approximately 40 different scenarios that were outlined. These examples are hypothetical activities that may be performed on medical devices. These examples include activities performed on infusion pumps, endoscopes, MRI, ultrasound monitors, non-device specific articles, and software. And each example is presented with multiple alternative scenarios that are intended to facilitate discussion today at our workshop.

So I'd like to now introduce our breakout session, Flowchart, Software, and Examples, that will encompass the rest of this morning's session before lunch.

The goals of this breakout session are to pressure test the flowchart; discuss how an entity would assess whether the actions are servicing or remanufacturing; how that activity

should be documented. So everyone should have step-by-step instructions in their workshop packet, and I'm just holding it up right now as well. I'm going to go through the workout instructions right now.

So, Number 1, everyone is already sitting at a table, so each person has been assigned a table number, and you've already been directed there, so thank you for that.

Number 2, once we actually break out, please introduce yourself to the table, including your name and affiliation.

We're asking each group to identify two different people: a facilitator that will help foster discussion and will be responsible for initially reporting your table's discussions during our reconvening session; number two, a scribe that will document each table's discussion for each example discussed during this breakout session.

An FDA staff member may be present at your table or will rotate between tables. The intent of this session is to obtain your feedback and comments, but FDA staff can assist you with clarifying questions.

Number 5, on your table you were assigned one example for which FDA is requesting your table's feedback and comments. We're asking everyone to discuss each scenario in the example.

As I already stated, the goal of this session is to pressure test the flowchart and complementary approach for software, and so each table should discuss how an entity would assess whether the actions described in the example are servicing or remanufacturing and how that activity should be documented. You should consider these examples in the context of the flowchart found on page 6 and the targeted questions on page 12 in FDA's white paper.

To consistently capture public comment, FDA has made a standardized form for participants to use. One form should be completed by the scribe for each table for each

scenario that is discussed. The completed form should accurately represent all perspectives at the table. Once we break out, FDA staff will be distributing these forms to you, and we also have an example that is filled out just as a hypothetical to allow people to sort of understand what we're looking for.

So as I said, for in-person attendees, each example discussed, the scribe should complete a form to summarize your feedback on the example. At the end of the reconvening session, FDA staff will collect forms from tables.

For remote attendees, FDA encourages remote attendees to participate in this session by choosing an example and completing the report-out template that's found on our webpage for this public workshop. And please email me your completed forms at the end.

If your table is able to finish the example that was assigned to you, please select another example from FDA's white paper. The scribe should complete a separate report-out form for each example that is discussed.

During the reconvening session, FDA will ask each table to discuss their feedback on their example and the flowchart. FDA has timekeepers to make sure that all tables will have an opportunity to provide their feedback on the examples and flowchart.

So I'm just going to give you an example of sample feedback that will also be distributed to you via paper.

So, for example, 1A (Infusion Pump) - Scenario 2, I'm going to present the scenario and then I'll go through some sample feedback.

While verifying the accuracy of an infusion pump flow rate, it is determined that the door of the infusion pump has been bent in a way that pinches the administration set. Due to this pinching, the accuracy of the flow rate falls outside the OEM's specified accuracy range. An adequate replacement door cannot be obtained and the existing door is

repaired.

So you'll find on these report-out templates that we're asking people to describe any assumptions that we make because we know that the examples are specifically a little vague to foster some discussion at the table. So the assumptions that we made is that the entity intends to bring the device back into its OEM-specified performance and safety specifications and intended use.

So going through the flowchart with A1, the infusion pump door contacts skin, so the answer is yes.

For A1.1, there was no addition, change, or removal of a component/part/material. Therefore, this activity does not significantly affect device performance or safety specifications.

A2, the existing door was repaired without adding a component, part, or material. The door was repaired without knowing the OEM dimensional or performance specifications of the door. So the answer is yes.

A2.1, while the exact door dimensional specifications were not known, the critical performance specification, flow rate accuracy, was identified in the device labeling. Given that the performance specifications were within an acceptable range, the change did not significantly change performance or safety specifications.

A3, using a risk-based assessment for this device type, there is no new or increased risk because it was a repair of an existing part, and there is no change in the performance or safety specifications. Therefore, the change is likely servicing.

And there are also two targeted feedback questions at the end of this report template that you'll see.

And so for (1), in this case, enough information was available to determine whether the device contacts body tissue, the importance of the dimensional specification changed

and how it could affect performance specifications, and whether there could be new or modified risks. This activity may represent remanufacturing if the device did not perform to specification. The entity performing the activity is responsible for determining that the device remained in spec.

And the second feedback question is entities could document that they bent the door back into place and describe any quality assurance testing used to ensure that the device performs according to its performance and safety specifications.

So, with that, it is now 8:40, and so we are running a little early, so we're going to give everyone 80 minutes, but we will check in, in 1 hour, just to see how everyone is doing on their progress, and if we can take an early break, we'll definitely do that.

So, for now, I'm asking for all of our FDA staff to please distribute the forms. We're going to break out. The instructions can be found at your table, and please start off with introducing yourselves to your table for a few minutes. Thank you.

(Off the record at 8:40 a.m.)

(On the record at 9:40 a.m.)

DR. SILVERSTEIN: Folks, could I have your attention for just 1 minute? Hi, folks, just 1 minute. So we have 20 minutes left in our breakout session. If you haven't started documenting your feedback, please do that now. We also recommend that the table discuss the feedback that's written down so that all perspectives at the table have been heard and everyone agrees that those were their perspectives.

Hey, sorry, could I have your attention? I promise, we're very pleased that everyone is enjoying their table conversations. We just wanted to remind you we have 20 minutes left in this breakout session before we take a break, and so please make sure -- hopefully someone from FDA gave you a little hint as to some of the examples that we'd like to discuss. If you haven't heard those suggestions, please raise your hand and someone will

come by your table. Please make sure that the scribe reads out the feedback on the report-out form to make sure that everyone at the table agrees that those were the perspectives that were expressed during this breakout session. So we have 20 minutes left. Thank you.

(Off the record at 9:42 a.m.)

(On the record at 9:59 a.m.)

DR. SILVERSTEIN: Okay. Hi, everyone. Welcome back. Can I have your attention, please? It's one of the most important parts of the morning. It is now 9:59, and we are ending our breakout session, and we are going to be taking a 15-minute break, so there should be some water, coffee, tea over there. Please keep your report-out templates on your table. We will collect those after the reconvening session, which is after the break. So we will reconvene at 10:15 a.m. Enjoy your break. Thank you.

(Off the record at 10:00 a.m.)

(On the record at 10:15 a.m.)

DR. SILVERSTEIN: Hey, folks, if everyone could make their way to their tables; it's 10:15 and we're going to be getting started hopefully in 1 minute.

(Pause.)

DR. SILVERSTEIN: Hi, folks. Please get to your tables. We're going to be getting started really soon.

(Pause.)

DR. SILVERSTEIN: Okay, thank you very much. We understand that all of the tables had really interesting discussions, so I'd like to explain how our reconvening sessions are going to work today. It will be very similar for our second that happens after lunch.

So as you all have figured out, each table was assigned an example, and we're going to use those assignments to make our way through this public comment section of the workshop. So we've preselected examples for discussion during reconvening that are

common for each device type or may have been submitted to our 2016 docket. If you were unable to get through those examples, we still welcome you to discuss one of your examples when your table is called upon.

And so these examples were chosen to highlight a different decision point on the flowchart or the complementary approach for software, so thinking about the three rows of the flowchart and software, we have just over 25 minutes to discuss each one of those during this reconvening session.

And so we are going to be switching between tables with co-assigned examples, so for example, if I start with endoscope, we'll go to endoscopes next and let them chime in if they agreed, if their discussions were different, etc.

After your table facilitator speaks, if a member of the table would like to provide additional clarification, please raise your hand, and we can hand you the microphone so that you can sort of add any clarifying points. We'd like this to be fairly dynamic, and so we'll also -- I'll be walking around the room as well throughout the process.

So when you start to discuss your example, it would be extremely helpful if you provide a very brief summary of the scenario that was presented in the white paper. We're not saying that you should repeat it verbatim, but hopefully everyone in the room should be able to understand what you're talking about.

This session is being transcribed, so we try to ask people to remember to say your name or organization or even just your table number before you start speaking.

And if anyone else wants to add a comment during any of this, you know, raise your hand and, depending on where you are in the room, I'm going to do my best to make sure that everyone has an opportunity to speak.

So, in terms of the worksheets, at the end of this session please leave them on your table or even hand them to somebody with the yellow ribbon, specifically me or some of

the people that you worked with throughout the breakout session.

And so we will consider the comments in the development of our planned draft guidance. And just in case you wanted to provide other comments, we do have a docket that's open, and we welcome everyone's comments in this room, remotely, and the rest of the public.

So, with that, I would like to start off -- and by the way, I just ask, if I call out your table number and I seem lost, if you could raise your hand. Sometimes it's going to be a little difficult for me to know where everyone is.

So, with that, I would actually like to start off with Table 1, and I'd like to discuss Example A, Scenario 1. And so we think that this example, sort of a critical tipping point, is going to be in the first question of our flowchart. So I'm going to make my way over to you. So who will be representing Table 1? Okay, great. And do you mind standing up and we can --

MR. MASTERS: Not at all.

DR. SILVERSTEIN: Sure.

MR. MASTERS: But we're going to rebel right away because Example A was the one you did already up on the board, where you went through the door and all of that stuff, so we just said -- we skipped over that one and went straight to B.

DR. SILVERSTEIN: Okay.

MR. MASTERS: Okay, so I'm Martin Masters. I work for Boston Scientific, and we were working in the infusion pump, and on Example B they had a stepper motor that they wanted to replace but they didn't have the specifications, and they just picked one off the shelf. And the problem we had with that is that there's not a chance in the world that any stepper motor you just pick off the shelf would work. You have to be able to get to the specifications, unless you do a tremendous amount of reverse engineering.

But going through step by step, A1, does it contact body fluids? No, because it's contacting something else that does contact body fluids. And then are we adding or removing components, parts, or changing the dimensional performance? Absolutely. And then that's for Scenario 1, which we're replacing the original motor and, number two, where we're going inside of it and fixing a winding, and to us, neither one of these is really real world because you're never going to crack over and replace a winding in a little, tiny stepper motor; it's just not going to happen. And, number two, you could never possibly replace one if you didn't have the specs. You could look up any stepper motor in the world to see the serial number, the model number, and go get the specs. So, to us, it would be more valuable if we did something a little more real world where you could talk about things.

And I think that in Example C we got to where you had a sensor, you've got a pressure sensor which is changing, and it's determined that this thing is not working anymore and we replaced it with a non-OEM. Again, the assumption has got to be that you can get to that specification. If you can't, you're just guessing, and that's just never going to be acceptable anywhere. The odds of it working are so low that they just don't exist.

DR. SILVERSTEIN: Okay.

MR. MASTERS: So that was what we went through. But in the first case in Example C, Scenario 1 was not a remanufacture because you met or exceeded, and that's an important point. If you have a sensor that maybe it's an old one and now you can get better ones and it's not the same performance but it's better but it doesn't change the way the final machine works, then it's fine.

DR. SILVERSTEIN: Okay.

MR. MASTERS: It's not remanufacturing. But that was the key, as far as you're transcribing this, it meets or exceeds, because if you're changing things that are electrical

components, anything that you're replacing that's gone end-of-life, the ones that are out there today are so much better but they do exactly the same thing. They just do it a little faster and a little cleaner, those sorts of things.

DR. SILVERSTEIN: So if I can ask a follow-up question. You said exceeds specifications. So how would you determine whether something would change the specifications now, because that's when we get into remanufacturing. So saying, you know, the OEM has a specified range, and if you're not aware of that, how would you really know whether or not that was just servicing or remanufacturing?

MR. MASTERS: It would be, again, if it -- that was what some of our team said. It goes back to what happens to the final performance that affects the patient.

DR. SILVERSTEIN: Um-hum. Okay.

MR. MASTERS: Then that is immutable. But if you've got certain components and you find this specification and you found one that's better, then they're certainly acceptable, but it doesn't change the way the final device works in terms of the patient safety and efficacy.

DR. SILVERSTEIN: Okay. Did you want to say something? Sorry.

DR. BINION: No, I think that was --

(Off microphone comment.)

DR. BINION: Sorry. Steve Binion from BD.

Fundamentally, where we -- I think where we netted out was if it met the -- if you could get to the specs and you met the specs, it was likely to fall under servicing. For those two scenarios, we looked at B and C, if you couldn't get to that determinate, then it was remanufacturing even if you couldn't prove it was changing the performance.

DR. SILVERSTEIN: Okay.

DR. BINION: If you couldn't prove that it met the original specifications, then it was

likely remanufacturing.

DR. SILVERSTEIN: Perfect, thank you.

So I'm going to come over, we're going to continue the infusion pump discussion, and so I'm going to go come over to Table 7 right now, and I see where you are. And so I'd like to kind of determine whether or not the discussions that were held at Table 1 are consistent or if you came to -- if you had a different discussion. So who's -- okay, sorry.

MS. MAGUIRE: Good morning, I'm Barbara McGuire. I'm with ISS Solutions and Geisinger Health System, and we discussed Example C2. And just to recap briefly, it was the frequency of an infusion pump upstream occlusion alarm, and the frequency of the alarm was higher than comparable devices, and a change was made to decrease the detection sensitivity.

So one of our first assumptions was that this change was made by a BMET, not by a caregiver or an end user, and we looked at -- our assumption was that the impact of the change was done by the biomed, not the caregiver. For A1, we concluded that that would be no, since there were no changes in parts. For A2, we looked at -- we concluded yes, because the specification had potential to change the performance of the device. And for A3, we concluded yes, because there was risk that the occlusion alarm could have changed.

So, in the end, we concluded that it would be remanufacturing because we couldn't determine if the change was within the OEM specifications, but we considered other assumptions. We also considered that if the change was made and it was a change that was -- we use the word "legal" or something permitted by the manufacturer. So if it was something that they provided instructions to the BMET, an ability to change that setting, that that could fall under servicing provided those instructions were provided.

And then we also talked quite a bit about the documentation aspect of it and what would be considered adequate documentation, and we discussed that there would need to

be a process in place as far as a policy to do a risk assessment as to the effect of the change, and if there were established procedures provided by the manufacturer to make this adjustment, then it could fall under servicing.

DR. SILVERSTEIN: Thank you. Does anyone else at your table want to add anything on top of that?

(No response.)

DR. SILVERSTEIN: Okay, great. Thank you.

So now we're going to be talking about endoscopes, and so I'm at the right table; we're at Table 8. Oh, Dave, are you the --

MR. FRANCOEUR: Yes.

DR. SILVERSTEIN: Okay, so I don't know if you got to it, but did you get to Example B, Scenario 3?

MR. FRANCOEUR: We did. Would you like us to talk about that first?

DR. SILVERSTEIN: Yes, please. So if you could just give everyone in the room a brief description of the scenario.

MR. FRANCOEUR: Yeah, sure. Again, Dave Francoeur, I'm with Sodexo.

So we're doing Example B, Scenario 3. It's around replacing the OEM -- it's around replacing the lens and the epoxy associated with the lens in an endoscope.

And so the first thing we did was we had to decide, because it's not necessarily stated in here, was it on the doctor's end or was it on the patient end? And so we made the assumption that we started with patient end. And so with that in mind, we talked here -- we went again with the criteria specifically as it is in the example; it's that the lens was reverse engineered and that the epoxy was medical grade. And so then we started down the triage tree, if you will, and so under A1, we made the assumption that it wasn't a significant change and that both the epoxy and the lens were of non-significant changes and

that we were going to continue down the line of being a servicer.

Then we went to the A2 aspect of it, which is, you know, the adding or the removing of the components, the parts, and change the performance specifications. The answer was, assuming again that the epoxy and the lens were of the same value and that they weren't going to have a problem, the fact that they were touching the patient, we evaluated that, but we made the assumption again that it wasn't going to have a significant impact and we continued down the servicer again. But we did note that if, in fact, there was a question, we would have kicked it over into the A2 status of a remanufacture.

And then just continuing on to A3, based on the scenario that we have in place here, that it was, in fact -- we continued down the vein of servicer because we did not see any significant impact, and the reverse engineering stated that it met -- or it met all of the OEM specifications.

DR. SILVERSTEIN: Okay, but what about the -- and did the group have any feedback on our last two questions?

MR. FRANCOEUR: Yeah, so we absolutely did. So right --

(Off microphone comment.)

MR. FRANCOEUR: Yeah, okay. All right, so around how would the different -- yeah, she was a phenomenal stenographer. So the different assumptions. First of all, again, if in fact we couldn't validate -- and we all feel that there is some onus in terms of making sure that the vendor choice, whoever that may be, has demonstrated that they've done what they needed to, to demonstrate the tools, the parts, the things that they're using are going to meet the criteria and meet the OEM specifications, so assuming that they were able to demonstrate that, then we were fine, you could move on. If not, then we felt that that would automatically push it to a remanufacturing status.

And then the second piece around which actions performed to document, we feel

that everything should be documented, that we work towards -- through a QMS system of some sort, that documentation is going to be paramount in terms of what we did, why we did it, how we did, what was the justification and the rationale associated with the things that we did so we can follow up in making sure that through repeat value analysis or, you know, in terms of those other things, that we're going to be tracking what we need to be doing.

DR. SILVERSTEIN: Perfect.

MR. FRANCOEUR: Correct? Anybody, thoughts?

DR. SILVERSTEIN: Would anyone else like to add something from the table?

(No response.)

DR. SILVERSTEIN: No.

MR. FRANCOEUR: Okay.

DR. SILVERSTEIN: Okay.

MR. FRANCOEUR: Thanks.

DR. SILVERSTEIN: Okay. Okay, so now I'm going to go to Table 13, which is also another endoscope table. And so if you would like to add anything on top of Example B, Scenario 3, you're welcome to. Another option for you is to discussion Example A, Scenario 1. And if you could stand up, please.

MR. JOSEPHSON: Yes. Hi, I'm Aaron Josephson. I'm with ML Strategies, which is a consulting firm. I'm here representing Karl Storz, which is an endoscope manufacturer.

So I did want to add some points on Scenario -- or Example B3, specifically around how some of these terms are defined, right? I think that it's important with respect to some of the assumptions that were made. We didn't quite get to such a hard conclusion as the other table because we struggled with some of these terms, specifically medical grade. You know, what does it mean for an epoxy to really be medical grade? It requires that

there be some testing done to determine kind of is it biocompatible, is it -- does it really have the same properties that were used in the original device? But if you think about it in terms of -- sorry, if you think about it in terms of endoscopes in particular, also you have to think about whether the impacts were reprocessing, right? And so a lot of these questions kind of came up and were really irresolvable, at least based on the information that we had at the table.

And so what we kind of concluded was there needs to be additional steps in the flowchart that call for conducting some sort of risk-based assessment, and this has the advantage of giving the entity conducting the activity, whether they're a servicer or a remanufacturer, the leeway to conduct an assessment in accordance with the ISO standards or some other standards that maybe are defined in FDA guidance to determine kind of where to land on some of these things. So that was kind of a key point to us.

With respect to Example A1, this was also challenging for us. The example here is an insertion tube cover in an endoscope was cracked and part of it needed to be replaced. The part that did not touch patient-contacting -- patient contacting, the section that did not contact the patient was the part that needed to be replaced. We struggled with this because endoscopes, a lot of the folks -- I think everybody at the table agreed, endoscopes don't have kind of two different sections. They're not designed in a way where you have a patient-contacting section and a non-patient contacting section on the insertion tube; it's just one long piece. And so maybe part of that goes into the patient, but as far as the entire piece is concerned, it's just a single piece, and so if you're replacing part of it, you're replacing all of it, right? That was kind of the conclusion that we drew, that we drew there.

Another assumption I think is important that I want to point out is with respect to kind of the environment and the conditions where these activities are being conducted. We spent a decent amount of time talking about what does it mean to be patient contacting.

Or, I'm sorry, what does it mean to be -- I think the language in A1 is directly or indirectly contacts body tissues or fluids. So it doesn't actually specify patient contacting, right? So any device, though, of course, somebody is manipulating it, and so maybe some specificity around do we actually mean the patient-contacting section or do we just mean any part that touches any human who is perhaps manipulating or operating the device would provide some clarity around that. Yeah.

DR. SILVERSTEIN: Thank you. And then, too, I think, for our two feedback questions, I know -- I don't think that you discussed documentation, so if you could give us some words about it.

MR. JOSEPHSON: I don't know that we got too far into documentation. I think we all generally agreed that having a well-balanced or a well-reasoned rationale documented would be good. It kind of gets to the point -- I should say we tied it back to our risk-based assessment recommendation, right? So if you're having risk-based assessments built into the flowchart and you're having the entity conducting the activity required to conduct those risk-based assessments at key points in the flowchart, as explicitly called out rather than kind of implied in the language, then that would be what would be documented, and that could be something, you know, to look back to, to verify.

DR. SILVERSTEIN: Okay, all right. Thank you.

Okay, so now I'm going to make my way to Table -- I'm sorry, I lost my -- okay, I definitely crossed off the wrong one, but it's okay. Sorry about that. Yeah, definitely. I definitely crossed off the wrong one. Thank you. Okay, so we've had a lot of discussions about endoscopes so far, and so we talked about B3, and we also talked about A1. And so who at your table would like to provide some feedback? Who was your facilitator? Okay. And if you could stand up, please.

MR. FOGLEMAN: Sure. Hey, my name is Greg Fogleman, and I'm with the

Department of Veterans Affairs; Table 2, endoscopes.

I wanted to echo the comments from the last table on endoscopes, Example A, Scenario 1. We concur, you don't replace part of the insertion tube when you get it repaired; you replace the entire insertion tube. And all three examples, we did Scenario 1 on all three examples, and we ended up with deciding it was servicing with a lot of assumptions, a lot of caveats. Hudson from Pentax pointed out that certain procedures are more high risk than others. An ERCP, for instance, is something that would be considered very high risk, and you know, in my field, if we send it out to a third-party repair company, how do we know the quality management principles are being followed; how do you know that? The same manufacturer's name stays on the scope regardless of the repair. So with a lot of assumptions for every example, we came up with servicing.

One thing I'd like to mention is the analogy of automotive repair. When you replace an automobile's engine, is that remanufacturing the automobile or is that servicing? So it was kind of an analogy that we made in the discussion, but that was our conclusion on all three examples: the insertion tube being replaced, the lens being cracked, and the fiber bundle.

On Example C, I would like to note that we just said we would replace the entire scope. If the fiber optic bundle was bent and needs replacement, we just -- that's time to replace that scope.

DR. SILVERSTEIN: Okay. And so, you know, kind of getting to what Aaron just raised about risk-based assessments and other aspects of the flowchart, I mean, did you guys sort of end with a higher-level discussion about, you know, any aspects of the flowchart that would really work to help distinguish between servicing or remanufacturing?

MR. FOGLEMAN: Well, on the flowchart, one of the main questions we had -- let me look at it so I can get it. On A3, it's really two questions. A3, is there a new or increased

risk? And is there a change in the performance or safety? So we had like a yes and a no on a couple of these examples on that, and so I think the change that we would recommend that I saw was on A3, either clarify that or make another diamond decision because that's really two questions.

MR. COLLINS: This is Blake Collins with Christiana Care.

One of the things that's on A1, though, was add, remove, or change component or part. Well, add, remove, or change is we wanted to make sure that it was the replacement. You know, yes, that's changed, but is that really replacement, etc., or am I just moving from one to another?

DR. SILVERSTEIN: Yeah, is it a change or is it --

MR. COLLINS: Right.

DR. SILVERSTEIN: Yeah.

MR. COLLINS: Right.

DR. SILVERSTEIN: So, yeah, so I mean --

MR. COLLINS: Change meaning a different kind versus replace with identical --

DR. SILVERSTEIN: Yeah.

MR. COLLINS: -- kind of a thing, right.

DR. SILVERSTEIN: Yeah, thank you.

Okay, so now we're on to Table 3, and we're going to be talking about MRI. And so who -- oh, thank you. So if possible, if you finished Example B, Scenario 1, that is one of the examples that we'd like to discuss, and if you didn't get there, then please discuss your feedback.

MR. SCHMIT: Okay. Okay, so I'm Mike Schmit with GE Healthcare.

So just Scenario -- Example B, Scenario 1, is that we removed the gradient coil from a magnet, repaired it, and reinstalled it into the MRI. So we did talk about this. So one of the

assumptions that we had was that it would get repaired to the original specification of the manufacturer, that there's a trained individual doing the repair as well, and when we went through the different diamonds, you know, it doesn't -- the gradient coil itself does not come in contact with the patient. Although a component, part, and material are being changed, it's not a different component, part, or material, so we did not move on to A2.1. We said no, and we moved down to A3, is there a new or increased risk or a change in performance of safety specifications, and we said no. So we considered this activity to be servicing. And as far as documentation, we would make sure that there would be the appropriate image quality, safety, and performance tests done at the end.

DR. SILVERSTEIN: Okay. Would anyone else from your table like to share some additional feedback?

(No response.)

DR. SILVERSTEIN: Okay. And in terms of just working through the flowchart, I know you went through some examples. You know, we'd like to hear sort of a higher-level perspective on whether you think it works or whether or not there could be some additions or clarifications.

MR. SCHMIT: Yeah, I think on the A2 we had some discussion about what it means to remove component/part/material or change -- add or remove component, part, or material because, in this case, I mean, you are removing the gradient coil, repairing it, and putting it back in.

DR. SILVERSTEIN: Yeah.

MR. SCHMIT: But you're not adding additional parts to the overall system, or you're not permanently removing parts from the overall system. So I think there just needs to be some clarification on what that means.

DR. SILVERSTEIN: Okay.

MR. SCHMIT: But our assumption was as long as in the end all the parts are there like they were in the beginning, we could answer that diamond as no.

DR. SILVERSTEIN: Okay, great. Okay, thank you.

So now I'm going to go to Table 9. I'm already here.

MR. NANNEY: All right. Well, I'm going to need my scribe here to help me out here.

DR. SILVERSTEIN: And so you're welcome to piggyback on the example that we just discussed, and also we'd like to hear some feedback about Example A, Scenario 2. So B1 or A2.

MR. NANNEY: Okay, A2, about patching it, we didn't think that was possible --

DR. SILVERSTEIN: I'm sorry, could you just briefly explain what the scenario was?

MR. NANNEY: Okay, let me find it.

UNIDENTIFIED SPEAKER: Here.

MR. NANNEY: Oh, you're good.

DR. SILVERSTEIN: Just so everyone in the room --

MR. NANNEY: Anyway, I'm Courtney Nanney with Catholic Health Initiatives, and my scribe here is John with DOTmed, so he's also recording us for future references.

(Off microphone comment.)

MR. NANNEY: So it's the reason I can't read his notes.

(Laughter.)

MR. NANNEY: Anyway, so the scenario was an MRI, it's determined that there's a large crack in the liquid helium reservoir. The entire reservoir is replaced with a non-OEM --

(Off microphone comment.)

MR. NANNEY: Oh, Scenario 2, okay. It is determined that there is a small hole in the liquid helium reservoir. The hole is patched with materials that are different than the OEM reservoir. One, we sort of changed it because we didn't think it was likely to have a hole in

the reservoir, and it's more likely to have a leak at the fitting. And then the question came up, is the -- do you replace it with an O-ring? And, of course, the O-ring would have to meet the manufacturer's specs, and we did have a discussion on not all O-rings are created equally depending on where it's being used. If it's being used in a stretcher, it's not that big a deal if you have an oil leak, but if you have an O-ring that can't handle the temperatures and the pressures, you could turn a small leak into a big leak. So assuming you can get a hold of the OEM specs and use the same materials, it's a repair. If you cannot, then it's a remanufacturing of it. So that's that scenario. And then what else?

DR. SILVERSTEIN: So I wanted to hear a little bit about documentation of some of these and, as well, just get some sort of like higher-level feedback. I mean, I know that you guys probably got through a few examples. You know, we're trying to capture higher-level feedback on the flowchart as well.

MR. NANNEY: And that's a good point. We did mention that documentation is critical.

DR. SILVERSTEIN: Yeah.

MR. NANNEY: As a matter of fact, we were very appreciative of the FDA with the romaine lettuce and the way you were able to track it back, and we figured if you can track lettuce back, we ought to be able to track, you know, our components back --

(Laughter.)

MR. NANNEY: Back to, you know, where we got it from, who put it in, so that if we do have an issue further down the road because, I mean, as we know, manufacturers can change stuff, we could have a service person that's not as conscientious, so we want to be able to document exactly where it came from and then just, you know, use that for our quality assurance.

DR. SILVERSTEIN: Okay.

MR. NANNEY: Okay. And the next one was?

DR. SILVERSTEIN: So I'm going to save something --

MR. NANNEY: Okay.

DR. SILVERSTEIN: -- for the next table.

MR. NANNEY: All right.

DR. SILVERSTEIN: Did anyone else at your table want to add something in addition?

MR. NANNEY: Yeah, right.

MS. TWEED: I would.

DR. SILVERSTEIN: Sure.

MS. TWEED: I'm not going to stand up, okay?

DR. SILVERSTEIN: Sorry?

MS. TWEED: I'm not going to stand up, okay?

DR. SILVERSTEIN: Okay.

MS. TWEED: Jina Tweed. I'm at PartsSource.

One of the things that we -- well, we talked about a number of things, but when we talked about documentation, we talked about the value of the tests, testing that needs to be done; the test, type of equipment, the calibration of the tools that you use in doing any of the servicing or even remanufacturing. It's critical, especially from a 13485 perspective of what's required. We also talked about risk assessment and understanding the risk associated with it from a safety perspective and a patient perspective. So we clearly said that, for the flowchart, you need to clearly identify required documentation, that we need to make sure that every step is documented and the type of equipment and everything that needs to be used.

DR. SILVERSTEIN: Okay. If I could tease out a little bit, I mean, so risk assessments have been mentioned --

MS. TWEED: Um-hum.

DR. SILVERSTEIN: -- a few times now. And so if an entity comes in and they don't have detailed information from the OEM, you know, how do you conduct a risk-based assessment? I mean, is it based on knowledge about device type? And so is there any -- how do I say it? Are there certain features that are much easier serviced versus maybe like a novel feature might be a little bit different, and would that make it more difficult for an entity to perform risk-based assessment if it wasn't a more common feature on a device?

MS. TWEED: I think so.

DR. SILVERSTEIN: Okay.

MS. TWEED: It's really hard to determine if it's not a common --

DR. SILVERSTEIN: Okay.

MS. TWEED: Yeah. But you do look at use of the equipment as a part of doing the assessment, even if it's not common --

DR. SILVERSTEIN: Um-hum.

MS. TWEED: -- to see if you can get to what you need.

DR. SILVERSTEIN: Okay, thank you. Is there anyone else?

MR. FISCHER: I'll just add that in the documentation process, you're not only documenting the specifications and the validation process but the source.

DR. SILVERSTEIN: Okay, thank you.

Okay, Table 14, go ahead. If you could stand up, if you don't mind.

DR. JACQUES: My name is Sam Jacques, and I come from Penn State Health, and we discussed both of these scenarios, and in general, right, we're in agreement with the other two tables related to how you go about assessing whether or not you look through the flowchart. We did have some flowchart feedback, if that's helpful.

So we agree with Table 13 that in A1, right, it's not really clear about direct or

indirect contact with bodily tissues. We went round and round about is it patient contact, is it caregiver contact, is it servicer contact, is it public contact? So we'd really like some clarification. I mean, we erred patient a lot of the time, but especially with the crack, right, in the tank, we were very concerned about others in the area, right, and what kind of state the impacts of those had. So we'd love some feedback related to that.

We also had a very long conversation around the word "significant," and nobody's brought it up yet, but "significant" is an incredibly subjective word. We toyed with the idea of changing it to "adversely" for a while and then hated that as well. So we actually recommend just striking it altogether and saying we need to go back to OEM specifications regardless if it's significant or insignificant, and that's where your documentation kind of talks to, right, what's the likelihood, what's the risk in that kind of piece. You know, "significant" is very different depending on who you talk to, and so it's really hard. You're going to need a very clear definition of what "significant" is, or we just say we need to meet minimum OEM specifications. Do you have a follow-up related to that?

DR. SILVERSTEIN: So I think the term "significant" allows for us to sort of provide some judgment there, and so, I mean, this is something that's in multiple FDA regulations.

DR. JACQUES: Yeah.

DR. SILVERSTEIN: So it also could significantly affect just the -- tripping the need for a 510(k). And so I think the flowchart, in theory, is supposed to help address some interpretation of the word "significantly" change.

DR. JACQUES: And that's fine. I think we would then go back to documentation; how do we document what our --

DR. SILVERSTEIN: Yeah.

DR. JACQUES: -- decision making looks like related to that, then? And then, finally, we had a very long conversation on box A3, and at the end, right, you needed to select yes

or no, did it in fact increase the risk or change your performance spec? Those of us in the servicing industry, right, say regardless if I replaced a part, and I'm going to call it servicing, we're still required to do functional tests to make sure that the part that I put in still works, right, and that we've not negatively impacted the device. And so we actually recommend getting rid of the "no." We always want that to be "yes." Does the change, even if it's part replacement, significantly affect the device or performance or safety specifications? We then document that we've done the safety check, and the safety check and the performance validation assures that we have, in fact, not done that and therefore we call it servicing. So that was our feedback from a flowchart perspective. But, in general, we agree with a lot of the rest of the tables, right? There's a lot of good comments related to judgment and justification and documentation, and we really support what you all said.

DR. SILVERSTEIN: Okay, thank you. Does anyone else at the table, would anyone like to add or clarify anything?

(No response.)

DR. SILVERSTEIN: Okay, thank you.

So, moving on, we're going to go to Table 10 for ultrasound. Thank you for raising your hand.

(Off microphone comment.)

DR. SILVERSTEIN: Yeah, okay.

MS. KANN: I'm Melissa Kann. I am with Stryker, and we have ultrasounds, and so is there --

DR. SILVERSTEIN: Can I interject? Yeah.

MS. KANN: Yeah.

DR. SILVERSTEIN: Yeah, so if possible, we'd like to hear about Example B, Scenario 2. And if you could just briefly describe the scenario for the group. And if you didn't get to

that one, I have a backup plan.

MS. KANN: Okay, was your backup plan by chance Example B, Scenario 1?

(Laughter.)

DR. SILVERSTEIN: Did you get to Example A, Scenario 2? Let me ask it differently.

MS. KANN: Yes, we did.

DR. SILVERSTEIN: How about that one?

MS. KANN: Okay.

DR. SILVERSTEIN: Thank you.

MS. KANN: All right, for B2. Okay, so this is where we talked about the ultrasound printer is malfunctioning and cannot print. An OEM replacement printer is no longer available, whether it's end of life or whatnot. The printer is replaced with one that is not specifically designed for ultrasound devices, however, will interface with the system and print high-quality pictures.

So going into two of the pieces that we looked at in terms of assumptions is that it's not part of the diagnostic function and it's not adding software and modifying the software in order to accept the new printer, so that it just would be more of a plug-in and then you can use that.

Going through the documentation, we said that no, it is not -- you know, in A1, it does not touch the patient directly or indirectly, and so that would lead you down to A2, and then adding in that it goes into the adding or removing the component/parts/materials, we said no because the printer, based on the assumptions, is outside of the definition potentially of a component, again, based on what is it -- what is the intended use of that printer and again going on that assumption that it's not a diagnostics purpose. And then getting down to A3, we said that it would be servicing, again, based on those assumptions that it may just be printing off a picture to take home or whatnot. So we said that would be

a servicing activity.

But in terms of looking at these assumptions and talking about the documentation, you have to go in and truly understand how is that printer -- you know, what is that printer being used for and documenting the full use of it to determine is it a component, is it an accessory, how is that? So you need to make sure you understand the use of that.

DR. SILVERSTEIN: And would anyone else at the table like to provide a comment before I ask a follow-up?

(No response.)

DR. SILVERSTEIN: Okay. So higher-level feedback on the flowchart, I mean, so we've already talked about trying to clarify what contacts body tissue means, risk assessment. Do you agree, disagree, or did your table discuss, I should say, or do you have any other high-level feedback from the table?

MS. KANN: We spent quite a bit of time starting, actually, the conversation to the table over here on the "significant." And so a lot of that went back to when you think about that definition and that terminology with at least the device mods guidance and the software mods, it really honed in on going back to that risk profile that you had set up originally when you launched that device, so making that tie-in of are you significantly changing that, so that looks at safety as well as effectiveness. And so for us, as an OEM, that's what we would always go back to.

So, again, I think if you are a third-party servicer, how are you building up that risk documentation that you have, especially if you are in that field of servicing ultrasound equipment? You know, Wayne here, he talks about the work that needs to be done on that, so you have to build up that documentation to see if that change would have an impact.

DR. SILVERSTEIN: Okay. And would anyone else like to add anything or clarify about the flowchart?

(No response.)

DR. SILVERSTEIN: Okay, thank you.

So I'm going to go to Table 4. Thank you. So hopefully you were able to discuss B2. Oh, thank you.

(Off microphone comment.)

DR. SILVERSTEIN: I'm sorry?

(Off microphone comment.)

MR. PASTERCHICK: Hi, I'm Andy Pasterchick. I'm from Becton Dickinson.

So our scenario, we had a fetal ultrasonic device. The ultrasound probe failed. It had significant damage to the housing and the lens. In this scenario, a replacement OEM lens could be obtained, but the housing was no longer available. So the original housing specs are unknown, and a non-OEM housing was used, and it has an unknown biocompatibility specification, and that was used for the replacement.

This is actually pretty straightforward for us. We answered yes to A1 because the probe is coming in contact with the patient, we assumed. That's what we were talking about when we were talking about contact with tissue. And then we believe that there could be -- that could be yes to A1 as well; we could be answering yes to Question A1. And then we even went down a step further and we answered yes to both A2 and A2.2 as well.

So we felt this is fairly straightforward remanufacturing, a remanufacturing issue. The fact that, you know, we don't have the specs on the housing, there's a great deal involved when you -- once you get into the housing in the ultrasound. For instance, you correctly pointed out the needle guides, we don't even know if the needle guides would work with this new housing, so there's, you know, a good deal happening here without specs, and we don't have the proper testing. So from a risk standpoint, you know, we can't properly test this ultrasound probe after it's been -- you know, after it's been brought back

into use because we just don't have any of the specs. And it was very clear in the scenario that the specs weren't there.

DR. SILVERSTEIN: Yes. Okay. And so in terms of -- so you said that you got through all of the examples. And so did you think that most of the group kind of agreed with the directions, you know, sort of like your -- I guess, was the group able to reach final consensus on whether most of these examples were remanufacturing or servicing?

MR. PASTERCHICK: Yeah. In the first scenario, we agreed across the board that it was all service, and in Example B, it was all remanufacturing.

DR. SILVERSTEIN: Okay.

MR. PASTERCHICK: And I don't think we had any dissent really.

DR. SILVERSTEIN: Okay. And so we've talked about a few items, the feedback from the different groups. So far we've talked about body contact, we talked about whether something is significant or not, we've also talked about risk-based assessments. You know, did your group also have those discussions, or was there something else from a higher level that you'd like to share?

MR. PASTERCHICK: Yeah, I think -- I'll talk and then I'll let them answer as well. I think, from the body contact, we just kind of went in assuming we're talking about the patient, and we didn't really have that much discussion about are we talking about the service provider or are we talking about the -- or the patient. We just assumed the patient. As far as risk, we talked about risk in every single one, and that was really -- you know, for instance, in the first two scenarios, Example A with changing the printer and changing the monitor, we looked at that as a much lower risk than when we're actually talking about making changes to the ultrasound probe. So, yeah, it did come up.

DR. SILVERSTEIN: Okay. Would anyone else at your table like to share any feedback? If you could stand up, please, if you don't mind.

MR. STRADTMAN: Sure. George Stradtman, BK Ultrasound.

So some of the things we were addressing when we were talking about this is how do we identify who performed the rework or remanufacturing activities, and I think that's difficult for a lot of us because our name is on the product, and if somebody's been changing things about it, we get it back having had some of these changes already performed to it, and does the end user know the history of all of those changes that have been performed to that probe?

Some of the other things that we were discussing was if you're altering materials in here, and even if you have chemical compatibility information, they're undergoing cleaning and reprocessing in many cases, so you don't know whether or not the new material is chemically compatible with the old materials and the adhesives used, and you have to look at the biocompatibility of new material combinations that may not have been considered, and in a sample size of repairing one probe, nobody's going through the necessary steps in order to validate that.

DR. SILVERSTEIN: Anyone else?

(No response.)

DR. SILVERSTEIN: Okay, thank you.

Okay, so now I'm going to go to Table 5. Thank you. Okay. And so for Table 5, if you got to it, Example B, Scenario 1.

MS. MARTORANA: Okay, we did get to that one. That involves a --

DR. SILVERSTEIN: Sorry, could you announce yourself, if you don't mind?

MS. MARTORANA: Oh, yes. Christen Martorana from Sigma Imaging Technologies.

And this involved a blade, a thin blade that had an intended use life of 30 uses, and the blade was sharpened. The idea was to sharpen it to extend its life beyond what was allowed for. Let me just go back.

In doing the analysis, A1, we determined that there was bodily contact, and we assumed that the patient was the subject. And that took us to A2. We said yes to that. We assumed a solid material coating for that. And then A2.1, we determined that by sharpening it, that we were changing the specification of the device, so we determined that it was remanufacturing.

DR. SILVERSTEIN: Okay.

MS. MARTORANA: Yeah, so --

DR. SILVERSTEIN: Significantly changed?

MS. MARTORANA: Yes.

DR. SILVERSTEIN: Okay.

MS. MARTORANA: Some of the other comments that -- we had said that if we had changed the assumption that the manufacturer allowed for sharpening, that we would've had to determine that the proper sharpening tools were used and that the process was followed for sharpening the blade.

DR. SILVERSTEIN: Okay.

MS. MARTORANA: And then the documentation with the design process validation --

DR. SILVERSTEIN: Okay.

MS. MARTORANA: -- would've been documented.

DR. SILVERSTEIN: So this particular example had a pretty large -- a lot of different examples, I think, that were across a broader device set, and so I think that your table is sort of ripe for a deeper discussion about high-level feedback and the flowchart. I mean, I think you've already heard what some of the folks said.

MS. MARTORANA: Um-hum.

DR. SILVERSTEIN: You know, were your perspectives consistent with what's already

been expressed? Is there something that other people would like to add on top, or do you agree with the other comments that we've heard today?

MR. CHALIFOUX: Hi. John Chalifoux with MERA - The Association for Sustainable Manufacturing.

Maybe just a comment to add is -- and it goes back to the word "significantly," and I'm going to just add a few words after that. But in defining remanufacturing, we agree that remanufacturing is manufacturing, and it states that, but it also says that it significantly changes the finished device's performance or safety specifications or intended use, and what it doesn't say is that that could actually be for the better. And remanufacturing in every other industry basically is the next best thing to new, and in this case, it can sound as if it's not as good as new, and maybe that's something that we can take a look at further.

DR. SILVERSTEIN: Yeah, thanks for your -- did you want to say something?

UNIDENTIFIED SPEAKER: No.

DR. SILVERSTEIN: Oh, okay. Okay, so would anyone else like to share any of their feedback at this table?

(No response.)

DR. SILVERSTEIN: Okay, we'll still have time at the end. So I have to come all the way over to Table 11, I'm sorry. So we're sort of running a little early for this reconvening session, so at the end, if someone who hasn't had the chance to provide some feedback, you can raise your hand and I'll come over to you; I'll make my way across the room. So we're now to Table 11. Okay, so if you got to Example B1, we would love to hear your feedback about it.

MR. CLUFF: Okay.

DR. SILVERSTEIN: If you could say your name and provide just a very brief summary.

MR. CLUFF: Sure. My name is Eric Cluff. I work for Abbott. B1.

DR. SILVERSTEIN: Or C2 is another.

MR. CLUFF: Yeah, C2.

DR. SILVERSTEIN: Yeah.

MR. CLUFF: The bird that whispered in our ear said that we should pay attention to C2, and so C2 was an entity of the battery of a reusable device has manufactured and needs to be repaired or replaced. Scenario 2 is an entity obtains used non-rechargeable batteries and restores them for resale. The entity receives the batteries that are due for replacement from their distributors, and the lithium cells are replaced with identical, equivalent, or superior cells.

We felt this one was fairly straightforward. The scenario itself was a little confusing because it talked about non-rechargeable batteries and then it introduced lithium cells. But the key takeaway from Scenario 2, for us, was simply that it was identified that they were replaced with identical, equivalent, or superior cells. Our assumption was that we could identify a battery based on specifications that are readily available and that there was no significant change to the functionality. So for A1 we answered no, for A2 we answered no, and for A3 we answered no, which led us to servicing.

A couple of other things: We felt that, from the documentation standpoint, it was important to document that an assessment had taken place and also really what the rationale was, you know, regarding that assessment. And then there was also good discussion regarding the use of correct engineering principles in identifying the specifications and everything that was associated with that, as well as being concerned with the supplier quality element of whoever is supplying the battery because you can see, from what they've published, what certain things are, but knowing how their quality systems are set up and how they're used is important.

DR. SILVERSTEIN: Okay. And in terms of just higher-level feedback on the flowchart,

what did the group discuss? Do you agree with the other comments that have already been expressed?

MR. CLUFF: Yeah, a lot of our discussions were also risk assessment based. We talked about, you know, that quite a bit as we were considering it. Again, a lot of our discussion was also based on engineering principles and just having to establish the rationale and the assessments that are appropriate throughout the usage of that flow. I don't know if there's -- did I miss anything?

DR. SILVERSTEIN: Okay. All right. Well, thank you. Sorry, it's a little tight over here.

(Off microphone comment.)

DR. SILVERSTEIN: Wait. Sorry, can I --

MR. BOALS: Frank Boals, Defense Health.

Based on the assumption that this is servicing, that means that the labels on those batteries remain intact and the original manufacturer's labels. The manufacturer is responsible for recalls on their batteries, and that has not been a minor issue. I do remember incidents where defibrillator batteries failed spontaneously. No notice. They just failed. Was that the intent of the group, that they do not have to be relabeled to identify the new source of the parts?

DR. SILVERSTEIN: Okay. Yeah, I mean, I think that this has been something that's come up very often, and we heard that a lot at our 2016 meeting about, you know, the availability and the use of high-quality parts. And so the point is well taken, and I think tomorrow during our Day 2 discussion, I think that's going to come up a lot when we talk about opportunities for collaboration. So thank you very much.

So we've gotten hopefully through every person who was assigned a part of the flowchart, and so we're going to be talking about software now. And so I am right next to the software table and who is -- okay, thank you. Okay. And so, as hopefully most people

know, we did not have a flowchart for software, and so we sort of had just this bulleted list and this principle. And so if you're able to, can you discuss Example B2?

MR. TOMCZAK: B2.

DR. SILVERSTEIN: And please state your name, and provide just a very quick summary of the scenario.

MR. TOMCZAK: Right, I'm John Tomczak, and I'm from BD.

The scenario is a device which connects to a facility's network contains software that runs within a Microsoft Windows operating system, and the scenario is, is that the device is an infusion pump which validates patient records accessed through the internet by the drug delivery information input on the device to avoid complications with the treatment. There's a cybersecurity vulnerability that is identified, and the OEM has not provided a solution, and the device is isolated from the internet until a cybersecurity update can be implemented.

So going through, the device can continue to work with potentially that featuring being disabled. The end customer has decided to pull the device and isolate it from the system until the patch can be in there. We thought that if it's part of the original specifications, that would be okay for the customer to be able to do that, so we thought that this would just be a standard servicing or use case opportunity with a device. So if that capability of turning it on and off is within the standard labeling and the bounds of servicing, we thought that was servicing.

So other questions that we had is if it -- what would change it to remanufacturing? If there was no formal switch or not contained with the existing device labeling, that -- or the functionality could become inoperable and you do something different to make it operable, then that would constitute remanufacturing because it's outside of the bounds of the original specifications in the IFU.

DR. SILVERSTEIN: Okay. And so I'm not sure if you were able to get through all of the examples, and I'm not going to pick on you about every single one of them right now. We're going to let the other tables discuss them.

MR. TOMCZAK: Yeah.

DR. SILVERSTEIN: But what I'd like to know is, you know, did this list -- was it helpful? Did you think that it was comprehensive, or do you think that there are other bullet points that should be either added, edited, or removed?

MR. TOMCZAK: We had a lot of discussion because we're looking at these scenarios in a very siloed aspect, whether it was servicing or remanufacturing. There are other aspects in the regulatory frameworks and other business legal ramifications that come about with this. So we kind of parking-lotted that and kind of framed it, our discussion, just basically on servicing and remanufacturing in that silo. But I think there's got to be a lot of other discussions on how you relabel, what you have to do, especially in third-party services or other contract service providers touching your device. We talked about pedigree of a device and maintaining it with the existing DMR.

So the one thing that we did think was missing, and we talked about it, is whether or not you add capability that's not directly related to the patient safety and efficacy of a device, such as passive data analytics or other types of things that you couldn't put onto your device that may or may not -- that just helps the OEM. And that was one thing that -- does that constitute remanufacturing, adding those passive capabilities to your device?

DR. SILVERSTEIN: Okay, thank you. Would anyone else at the table like to share some feedback?

(No response.)

DR. SILVERSTEIN: Okay, there will be another opportunity. So, unfortunately, I have to walk across the room again, and so just in thinking about sort of our last few tables, we

are going to have an opportunity for anyone sort of at the end to raise their hand. So if you'd like to sort of provide just a very brief summary at that point, I'll remind folks again.

So software Table 6. Okay. Okay, so if possible, could you please discuss Example B, Scenario 1?

MR. TREVINO: Well, we focused on Example A --

DR. SILVERSTEIN: Okay, so how about Scenario 2?

MR. TREVINO: Terrific. I'm Scott Trevino from TriMedx.

The scenario here is an infusion pump with an outdated drug library in its software, and the scenario is where the OEM has an updated drug library that's no longer supported for an older version, and modifications were made to the software so that it could be installed with -- an older version of the device could have a newer version of the library, essentially. So when we looked at this, the assumption we made is that the modifications were not approved by the OEM, and the OEM provided no specifications or requirements on the device, therefore precluding one from testing the system with new software.

And we also noted that without access to those service materials, system specifications and so forth, it would be difficult, if not improbable or unlikely, to actually test for that. Given that, this is remanufacturing, in our opinion, as it could significantly affect the device safety and performance. And, again, without access to that information, you can't make that determination, so therefore, you have to make the assumption that it could potentially affect those things. If there was a different assumption here, that was the other question we were asked, if the OEM, for instance, provided specifications and instructions and implied that we could potentially verify and validate that change on that device, and you know, under this scenario, assuming again that the OEM had not provided those specifications, what would you have to do? You would have to characterize the device, its performance, its specifications, safety specifications, as well as performance,

conduct formal design process as you would under, you know, the current 21 C.F.R. 820 and so forth and also conduct a change assessment, design assessment and impact, and perform a 510(k) evaluation to determine if you actually do significantly change the intended use of the device and a new 510(k) is required. Again, I think it should be noted, without accessing ownership of the design, you would be unable to do those things, in the opinion of the team.

What constitutes integral software, and how would you determine what is integral software? It was consistent for each scenario, and what we would say is that any software type, you know, what you have to look at is an impact assessment based on the risk assessment that's done formally on a device. Software is quite complicated, and you'd have to understand how it touches a system based on the specific scenario, and that would go back to the risk assessment with severity and probability of harm. And looking at the FDA list of activities, the feedback, I think, we would have there is we should add the execution of OEM-provided instructions, updates and upgrades, and expand upon that a bit.

I think adding significant changes to intended use and safety performance as part of those updates, they do and will happen as part of an upgrade or an update. For instance, you know, the diagnostic capability of a device may change from, you know, general cancer imaging to cardiology, and that's a significant change to the intended use of the device, and it might require a new filing and so forth. But if it's provided by the OEM as an update, that's standard servicing. And maybe a final comment on the overall flowchart. It would seem for -- you know, at least for, you know, pointing out something obvious, I think the first question really should be if this is part of the instruction for servicing or operator manual, you should sort of not pass go and go right to servicing and not have to go through the same set of questions; they seem redundant and unnecessary in that case. And I think that applies to not just software but other examples.

DR. SILVERSTEIN: Okay.

MR. TREVINO: Scot, did you have any other --

MR. MACKEIL: Yeah, I have a quick one. You know, as part of this discussion --

DR. SILVERSTEIN: Sorry, Scot, could you announce yourself, please?

MR. MACKEIL: My name is Scot Mackeil, and I'm a biomed in a 1,200-bed academic medical center in Boston and, you know, when you -- as part of the discussion, you realize how important software is to some of the devices that we work with, you know, an IV pump complex, you know, electromechanical/digital construct, the malfunction of which can cause patient injury or death. You know, our scenarios talked about modifying -- the potential of modifying software, and you know, in the real world, I can't think of any real scenarios where that would ever happen, except for one where it's, say, a large population of devices were suddenly to be orphaned by a change in the industry and an ISO or a third party were to undertake updating the hardware and the software to continue the lifespan of those devices, and in that case, you know, you would definitely be looking at manufacturing and subject to a robust QMS and then some labeling so that end users would clearly understand what they were buying and what they were getting into and make risk and purchase evaluation decisions.

DR. SILVERSTEIN: Okay, thank you. Okay, would anyone else at this table like to share anything?

(No response.)

DR. SILVERSTEIN: Okay, thank you.

So we're going to move to Table 15. And who's your -- okay, all right. So far, hopefully I have this right, we've talked about Example A, Scenario 2 and Example B, Scenario 2. So if you discussed Example B, Scenario 1 or A1, we'd love to hear your feedback.

DR. GOLD: Okay, my name is Fredric Gold. I'm with Hologic.

So Example B, Scenario 1 is a device is no longer supported by the OEM, a cybersecurity vulnerability, and there was a Microsoft patch that was updated and installed. So the discussion was again using the complementary approach, not the flowchart, was that installing the cybersecurity updates in the device no longer supported meet the service definition. Some of the discussion was updating to the OS may require validation. It's probably not service. It may be remanufacturing. The risk of updating as to whether it changes a spec needed to be looked at. And can you remanufacture software was the question. Some different assumptions that we would look at is whether or not an update could be validated by the user, what operation -- what the operation manual actually allows you to do and who is performing the changes to the OS. Some actions that we would look for, for documentation would be validation of the changes and understanding the agreement between the OEM and the user.

DR. SILVERSTEIN: Okay. So actually you said something that I'd like a little bit more follow-up on, and hopefully I'm quoting you correctly; you said that it may not be servicing but it might not be remanufacturing. Is that accurate?

DR. GOLD: We said it's not servicing, and it may be remanufacturing.

DR. SILVERSTEIN: Okay. And so, you know, one of the things that we kind of talk about in software is that it may not be servicing, but is it remanufacturing? You know, do you think that there's a gray area, or do you think that it's always a sharp line in the context of software?

DR. GOLD: So based on our discussion, there was a lot of gray area.

DR. SILVERSTEIN: Yeah.

DR. GOLD: We had a lot of kind of going back and forth as to whether it could be service, whether or not it would be something that, based on the original validations that

were done, whether if it was done by a user, we were talking about in a hospital, whether or not they could actually do the servicing, call it service, but whether or not that actually met that it was a change in the intended use of the specs and whether that would actually constitute a change to be considered remanufacturing. So it was back and forth a lot.

DR. SILVERSTEIN: Okay. Would anyone else at the table like to provide any comments? Okay.

DR. WANG: I'm Binseng Wang representing the American College of Clinical Engineering. We did not have time to really discuss this, but I would like to share a little bit of ideas that we'd like to comment, suggest FDA to consider about the list of activities that was in the white paper saying that these are the allowed actions, activities.

We definitely agree that those activities listed by FDA are good. However, I think we need to add a few more for the sake of clarity for the people in the field. For example, accessing the diagnostic repair information that manufacturers provide with their own staff and also their representatives in the field.

Second, collecting data generated by the device operating its self-diagnostic software for analysis that can potentially improve the safety and maintenance of the device, for example, in the future, for predictive maintenance, that would be extremely useful.

Third, running natural-based diagnostic and cybersecurity scanning software, we should be allowed to do that without interfering with the device software, the so-called integral software.

And, number four, performing backup of the system software, if possible, to the organization's software storage system so if this device has a problem, at least we have the data that's generated by the device stored somewhere else. If the application software can also be safeguarded in another area, that would be nice as well. Thank you.

DR. SILVERSTEIN: Okay, thank you.

Okay, so I've checked off my list, but I just want to make sure, has any table not been called on? Just generally.

(No response.)

DR. SILVERSTEIN: Okay, thank you.

So we have another 30 minutes in this session to get feedback, and so if anyone would like to provide -- and we're really just trying to talk about the flowchart and what we call the complementary approach for software. If anyone would like to provide, maybe, 1 or 2 minutes per person some feedback, please raise your hand. Yeah, I'm going to go to this gentleman first. Thank you.

MASTER SERGEANT JOHNSON: Good morning, I'm Master Sergeant Johnson from the Defense Health Agency. I want to bring up some comments that we talked about in the group.

One, we're assuming that the manufacturer's exceeding the standard, not meeting the standard. So components are being put into equipment. If we find something that meets or exceeds the standard, then that constitutes remanufacturing.

Part two of that is training on the biomed, who's available for that training and when is it available? Is it available to third parties?

And then part three of that, we also go forward on things. When we look for information that, say, for example, replacing an infusion pump door, are all the parameters available to the biomed to make that decision, if that institution is making those changes, in order to actually do that risk assessment? Everything goes back to patient safety and patient centeredness.

Now, there's some give and take, and that goes back to that collaboration we're going to get into tomorrow, but having that information available to the institutions to

make that risk assessment, it's ultimately their responsibility. Now, the same thing when we talked about the automobile. You know, do you take your vehicle back to the dealership to do the service and maintenance at all times? I guarantee half of you don't and do the oil changes and tires and so on and so forth. The same thing with medical devices; there has to be a give-and-take and some kind of, you know, negotiation and a balance between the two, third party as well as the manufacturers and what their -- what risk are you going to accept, but getting -- actually, those are the biggest factors.

It goes to the standard, are we meeting, or are we exceeding the standard? Are we putting in a plastic part when a ceramic part can do? Are we using medical-grade epoxies when something better is out there on the market, an innovation and excelling and going beyond those standards that are of what we should be getting after, not just is it remanufacturing, is it servicing. You're limiting yourself to those two silos of information. It can go either way quickly.

The same thing with software; software changes radically. A lot of manufacturers use stable software platforms, and we're talking XP made to go into 7. A lot of them are having a hard time going to Windows 10. We're talking RMF network. I can't put stuff on the network if I can't maintain it. You guys push updates and patches, and that creates a bigger problem because there's more to just a medical device than just a silo of servicing and remanufacturing. You got that entire life cycle sustainment.

DR. SILVERSTEIN: Yeah. Yeah, I think you also provided an excellent teaser for our next breakout session after lunch, which is access to information. And so we're kind of going to be considering these examples and what does a servicer or a remanufacturer need in order to complete these activities.

MR. NELSON: My name is Kim Nelson, and I'm with Summit Imaging.

One thing we noticed here at the table is how many assumptions are required in

order to decide whether it's remanufacturing or whether it's maintenance or service, and we had to make -- we all had to make some assumptions about what that was, and those assumptions might direct the whole process. Okay, number one.

Number two is, and I think it's interesting, is that we have to decide about the training required for the end user, and I'm not talking about the patient. I'm talking about, for example, is a monitor working or not working or is it working up to OEM standards or not working up to OEM standards, and that has to be done by the end user with -- the first may be a visual test. And so that's a complication as well. So it's a training of the person who's not the only one who says this is not working, and number two says this is working, you know, exactly what's that training in that issue.

And then the final one, for me, is that we need to make sure that testing by third-party providers is documented and that testing somehow is reliable enough for you to be -- as the end user to say yeah, the testing was valid, and we now can decide, reasonably, if an OEM provided quality or not provided quality and that's a real issue, what testing are you using, and that needs to be documented and supplied to the end user.

DR. SILVERSTEIN: Okay, thank you very much. I promise, I'm going to come back.

DR. JACQUES: I'll be quick, I promise. Again, Sam Jacques from Penn State Health.

So we had a quick conversation about the integral software, right, and how do we know that it's integral or not. And we argued, or at least I argued at this table, that all software, we actually need a complete software bill of materials for all medical devices because, right, a cybersecurity vulnerability may affect a non-significant portion of software and yet still affect intended use of the device. And so we advocate for, right, a complete software bill of materials for all the software on the medical device.

DR. SILVERSTEIN: Okay, thank you.

I saw a hand over this way. Oh, thank you. Okay, Rob.

MR. KERWIN: Rob Kerwin from IAMERS.

To follow up Dr. Wang's point, and the gentleman from Summit, sort of the elephant that may be in the room is getting adequate information and making sure there's sufficient information in order to address the assumptions, the issues of the appropriate diagnostic information that's otherwise being provided by the owner.

And then the other point is, you had said, in your flowchart, you thought there was some discussion of what is a significant change. Can you maybe elaborate on that?

DR. SILVERSTEIN: Elaborate on which aspect? I mean, I can clarify what we put in our white paper, but I just wanted to clarify that this session is really about public comment. You know, FDA kind of came out already with our white paper.

MR. KERWIN: Because, respectfully, I didn't see a delineation in the flowchart as to what's significant.

DR. SILVERSTEIN: Okay.

MR. KERWIN: Okay.

DR. SILVERSTEIN: So our intent, and we'd love to hear your public comments about whether we got it right, is that sort of the accompanying text that would be in the .1 sections would help people interpret -- entities people to interpret whether those activities significantly change performance or safety specifications. And so, you know, we would love to hear your comments right now, and we also have a docket that's going to be open for about a month and a half, so we look forward to hearing everyone's comments. Thank you.

MR. AGGIS: I'll save you some steps.

DR. SILVERSTEIN: Thank you.

MR. AGGIS: My name is Greg Aggis (ph.), and I work for Stryker Corporation.

One of the things in the flowchart that I noticed was that in A1.1, does the change significantly affect the device performance or safety specifications, I think one critical factor

as well is sterilization validation. So a lot of these devices, or some of the devices, are devices that are totally sealed and have to be opened and then resealed to perform a repair or service to them, and manufacturers are required to validate sterilization by all modalities that they put in the IFU. Yet, other vendors that may repair those have no requirement to validate theirs. And we have examples, and have seen examples in the past, where minor small changes, for instance, they'll put plastic inside of an object that is going to be sterilized via Sterrad and that plastic, if it's not the right plastic, can absorb the sterilant and render that process ineffective or reduce the effectiveness in that process. So I think that's a critical component that should be included in the flowchart.

DR. SILVERSTEIN: Thank you. Okay.

MR. NANNEY: Again, I'm Courtney Nanney with Catholic Health Initiatives, and I have a concern with cybersecurity and some things sneaking through under the guise of cybersecurity. We got a recent one from a manufacturer that says, please, you know, patch your software. Come to find out the only patch it did was lock out any third-party disposable from being used on this device. So that gives me some concern. So we're like, well, I don't want to upgrade so we can't have any competitors in the disposable side. So I'd just like to make sure we have truth in advertising. If it's true cybersecurity, that's fine. If you're trying to lock out a competitor, then that's not quite as good.

DR. SILVERSTEIN: Okay, thank you.

MR. ZAJAC: Hi, Mitch Zajac from Butzel Long. I'm an attorney in Detroit.

I'll try not to pick a side on the issue, but as an attorney, I have, I don't know, a want to understand the rules of the road, and there's a lot of discussion that's going on about the definitions, the definition of significant, the definition of remanufacturing. You know, the gentleman from Stryker just pointed out that manufacturers have a responsibility to certify compliance with certain different regulations. Well, you know, if we classify a

remanufacturer as a manufacturer, but then there's also instances, as I understand, that that remanufacturer may not have to put their name or their own certification on this previously manufactured part, I believe that creates a little bit of controversy in terms of the definitions. So, you know, there's definitions of what remanufacturing is in the ITC, and it talks about taking a component that was once used, going through all the processes to make it like new or better, as my colleague John mentioned previously.

So I think it's really important that we set the foundation of what our definitions are before we can quantify or characterize whether the flowchart is accurate or if it's detailed enough and so on. So I think, you know, I would really encourage, as we go through tomorrow, especially to level set on what those definitions might be.

DR. SILVERSTEIN: Yeah, I mean, terminology has been a really important part of this issue, and I think going back to our 2016 workshop, we had put out some working definitions of terms. You know, the remanufacturer definition is in 21 C.F.R., and some of the other definitions, at least FDA's perspective on them, is in our May 2018 report, and we also know that there are some standards out there. But I think making sure that we're all sort of speaking the same language is really important when we're trying to move this issue forward.

Would anyone else over here like to add anything?

(Off microphone comment.)

DR. SILVERSTEIN: Oh, thank you.

(Off microphone comment.)

DR. SILVERSTEIN: Sorry, can you just wait until I bring the microphone over? Sorry. Thank you.

MR. BOALS: Frank Boals, Defense Health.

Can you clarify the FDA's position? My assumption was that remanufacturers, being

a manufacturer, would have to label the product with their information, that they could not just leave it with the original information.

DR. SILVERSTEIN: So remanufacturers, according to 21 C.F.R., are a subset of manufacturers, and so there are certain requirements that they are held to. And so depending on the activities that they're doing would depend on whether or not they need some kind of marketing authorization or something like that. They would be subject to 21 C.F.R. Part 820, which is the quality system regulation. And so that's really what we're talking about here because remanufacturing has requirements that are in place and have been implemented.

So I haven't forgotten about you, Table 6. Would anyone along the way -- and I promise that I'll get to you, but would anyone along the way like to add a comment before I head over to Table 6?

(No response.)

DR. SILVERSTEIN: Okay. We have plenty of time.

Okay, Pat.

MR. BAIRD: Thank you. Pat Baird from Philips.

I actually wanted to rewind way back to right when we had first started, and you had the slide up there talking about the damaged door on the infusion pump, and there's a couple of things that I sort of assumed when I was reading that case, and I was just hoping that if you do use that example in the future, you clarify a few things.

One thing is, if you remember, this was the damaged door, and can we swap it out with a different door? One thing that I assumed that wasn't in the narrative was like there weren't other sensors in the door, that the door, you know, it seemed like, in that example, and I assumed the door had only the one function, which is to push up against the tubing. But I know in the past I've had sensors on the door, and if you swap out the door with

another one, well, that might require recalibration, and it might require a bunch of other work that doesn't make it just a like-for-like. And so either way you wish to clarify that, but you know, there are other factors there.

And then also I know that you could -- oh, all tests, it must be a like-for-like because I tested the device and it's within spec. I would like clarification that testing the device doesn't mean run the pump at 5 mL an hour at room temperature and see if you're within the published, you know, tolerances. Instead, it must include, because OEMs had to test it, what's the highest rate, what's the lowest rate, what are the temperatures, what is the viscosity? There's lots of other factors that go into that testing, and I know that doesn't need to be an Infusion Pump Testing 101 kind of document, but I wanted to make sure that those kinds of requirements are conveyed in whatever the final product is.

DR. SILVERSTEIN: Yeah, I mean, we were intentionally vague in our examples, one, because we want to foster discussions that hopefully -- they look like they're happening at the tables. And so our draft guidance, I think, would be a little more definitive in the end.

MR. BAIRD: You succeeded in vague, yes. Thank you.

(Laughter.)

DR. SILVERSTEIN: We're here to hear public comments, so thank you.

Scot, did you want to say something?

MR. MACKEIL: Yes, sir. Scot Mackeil.

As a guy who's spent a requisite number of years in the pump room as a biomed, ditto the past comments. I mean, you know, any biomed has seen too many infusion pumps. But to go back to the insertion tube and epoxy discussions and the biocompatibility discussions, I was fortunate enough to attend DeviceTalks Boston, and they say you don't want to see how sausage is made. Well, when you go to a conference like that, you meet all the vendors and the subcontractors and the providers of these materials, the software,

these compliance packages, these devices, these motors, these switches, and you understand what a small industry it really is. And it's interesting, as you walk around and you see examples of their work, wow, I have that in one of my pieces of equipment. Wow, you wrote the software that runs my Draeger anesthesia machine. That's amazing; it's a small world.

But I think it's really important, when we start to take up the discussion of labeling, that there be -- to speak to a lot of these examples, that there's a bill of materials included so you can know which type of epoxy to use when you're replacing a lens on the distal end of a scope, so you can know which type of urethane tubing to use to replace the bending rubber or what material to use to replace the bending rubber on an endoscope, or if you have to replace the sheath on an insertion tube, you should be able to refer to a specification, and you should know you're going to get it right because you've seen the specification because it's part of the labeling.

And that would really help everybody in the industry if we know what we're -- what we have to use to do what we need to do to make these devices repaired and safe for the people like our doctors and nurses who are going to use those and the biomeds, like me, who have to make choices about which vendor to use to send our stuff to for repair one way or another. So that's where I'm coming from. Thank you so much.

DR. SILVERSTEIN: Thank you.

Okay, please raise your hand just so I have an idea from the room -- okay. Thank you.

MS. MAGUIRE: Hi. Barbara Maguire from ISS Solutions, Geisinger Health.

I just have a comment regarding the documentation that I'm hoping will be clarified in the future by FDA. We had some debate here, and we've also had some debate prior to this workshop, of what constitutes proper documentation if you're using a non-OEM part,

because that could range from documenting some kind of purchasing controls such as you validate your second-source vendors through some process and maybe you do that periodically so would that be sufficient. Or that you document some kind of risk assessment process that is done by management to determine what devices or parts are higher or lower risk and would be good candidates for having non-OEM parts if the need arises. Or at the most specific level, documentation could mean that there needs to be documentation by the technician every time they use a non-OEM part, which would be the most complete way but could be burdensome if you have those other controls in place. So I'm just hoping that the FDA offers more clarification on what documentation means in that case.

DR. SILVERSTEIN: Okay, thank you.

Binseng.

DR. WANG: My name is Binseng Wang. I previously spoke in the name of the American College of Clinical Engineering, but now I want to make sure that you understand I'm speaking for myself. Myself being a patient. I'm old enough, I guess, you people can understand that I feel myself a patient. And I want to make a comment sticking my neck out, and I hope Joshua will protect me because I'm going to venture into that discussion about what is significant, okay?

I think we need to have some type of common sense here because it is not possible, as was mentioned before, to find a new part, even the manufacturers themselves cannot find the same part year after year after a certain amount of time. If you, for example, replace a rechargeable battery that was initially specified for 100 mA, now you have a new one that is 1,200 mA, there's a change but is that a significant change or not, I think that is the crux of the question here. Even you folks, manufacturers represented here, go through the same process when you decide whether you need to submit a 510(k) when you make a

modification. Again, you have to determine whether it's a substantially different change or not. Or when you submit a brand new 510(k), you have to decide whether it's substantially equivalent. The words "substantially equivalent" is, for me, someone who is Brazilian and Chinese actually trying to speak English here, significant and substantially, they're very similar in my mind. In other words, require judgment and require a little bit of common sense here. If we want to be very strict and say no changes whatsoever, period, then we might as well all go home and pray to God that we are going to die tomorrow because there is no way that medicine can advance without any -- some change, okay? We don't understand how the human physiology and pathology works. We are doing our best to guess how we can help the patients and reduce the suffering.

So we have to have some tolerance for using a little bit of common sense here to allow changes to be made that is not going to harm the patient, not going to change the intended use or the performance of the device, but we cannot be so strict that we can only work within that square box and that's the end of the discussion. Thank you.

DR. SILVERSTEIN: Okay, thank you.

So I'm making my way over to Table 1. If someone has not had the opportunity to say a few words and would like to, along the way, please raise your hand, and we'll be wrapping up this session in the next 5 minutes or so.

MS. JONG: Good morning. Chin Jong (ph.), BD Biosciences.

I have two quick points I want to make. First off, I think listening to the discussions here, we all agree whether an activity is servicing or remanufacturing and documentation is very important, but understanding FDA's responsibility only applies to remanufacturing, not servicing. I may have that wrong, but how would you regulate someone who's performing servicing only and require them to document what they've changed, what the risk assessment is, how they determined that what they're performing is servicing. So that's

something that I have a question for; how do you enforce that requirement?

The second one is for when the guidance document comes out, I would like to see examples for an in vitro diagnostic device.

DR. SILVERSTEIN: Thank you. Okay.

Did you want to make one last comment? Okay, so this is going to be our last comment, and then I am going to summarize our session.

MR. WATKINS: Wow, the last one. This better be really good then, I guess. My name is Jim Watkins, and I'm with MacuLogix.

And on the topic of significant change, and this is a question for the group to ponder, would it be beneficial if we define who, in an organization, gets to make that determination, whether it's the technician that's at the bench doing the assembly or is it the design engineering team that did the original design intent that really fully understands? And if we document who in the organization is capable of making that change, does that help us all better determine when a significant change is being made?

DR. SILVERSTEIN: Thank you.

Okay, so thank you very much. We're still running a few minutes early. I'd just like to very briefly summarize what I've heard, and I apologize if I haven't done it completely right, but I promise you that beyond this list we're going to be going through the transcripts and make sure that everyone who expressed an opinion, that is considered when we're developing our draft guidance.

And so we heard a lot about the risk-based assessment and the importance of it. I mean, some people think that it should be further emphasized moving forward, and I also heard that risk is inherent to every step of the flowchart, and so that's really helpful to know.

Further interpretation of the term "significant": I think that that's not very

surprising to anyone in this room. And so if anyone has a comment that they'd like to submit to the open docket, we look forward to hearing any more clarifying points about how we can better interpret the term "significant."

Quality management and training, also not new topics but very important when any entity is assessing the activities that they're performing.

Access to information and specifications, including a software bill of materials, we're going to be talking about that this afternoon, so I think that's an excellent segue.

Clarifying whether we mean patient contact, healthcare provider contact, servicer contact, or all of the above, I think that's something that could also be done in our draft guidance.

Documentation: Again, I think it kind of -- it definitely dovetails well with the quality management framework, but I think it's worth mentioning that I heard almost consensus in this room that documentation in this space is absolutely vital.

So thank you very much. It is 11:50. We're going to be breaking for lunch for an hour and 10 minutes, so everyone please try to get back a few minutes before 1:00. I mean, we'll be talking about access to information, labeling, and other considerations. Thank you very much.

(Whereupon, at 11:52 a.m., a lunch recess was taken.)

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

(1:00 p.m.)

DR. SILVERSTEIN: Okay, hello. Hi, everyone. Welcome back. We apologize for the lights. If anyone needs to move because the lights are in their eyes, we fully understand. Please be comfortable where you're sitting, because looking at them from here, I understand that they're very bright and I've heard a few people talk about that.

So we'll go ahead and get started with our next session, which is called Access to Appropriate Servicing Information, Labeling, and Other Considerations.

So another disclaimer: The information in these slides is for discussion purposes only and does not represent draft or final guidance. It is not intended to propose or implement policy changes regarding servicing and remanufacturing or the applicable statutory and regulatory requirements for entities conducting these activities.

So labeling has a role in assuring the safety and effectiveness of devices that undergo servicing. Some product specifications may be provided in labeling or other publicly available information, while other specifications may not be available to entities. Devices are subject to labeling requirements under the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Several electronic products have performance standards under 21 C.F.R. Chapter I, Subchapter J, Radiological Health, that have informational requirements. Trade secrets and confidential commercial information are protected from public disclosure.

So I'm going to briefly go through some relevant labeling requirements.

And so labeling must include adequate directions for use under Section 502(f)(1) of the Food, Drug, and Cosmetic Act and 21 C.F.R. 801.5.

A device is misbranded if its labeling is false or misleading in any particular under Section 502(a)(1), and labeling may be misleading if it fails to reveal facts material with

respect to consequences which may result from use of the article under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual under Section 201(n).

Prescription device labeling must include any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended.

Instruments that are part of in vitro diagnostic devices must include service and maintenance information.

And the quality system regulation requires the establishment and maintenance of procedures related to verification of incoming product, design controls, and device labeling, among others.

For electronic products, those with performance standards generally include requirements for manufacturers to provide, at a cost to not exceed the cost of preparation and distribution and upon request, certain information to purchasers, servicing dealers and distributors, or others.

These informational requirements apply to laser products, ultrasonic therapy products, and diagnostic x-ray systems. They also generally include adequate instructions for service adjustments and procedures, clear warnings and precautions to avoid exposure to radiation within certain emission limits, and a schedule of maintenance necessary to remain in compliance with the applicable performance standard.

Trade secrets and confidential commercial information are protected from public disclosure by the Trade Secrets Act, Exemption 4 of the Freedom of Information Act, and 21 C.F.R. 20.61. And it is also a prohibited act to disclose trade secrets to unauthorized parties under Section 301(j) of the FD&C Act. And so FDA must comply with statutory and regulatory requirements regarding the protection of trade secrets and CCIs that are

submitted to the Agency.

And so now I'm going to introduce our next breakout session with the same title as our larger session: Access to Appropriate Servicing Information, Labeling, and Other Considerations.

The goals of this session are to gather information and public comment to help inform future draft guidance. We'd like to discuss what information concerning device specifications and servicing should be in labeling to reasonably assure the safety and effectiveness of reusable devices. Step-by-step instructions can also be found in your workshop packet on the right side, and I'm going to go through those instructions just like we did this morning.

And so, in general, we'd like for people to remain at the same table from the previous breakout session, and the same people designated during the previous breakout session may continue to be the facilitator and scribe, or you may choose new people for these roles.

Like this morning, an FDA staff member may be present or will be rotating between tables. You can ask them questions, but again, the intent of this session is to obtain public comments.

On your table you have been assigned examples, just one example, for which we're requesting your feedback and comments, and please discuss them and complete a form as needed for each scenario, or you can group them if you think it's reasonable to.

And so the goal of this session is to discuss what information about device specifications and servicing should be included in labeling to assure the safety and effectiveness of reusable devices. So we'd like for you to consider them in the context of the previous breakout, but we also look forward to hearing your higher-level feedback as well. And so to consistently capture public comment, we do have a standardized form. It

should have already been brought to your table. If you don't have any, please raise your hand when our breakout begins. And we also have similar instructions for remote attendees that they can access our webpage for this workshop and email completed forms to me. And so if you finish the example that was assigned to you, please continue to discuss others or try to sort of form higher-level feedback in terms of access to servicing information, labeling, and other considerations.

And we'll rotate again throughout the tables to make sure that everyone has a chance to provide some comment, and we'll be making sure that everyone's making timely progress on these.

So, you know, the three questions that we'd like feedback on are:

1. Which device technical, performance, or other product specifications should be included in the device labeling to facilitate high-quality, safe, and effective servicing?
2. Are there any additional component/part/material specifications that should be included in labeling to facilitate high-quality, safe, and effective servicing?
3. Is there any additional information about software that should be included in labeling?

So, with that, we will be going until 2:15, so you have just over an hour. Break out. Everyone should have forms, and let's talk about access to servicing information, labeling, and other considerations. Thank you very much.

(Off the record at 1:09 p.m.)

(On the record at 1:50 p.m.)

DR. SILVERSTEIN: Hi, everyone, I just wanted to check in. We have about 25 minutes left for this breakout session. So hopefully at this point you've been able to get through the examples that were assigned to you. We just assigned -- sorry, could I just have everyone's attention just for about 30 seconds? So everyone was assigned an example just to

contextualize these questions for you. Now that you've had a little bit of basis to ground, we'd also like to get your higher-level feedback on these three questions. So if you haven't started sort of allowing for those thoughts to coalesce, now is the time to step a little bit away from the example and think a little bit more broadly, and we'll be doing sort of a little bit of specific and general discussion for our reconvening. So you have 25 minutes left, and in 25 minutes we'll also take a 15-minute break. Thank you.

(Off the record at 1:51 p.m.)

(On the record at 2:14 p.m.)

DR. SILVERSTEIN: Hi, everyone. Welcome back. It is 2:14, about to be 2:15. We're going to take a 15-minute break, and then we're going to reconvene, and we'll have an opportunity for public comment at that point. So we'll see you in 15 minutes. Thank you.

(Off the record at 2:15 p.m.)

(On the record at 2:34 p.m.)

DR. SILVERSTEIN: Hi, everyone. We're going to get started in a few minutes. Please find your seats. Thank you.

(Pause.)

DR. SILVERSTEIN: Okay, so thank you very much. So we are now starting the reconvening session for Access to Appropriate Servicing Information, Labeling, and Other Considerations. And so similar to what we did this morning, each table was assigned an example just as a starting point to talk about the three questions that we are requesting feedback, and so halfway through the session we asked people, okay, you've grounded yourself in this example and now let's start to think about these questions from a little bit higher perspective. And so the format for this session is that we are going to start off with a little bit of high-level feedback, and we might do some deeper dives into specific product areas as some of those issues are teased out. And so we are asking for broad feedback

about access to information within the context of all we've discussed thus far, and I plan to switch between tables, and one of my FDA colleagues, Linda Ricci, has volunteered to cover the other side of the room. So in case I can't see you, then raise your hand and Linda will make sure to let us know that you're asking to be heard.

And so similar to this morning, after your table facilitator speaks, if anyone from the table would like to provide some additional comments, we have time for that. And, again, like this morning, we'd like to collect our worksheets at the end of the session to make sure that all of the feedback that was discussed at the table is heard.

So, with that, I am going to start closest to me, mostly because I could save some time. Okay, thank you. So I'm going to start here with Table 3.

Peter, I think you've been democratically elected.

(Laughter.)

DR. SILVERSTEIN: And so I think just to start off our session, let's start off with Question 1. And so Question 1 is what device-specific technical -- or excuse me, which device technical performance or product specifications should be included in the device labeling to facilitate high-quality, safe, and effective servicing?

MR. WEEMS: So, you know, I think we had a --

DR. SILVERSTEIN: Sorry, could you please stand up --

MR. WEEMS: Sure.

DR. SILVERSTEIN: -- and also say your name?

MR. WEEMS: Sure. Peter Weems with MITA.

You know, I think we had a very useful discussion in terms of, you know, sharing our perspectives on this issue. I mean, I think that our table was -- I don't know how the other ones are but, you know, unique or interesting in that we had manufacturers, HTMs, and third-party servicers at this table, and I think that each one of those stakeholders has, you

know, a different business relationship with the other stakeholders present at the table and therefore have different perspectives on this issue.

(Laughter.)

DR. SILVERSTEIN: Well, if you're willing or if someone else from the table is willing to share, we'd like to hear those perspectives.

MR. WEEMS: So I think, you know, from -- I think from the manufacturers' perspective, that what is already provided is sufficient for safe and effective servicing of medical devices. You know, I think that part of our discussion focused on the difference between what is necessary for performing those activities and what would be additive to efficiency or productivity. And, you know, I think that around those questions of efficiency and productivity there is difference of opinion stemming from different competitive interests and -- do you want me to keep going?

(Laughter.)

MR. WEEMS: I think I've answered the question sufficiently.

DR. SILVERSTEIN: Okay. Okay, so now we're going to go to Table 2. And so I'm --

UNIDENTIFIED SPEAKER: We can just say ditto.

(Laughter.)

UNIDENTIFIED SPEAKER: Not quite.

DR. SILVERSTEIN: So who's been appointed or elected, or volun-twisted?

MR. FOGLEMAN: Me. Hello.

DR. SILVERSTEIN: And so, again, I think for now let's focus on Question 1.

MR. FOGLEMAN: Well, this stimulated a lively discussion at Table 2. Based on the piece of equipment, the user manual should list any user serviceable items with details on how and how often to perform the activity. The service manual, if applicable, should provide sufficient details to perform the service activity as well as any performance function

testing parameters. It should also specify any relevant documentation needed to describe the activity and outcome. It is also appropriate for an OEM to have a service segment in their business model. We have to be careful to protect intellectual property in these disclosures.

DR. SILVERSTEIN: Okay, does anyone else want to share something from this table?

UNIDENTIFIED SPEAKER: No, thank you. That was a collective statement.

MS. FEDERICI: I'll just say it was a challenging discussion, and there are still concerns from a competitiveness perspective that exists. This is kind of an initial starting point.

DR. SILVERSTEIN: Yeah. And so I guess compared to where we started, like before this workshop and some of the more recent activities, do you feel like there seems to be a little bit more consensus at least about what is a trade secret and what is not? No, okay. I'm sorry to steal the microphone away from you, Tara. Mine ran out of batteries. Yeah, okay. So I'll be handing off the microphone. And so, you know, we had a lively discussion this morning about infusion pumps and I wonder --

(Off microphone comment.)

DR. SILVERSTEIN: Yeah, thank you. I'm going to hand it off.

MR. MASTERS: So when we were talking about the stepper motor example, and we talked about it, and that particular example doesn't lend itself for any kind of a deep discussion about software upgrades, what sorts of the things, because there's just no way that would ever be considered field serviceable without some sort of an authorization from the manufacturer. But assuming that there is some sort of a field repairable unit that were in there, then we would like to see -- in the IFUs, you would naturally have to have -- or service manuals -- calibration procedures, performance procedures, part numbers, installation instructions, I mean, the things you would need to know to be able to do that. But, normally, for instance, we don't -- in the consults we have, we don't have anything that

somebody that's just out there in the field and picks up a book would be authorized to do.

And are there any additional components? The things that leap to my mind are things like fuses, there are ratings on fuses, and if you put the wrong ones in, they can explode, so things like that. And those are already on -- usually for 60601-1, those things are already listed on the back of the label next to where the fuse goes.

And is there any information about software? Again, for the stepper motor example, there's just nothing -- I mean a stepper motor, if it doesn't plug in and work, then no, you're not going to go reprogram the machine to be able to make it work. But if a system were upgradeable software-wise in the field, then you would expect, at least somewhere in the user interface, to see the version number on it so that if there was some kind of a problem, a security flaw that was found or a patch that was generated, you would know what version you had and you'd be able to say, oh yeah, I've got this version and I need the upgrade.

DR. SILVERSTEIN: Yeah. Okay, thank you.

Okay, so I'm going to come over to you now.

MR. JONES: Which one do you want, this one? All right.

So, hey, I'm Brian Jones with Steris.

We were more like Tables 2 and 3, I believe, on this one, so I don't know if I can add a whole lot more to that. We had the battery example, which I think what was kind of unique about ours was that that's kind of an accessory to a lot of devices and wasn't contained inside the medical device itself. So short of providing the part number for the replacement battery or the part number for the replacement cells that would go inside the battery, there's really only maybe a few other things that would be interesting to have as far as labeling goes. We mentioned about the power characteristics, which is probably already there, the charging method for the battery and maybe the cycle associated with that. And then the reprocessing method, you know, however the original battery is being

reprocessed inside the hospital, maybe should be a consideration in terms of the replacement battery as well, too, and then all of the other ESB and safety guidelines that would go along with that. But like Table 2 and like Table 3, we recognize the competitive nature around all of these discussions, but those were some of the comments that we had.

DR. SILVERSTEIN: Okay, thank you.

Okay, so I think we already started to talk about software, and so I think that's a nice segue to come over to Table 12 and I can -- everyone's smiling, so I think we had a good discussion over here. Who would like to -- okay.

UNIDENTIFIED SPEAKER: The same lively discussion that other tables had. We boiled down that software is kind of a different animal that you don't want to make source code or any proprietary information available. We did talk about some basic configuration and making that available to them, to the service providers, but we thought that this probably wouldn't be the place to regulate this type. This has to get part and parcel with their software development plan and the design controls aspects and how they're going to make it fit their use cases and their business model. So that's kind of where we ended up is that, basically, don't provide anything to them. You're not obligated to provide it unless -- because you can't extend your quality management system to other people that you have no control over.

DR. SILVERSTEIN: Yeah, but I think what you started to say was that you might be willing to provide more information than you are currently. Was that accurate?

UNIDENTIFIED SPEAKER: No, we just tried to think of different ways.

DR. SILVERSTEIN: Okay.

UNIDENTIFIED SPEAKER: Our preference is not to provide anything. We tried to look at different ways to maybe help facilitate a discussion.

DR. SILVERSTEIN: Yeah.

UNIDENTIFIED SPEAKER: But we think that, ultimately, all the liability ends up on the OEM versus all the different people that are making money throughout the systems but have no liability whenever they're accessing your device.

DR. SILVERSTEIN: Okay, thank you. Does anyone else from the table, would they like to add on top?

MS. BENEDICT: Well, this is Marcia Benedict from Steris.

Just that we agreed with what was stated elsewhere, that it's appropriate and I think probably is currently within labeling to say what is the version that is on the software currently, on the software-containing device currently --

DR. SILVERSTEIN: Okay.

MS. BENEDICT: -- so that people know, you know, if it's been upgraded, for example.

DR. SILVERSTEIN: Thank you.

Okay, so I'm going to snake my way back to endoscopes. And so I wonder, you know, endoscopes are -- definitely they're a critical device that are used in the GI system, they're regularly serviced by OEMs and third parties, and I wanted to try to do sort of a deeper dive, if someone is interested, to talk about sort of what kind of specs are in the labeling for endoscopes currently and which of those specs we actually think are trade secrets or not, and is there anything else that could not be considered a trade secret that people would be willing to put in labeling. And I just wonder if anyone would like to start off with that discussion. No? Aaron, thanks.

MR. JOSEPHSON: I'm going to pull a Peter and kind of not answer the specific question asked. So, you know, we, I think, like the other tables, had a lot of discussion around this. Kind of where we came out was, you know, something that's worth exploring could be the provision of what we ended up calling functional specifications, so things that can be measured relatively easily. In the context of an endoscope, you have maybe the

articulation, angle of certain components that bend, more just the length or other properties of a lens or something to that effect, things that to the extent that servicers or anybody, for that matter, can easily reverse engineer these things, possibly something that could be worth providing to help -- to help, you know, ensure that the servicing is being done correctly.

And the more difficult discussion, I think, or the further down we got on the page, I think it got more difficult because when it comes to component, parts, and materials, we had a lot of discussion about in the context of our example, one of the components for discussion was epoxy, and there was a lot of discussion about, well, do you have to provide the chemical, the chemical formula for the epoxy? Not as much kind of consensus on that point, but worth discussing, I think.

Kind of the flipside to this is that to the extent that this information is being provided by OEMs, I think the OEMs wanted to be sure that the servicing entity is -- or again, whoever is performing these activities because, as previously mentioned, it could be the OEM's servicing department, that they are following a quality system, that they have kind of the components of a quality system in place and are following it as kind of the check on the use of this information appropriately.

DR. SILVERSTEIN: Thank you.

MR. HAMILTON: Yeah, just to add a little bit. Stan Hamilton, Rebotix (ph.).

Just to add a little bit to that, from the discussion, because I think it's a point that may be interesting for you to take away. You're trying to encourage all service providers, whether they're inside OEMs or outside OEMs, to take a risk-based approach, I think, is certainly part of this. And so as we discussed the functional specifications, something that was discussed at the table, I won't say we agreed to anything just like he won't, but is that in order for that risk-based approach to really work, safety risk-based? And, you know,

again, with the principles of 14971 and for the kind of things that the device manufacturers are doing on the front end, you know, there's aspects of that that relate to the impacts of service changes and that kind of thing.

But in order to really follow up on that and do that correctly, then when those functional specifications are provided, they need to be adequate to understand hazard causes and controls and where those tie into acceptance criteria. If you don't have that, you know, you have to try to reverse your way back into that. Sometimes there are standards that have -- you know, there's enough information for some devices, there are standards out there for performance and all, and you can back your way into a lot of that. Obviously, for a lot of things like, you know, you had biocompatibility stuff, there's tons of stuff on that. You don't need that so much. But where there's functional performance things that relate to safety, you know, if you want this risk-based approach to work, that has to be provided.

DR. SILVERSTEIN: Thank you. All right.

MS. KANN: Melissa Kann with Stryker.

So we, like everybody else, had a lot of debate. We actually ended up taking this from -- point it back to more of a general discussion versus the exact example because we kept getting ourselves completely hung up on that. But, really, what we were saying is that you can't apply anything just across the board in kind of a peanut butter approach. You have to look at the device, and this needs to start with the OEM during development, you know, potentially start with what is the device-specific needs and looking at the classification as well as any potential risks of the device. From there, then, the OEM could identify potentially what could be repaired, and again, this is coming out of that risk-based approach, and then they could -- whether it's providing field-replaceable unit information with training and service manuals, whether it's entering into agreements with the --

whether it's the hospital biomed department and conducting training with them. But it all kind of starts at that top level and determining what is it that, based on us who have spent, you know, 4-plus years developing and designing these devices, you know, and going through our process validation, we can determine potentially what could be serviced and provide that information.

DR. SILVERSTEIN: Okay. And is that something that you currently do or --

MS. KANN: No.

DR. SILVERSTEIN: Okay.

(Laughter.)

MS. KANN: I'm opening it up.

DR. SILVERSTEIN: Okay, thank you.

MS. CLAY: Hi, Regina with BD.

We also said the service instructions for the field-replaceable units would be only for field-replaceable units because we don't develop them for anything that a manufacturer isn't already servicing.

DR. SILVERSTEIN: Thank you very much.

Okay, we're on to MRI, Table 9.

UNIDENTIFIED SPEAKER: I'm your best friend at 3 o'clock in the afternoon. So as with the other tables, there was no consensus as to what falls within labeling and what falls into intellectual property. There was also no consensus over whether there should be a warning on non-OEM/FDA-registered devices manufactured by ISO-certified companies with respect to things such as warnings which may be omitted when non-OEM equipment is installed. But there was recognition of a need to address counterfeit or safety issues, but such should not lock down the device. However, there was a consensus with respect to issuance of safety notices and recall notifications, officially released non-safety related field

change orders, corrective action notices, error codes, calibration information, spare/replacement/renewal part information, planned maintenance, and PM checklist.

Software keys: Well, software keys, there was some observance that access should be provided, the scope of which, I think, there was no consensus. And a list of OEM-approved validation antivirus options, if available. No real consensus on that. But validation testing information, there was general agreement with respect to that.

DR. SILVERSTEIN: Okay, thank you.

Okay, we're off to Table 14.

MR. CARR: Thank you. Dennis Carr with Steris.

We talked a lot about the requirements for tools and test equipment to be identified, and the other table that mentioned as well, too, about the test procedures, the expected results, and any tolerances that would be allowable for that expected result, performance and safety specifications which we are required currently under labeling to provide.

Software keys, as well mentioned as well, as if there are -- a trend in the industry these days, a lot of companies are going to service applications that are not on the device itself but in a separate software package, and we just -- we thought it would be helpful to identify what functions were available on the device versus on the applications and to detail that as well, too. As others have mentioned, calibration procedures should be part of that labeling.

Components we talked about, component specifications, mainly around wear items as well as preventative maintenance components. Not to level that it would interfere with intellectual property, but just general specifications for those components and materials, such as like O-ring material may be critical, especially if that material is within a critical part of the device itself, so that was another thing that we talked about as well. We thought if

it's in -- also identifying whether these components were actually within that critical function of the device or whether they were outside of the critical function of the device.

Software: We talked a lot about the revision levels, both major and minor revisions. The revision history, so changes, what has changed since the last revision update for that device we thought was important.

DR. SILVERSTEIN: So is that something -- I don't know whether you have any software products, but is that something that's already available in your labeling or --

MR. CARR: We do publish the software revision level.

DR. SILVERSTEIN: Yeah.

MR. CARR: But not necessarily what's changed from one revision to the next.

DR. SILVERSTEIN: Okay.

MR. CARR: And that's what we thought might be important to know; okay, so you're making this minor update to it, what is included with this update.

DR. SILVERSTEIN: And would you consider that kind of history to be a trade secret?

MR. CARR: It could be.

DR. SILVERSTEIN: Or confidential? Yeah.

MR. CARR: It could be.

DR. SILVERSTEIN: Yeah.

MR. CARR: So the other things we talked about, I think a lot of them are already in the labeling; again, technical data sheets, packaging specifications, product info, electrical schematics or mechanical schematics for the device, and bulletins and service content. And lastly, we talked, as far as the software, is where the patient -- if there's any patient data that's stored either locally or in a cloud server, and can it be transmitted or has it changed in any way.

DR. SILVERSTEIN: Okay.

DR. JACQUES: Sam Jacques, Penn State Health.

We had a brief conversation around some of the intellectual property, and we brought up -- and no one has yet, which is why I'm bringing it up, the EU medical device directive and kind of the language that's in -- they're now directives, but they're moving to regulations in the EU, and we actually thought that language was really helpful because it delineates some of the trade secret stuff, so if you're okay, I can just read it.

It says that "where appropriate, instructions for use must contain all information needed to verify whether the device is properly installed and can operate correctly and safely, plus the details of the nature and frequency of the maintenance and calibration needed to ensure the device operates properly and safely at all times." So we kind of threaded through some of the trade secret stuff by just saying, right, we're going to focus on safety.

DR. SILVERSTEIN: Okay, thank you.

Okay, so I'm going to come over to our next endoscope table, and I also am curious to know if some of that functional performance information was discussed at your table. Wow. Who would like to --

(Off microphone comment.)

DR. SILVERSTEIN: Okay, thank you.

MS. THRALLS: Hello, my name is Veronica Thralls, and I am with Intuitive Surgical.

So our table was discussing endoscopes, and we had Example 8A1 that we were working through and -- but before we got into the three questions that we needed to provide feedback, we had a really rich discussion, as most tables did, and the level of ownership and engagement between OEMs, third-party providers, and servicing companies, right, and really the big takeaway is from the morning discussion and even now discussing access to information is that the level of accessibility to information greatly determines

whether an activity is going to be classed by service or remanufacturing. So that was a big takeaway for us, and it was an important one to highlight.

In terms of our specific example, which was the scope that had the crack in the non-patient section, what we reviewed in the label to really have the device restored and make sure that is high quality, safe, and effective is that we would need the specs for the sheath that covers the endoscope, the glue, the source of where those are coming from, technical data sheets, the testing that was done to validate that and to make sure that it's performing as intended. I think that that is what we discussed.

Flexible scopes present an additional challenge because they need to be reprocessed, and they need to be at a high level if infected or sterilized, so we talked about the importance of having that information. And to the level that you don't understand that, if you're a third-party service company, you could be replacing the sheath for something that will not be compatible with the intended sterilization modality, very different from a steam to, let's say, low temperature peroxide if you went with another modality.

And the one thought that we had as well is that when we talked about the sterilization and reprocessing of devices -- potentially, this is mostly my thought. But when you have devices that are stated to be reusable for a certain number of times, then how do we ensure that when a device is repaired it still can meet the intended life expectancy for that device, so the tests, you need to cover the useful life and not just, okay, we've got to do work once. In terms of software, for our example, there was no software involved.

DR. SILVERSTEIN: Did anyone else at the table want to share any thoughts?

MS. THRALLS: And we wrote the additional input --

DR. SILVERSTEIN: Thank you.

MS. THRALLS: -- that we had from our discussion.

DR. SILVERSTEIN: Thank you.

Okay, so I'm not sure, are you also -- okay, thank you very much. So I know we started off with software here, but I was wondering, you know, did you have a higher-level discussion about physical devices, software devices? Or kind of walk us through what you discussed.

DR. GOLD: Sure. So I'm Fredric Gold from Hologic.

So we spent some time looking at it from a software-specific standpoint, just looking at it from a diagnostics standpoint and what the hardware was, what the software was, what the release was, whether or not things were compatible. So from a higher level, it was what should be on documentation in order to understand what could be done. But then we also got into a discussion about just who should be doing the service, so we got into the serviceability question and being designed for serviceability, whether it should be designed in for a user level or an OEM-level serviceability or potentially from a service provider level.

DR. SILVERSTEIN: So just to ask a follow-up question on that, I mean, how would you even determine -- I mean, would you refer to the labeling to see whether or not that's already addressed or --

DR. GOLD: So we were talking about like an operator's manual.

DR. SILVERSTEIN: Yeah.

DR. GOLD: So if that was provided to the user, then they would have to go through that and say, okay, here's what they can do as opposed to then they would have to call a technician in to do it versus what would have to be sent back to the OEM to have them perform it. Then we talked about software keys to allow access to diagnostics and data, the service logs, the error codes, and stuff. Also, how do we build risk into the serviceability, so what's allowed to be done by the user level, what's allowed to be done by the service level based on what the instrument actually is.

DR. SILVERSTEIN: Okay, thank you. Anyone else?

(No response.)

DR. SILVERSTEIN: Okay, so I'm going to jump over to our ultrasound table, and I'm wondering who's -- okay, thank you. Thank you.

MR. PASTERCHICK: Hello again. Andy Pasterchick, BD.

So we had ultrasound, and we had a couple of different discussions. In two of the scenarios, the part in question was no longer available, and so a lot of our discussion was around that. One of them was more straightforward and it's actually fairly common, and that's printers. So the idea is that the OEM-provided printer is no longer available; the customer needs a printer. So we felt, in that case, you know, it's our obligation to provide them with the specs they would need in order to operate with our device, things like, you know, how do you -- what are the drivers for the printer, how do you connect the printer, what are the interfaces for the printer, that type of thing. Fairly straightforward. Obviously, we wouldn't provide them any specs on serviceability because it's not our printer, but we could provide them with the basis they would need in order to print using our device.

The other piece would be a little bit more complicated; it was for an ultrasound monitor. In this case, the monitor is no longer available, but the customer, you know, in this case needs to get -- you know, wants to try to find a monitor. We could provide them with certain specs. We could tell them -- we could give them the specs on our old monitor, on the one that's no longer available, the electrical requirements, some of the -- you know, that are mentioned, size, weight, all of that's applicable to an ultrasound system. But we couldn't validate for the customer, so that's the challenge there. And, you know, it's a service issue, but we can't validate a non-OEM part. We can give them all of our specs, but if they go out and they buy something off the shelf, it's a non-validated part, and there's nothing we can do about that, and we can't take responsibility for that.

The third discussion we had was one along the lines of now it's getting into remanufacturing. So, in this case, what you have is you have a subcomponent of an ultrasound probe that fails. It's not a serviceable part, so it would not be something that we would allow our service teams to change in the field; it would not be something we would sell to a customer. So, you know, in the end, the response to the customer would be you're going to have to buy a new probe because it's not a serviceable item.

DR. SILVERSTEIN: Okay. I think a lot of what you've been talking about is sort of like end-of-life issues and --

MR. PASTERCHICK: Right. Yeah, we had a lot of discussion around end of life.

DR. SILVERSTEIN: Okay. And so I'm just wondering, you know, when you're interacting with your customers, you know, how are you providing this information? I'm guessing that some of it's not in your labeling, and is it just through like a telephone conversation or --

MR. PASTERCHICK: Well, if you've got a good end-of-life life cycle management process, you're communicating to your customers fairly early on, and you're giving them enough advance notice that they can start making educated decisions, you know, at least 12 months out. You know, you want to get -- what you want to do is you want to provide them the information when their -- prior to their buying cycle so they know that this product is going end of life and they can make appropriate decisions. What would get you into trouble is when you announce something's going end of life and the customer has already made a purchase, and now they know they're going to be stuck with something that is not going to be supported for much longer. That's what gets you into -- you know, that's where the problems are. But that's more of a life cycle management issue, and based on my experience with several companies, we tend not to do it very well. We get into trouble with customers quite a bit with our end-of-life programs, so it's something we need to get better

at.

DR. SILVERSTEIN: Okay, thank you.

MR. PASTERCHICK: Thanks.

DR. SILVERSTEIN: Okay, so I'm going to come over here to Table 5, and who's been elected to speak? Thank you.

MR. MORGAN: I'm Dave Morgan with Sigma Imaging.

So we had the rechargeable -- I'm sorry, not rechargeable, battery example, 5C2, and there's probably not much new I have to offer that hasn't already been covered, but just some answers for Number 1 there. Chemical composition was one of the things on the label we want. Let's see here. It's the only thing that hasn't been covered already. And for Number 2, some things on the label, disposal instructions, compatibility info, what is serviceable and what isn't. And now I'm kind of just branching out more broadly, not just the battery example. Removal and installation procedures, field testing procedures, and -- yeah, that's all I have new to add.

DR. SILVERSTEIN: Okay, thank you.

All right, so we're over to Table 6. Pat, thank you.

MR. BAIRD: Okay. Pat Baird, Philips.

We started out looking at the example, and this was the infusion pump drug library, and the question is, you know, how does service take and apply to that? And then since there were three questions to be answered, we used some compression techniques and came up with one answer for all three by changing the question that was given to us. So I don't know if that's off-label use or not, but anyway, we're going forward with it.

(Laughter.)

MR. BAIRD: I feel really lame here. You people must be tired if you're laughing at that. So we took a step back and asked ourselves with saying just sometimes software

needs other components other than, you know, the core therapeutic software to do its job. There needs to be operating -- depending on the application, there could be operating systems, network drivers, all kinds of other things that we rely on, and so what we thought would be useful then -- or what would constitute servicing would be when you need to take and update those network drivers for some reason or another.

We thought it would be useful if we had some sort of matrix, and it might not actually be coded as a matrix, but just saying here, for this part, we know it's compatible with this version, that version, and the other version. For this other software component, it really needs to have a network driver or Java version X, and just having this sort of list, it's not quite the software bill of material but a similar concept of giving you enough information about the components that go into this system that are field replaceable, as it were, and listing those things out.

We then got into a discussion about the logistics of it, you know. That's not something we can really ever print out because as soon as we print it out and hand it to someone, it's going to be obsolete, so we need a webpage. But then because some of our products in other countries and e-labeling is a challenge, and so we started getting into some of the operational challenges that would come with developing something like this. But in an ideal world, we thought this might be useful.

Let me see what else I'm missing. And also then, you know, in an ideal world, talked about some other things. There was also a suggestion of, just like there is in the service manual, some hardware, instructions about replacing hardware things. You know, should there be a software section; would it be nice for there to be a software service section in the service manual? And I'm thinking that we can bring up that tomorrow as part of the collaborative community. Did I miss anything?

MR. NIEDELMAN: I'll go next. So software, like Pat said, a software service manual.

The NFPA denied -- defined -- the service requirements for a service manual quite some time ago, and that definition has gotten a little old as devices have matured, and so many things are software driven and, you know, complex electromechanical constructs driven by complex software systems.

You know, one of the things we have -- sorry. You know, hospitals are complex via systems, workflows, processes, digital and physical technologies that work in concert to create the environment of care that in turn enables caregivers to have a healthcare facility that functions safely, efficiently, effectively, and enables them to deliver care to their patients safely. Software plays a huge role in that.

You know, when you're a biomed, you get a call to -- a physician calls you into the room, and the device has become broken to them, which means it's not meeting their expectations, and it's not working as they expected, and there could be a physical cause, there could be a use error, or there could be, you know, an unexpected thing that the software is doing that caught them unaware or it's not measuring to their expectations. So when you deal with servicing a software-driven device, just like Pat said, you need a software service manual so you can measure and define is the doctor -- did he find a glitch or a problem with that medical device as a result of the software that drives it?

When you look at some of the ECRI and FDA recalls, a lot of them are specific to things related to software. So one of the reasons biomeds need good tools for evaluating and servicing the software aspect of a device is in support of the mission of the FDA to, you know, issue these recalls. If we can test a device and make sure that its software is functioning as the manufacturer says in that software service manual and then we find something that doesn't add up when we follow those procedures, now we've identified a potential problem. And that goes doubly, so when that physician has written a safety report in conjunction with what he called you to the room for and the way that that device

may or may not have malfunctioned, so it's a complex issue, and so that's why we really need to do a much better job with the software side of the service manual. So I hope that, I hope that makes sense.

DR. SILVERSTEIN: Okay, thank you.

Okay, so Table 7, I haven't forgotten about you. Thanks.

MASTER SERGEANT JOHNSON: I'm Master Sergeant Johnson, Defense Health Agency.

We actually had the infusion pump door as our initial problem, and we broke away from that because we identified that as a field-replaceable item most commonly with infusion pumps, so we went to the broad overview.

For Question 1, we looked at it as did the manufacturer authorize that part to be replaced? Is that something the manufacturer is comfortable with for that service, regardless of if it was their biomed, third-party biomed or an institution biomed to replace that part in the field? And if it was required by the OEM, was it also included with automated self-tests and specific requirements after that part was replaced and what area of the test, going back to what the gentleman said a minute ago.

Another part for something that we would like to see and brought up was the test equipment requirements for calibration and verification. It's one thing to say, hey, test within these parameters; we're looking for this result, but what's the test equipment? A prime example, electric surge. When you're running a power resistor, what percentage of that power resistor are you looking for; is it 5%, 10%, 20%? So having those values of what specific test equipment requirements are critical, not just a fluke of 754, I mean, whatever that modality is, give us the requirements of the performance expectations of that device.

The second part: Once you go through and actually have the field-replaceable components, actually have the process written out, specifically what parts were removed

and what parts were replaced and have that common across the board to give those biomeds the tools that they need to successfully repair that equipment in the field or whether it be their own service engineers, field service technicians or the biomed at the institution.

So going to Question 2, this is a big "if" in regards to additional components, parts, and materials. If the OEM supplier agrees to his parts specifications or requirements for testing under the agreement from the buyer to the manufacturer, that goes to are we allowed to have that information, that software key to that dongle or that proprietary detail to get into that level of troubleshooting in that part of servicing.

DR. SILVERSTEIN: So if I can ask, do some of your buyer agreements have those stipulations in there?

MASTER SERGEANT JOHNSON: I'm a little different; we're the DoD, so we're in the same footprint you are with the FDA, so the nondisclosure agreement kind of goes in here, that we get some of that information.

DR. SILVERSTEIN: Okay.

MASTER SERGEANT JOHNSON: Part of the problem is we talk to third-party institutions, and we're talking with some of other manufacturers here. They give that based on the relationship, so it depends on how many units you buy, what relationship you have with the manufacturers; it depends on what they're willing to give you, and it's not consistent across the board. You'll have some that will, some that don't, and that was the consensus we had across the table, but it's all a case-by-case scenario and device-by-device scenario depending on what's available. So that's one of the issues that we saw there going across the board, and it's if the OEM agrees to release that information or they feel comfortable that that institution is capable of maintaining that support and giving them the information in the field to actually do the repairs.

And then part three, the software. The big thing on that was software versions, firmware versions of each component that goes along with that, from the main component itself all the way down to modalities plus a bill of items and materials of the software. And to put some foresight and some future on this, we're looking for inputs and outputs. We already know we're going to electronic health records, so we're going to have the devices and medical equipment that's going to be communicating to a patch of some sort or a kind of health record that's not going to be to manufacturer-specific GEUs, Fuji packs.

Actually, it's going to go back to something. EKGs we're going to be able to send to a cardio that might not be in that institution, and it's going to have go on a network. So being able to see those inputs and outputs on a standard DICOM setting is going to be critical to future care and making sure that the patients get the support they need. And for the biomeds, make sure we have that up front, to have that connectivity to troubleshoot to make sure that's working correctly is critical.

DR. SILVERSTEIN: Okay, thank you.

So we have a few minutes left. I just wanted to give another opportunity. If somebody would like to have maybe about 1 or 2 minutes, please raise your hand. Thank you.

MR. NOWAK: Thanks, Josh.

Chris Nowak, Universal Health Services. We're predominantly an end user of devices.

So I think I wanted to address the software perspective. From the end-user perspective, the software that we're concerned about is that patch management opportunity and the delays in validation of software coming from the OEM after a patch comes out, so the vulnerability lies with our device in our facility that gets hacked. The OCR will find the facility. They're not going to find the manufacturer; they find the facility if we

lose patient-protected information. So the ability for us to have that validation completed in a timely manner, have our ability to load patch management rather than wait for a service engineer that's certified by the manufacturer, which is another misnomer. You know, my friend John over here talked about we assume that the OEM -- and I've heard it throughout the entire day today, that the OEM and all of their employees are following the ISO 13485 guidelines, that they put in the processes that they're supposed to follow, and quite frankly, that doesn't happen. It always comes down to the individual and the individual performing the service. Whether it's my individual or the OEM individual, time and again we see that where the process doesn't get followed. So, you know, I really wanted to address the software and the patch management perspective and how that impacts patient care from our perspective.

DR. SILVERSTEIN: Thank you.

MIKE: My name is Mike with Christiana Care Health, and this is, again, with software.

I would say that additional information needed from software would be a one-line network diagram so we know how all the software communicates but internal to the system and with the world outside. In case it needs to be isolated, where do we drop in a firewall? All the software on the device, the manufacturer, the revision, the release data, and the latest patch should be provided at least at purchase so we know what's on the device. And then what's the upgrade schedule? Do you guys, as a manufacturer, do you every 6 months stop and go all these software programs on our device? We're going to release a patch that addresses all the vulnerabilities in all the software every 6 months, every 8 months, every year, never? What's the upgrade schedule? So that's my 2 cents.

DR. SILVERSTEIN: Thank you.

Hey, Linda, there's a question in the back or a statement in the back. Thank you.

MR. JOSEPHSON: Hi. Aaron Josephson again.

Something that was discussed at our table, a little bit off topic and so certainly not -- my comments now are not representative of the table, but something that we didn't really see discussed or didn't see an opportunity to bring up in another context over the day and a half that we're here is enforcement and this notion that we're here to kind of draw a line between servicing and remanufacturing for the benefit of patients. But it's meaningless or close to meaningless if the Agency doesn't kind of take the appropriate steps to ensure that entities performing the activities, whether they're servicing or remanufacturing, whether they're being done by a servicer or an original equipment manufacturer or you know, are appropriate, fall kind of into the appropriate bucket. And so there certainly was a lot of, a lot of viewpoints at our table about that. I think it's something the Agency has to consider the best way to make sure that folks are really following whatever the final policy ends up being.

DR. SILVERSTEIN: Thank you.

Okay, so I'm not seeing any other hands. Just one last opportunity.

MR. CHALIFOUX: Thanks. John Chalifoux from MERA - The Association for Sustainable Manufacturing.

I'm just curious, for those in the software space, if the Digital Millennium Copyright Act came up in any discussions or how it might apply, obviously, particularly for third parties that might need to flash software.

DR. SILVERSTEIN: Sorry, Rob, did you want to go ahead?

MR. KERWIN: Yes. In deference to my fellow member of the bar, I wanted to say that we also were disturbed that, from time to time, when service access keys are not provided, that there doesn't seem to be the mechanism that there once was to discuss with the FDA, which to our knowledge is the primary entity to regulate access to service keys

because, as you know, under the Federal Food, Drug, and Cosmetic Act, only the FDA can enforce the regulations. So there used to be a program where you could contact by phone -- I think it's Timothy Ulinowski (ph.) -- to sort of explain what your problem is and the FDA would intercede, but there are no consequences, to my knowledge, no penalties assessed when there's not cooperation on the service access key, and we're concerned that that's a right with possibly no remedy.

DR. SILVERSTEIN: Okay, thank you.

I wasn't sure if anyone at the software table wanted to answer the question that was asked. No, that's okay. I think we've run out of time for this session anyway, so we're going to pivot right into the next session, which is about guiding principles.

Okay. So now that we've concluded our session on access to information, I'd like to introduce our final topic for the day. So Laurel Burk earlier provided a summary of our guiding principles this morning, and now that we've walked through the flowchart and the complementary approach for software, and we discussed access to servicing information, labeling, and other considerations, we'd like to discuss the guiding principles identified in our white paper. So, again, I'd like to disclaim that the information in these slides is for discussion purposes only and does not represent draft or final guidance. It is not intended to propose or implement policy changes regarding servicing and remanufacturing or the applicable statutory and regulatory requirements for entities conducting these activities. So in our white paper we identified initial thoughts on guiding principles that we are considering in future draft guidance. These guiding principles are designed to help FDA and entities determine whether activities are servicing or remanufacturing, and we're seeking feedback on whether stakeholders agree with these guiding principles and whether any principles or considerations should be added or removed.

So I'm going to go through the guiding principles now.

And Number 1 is that servicing does not significantly change the safety or performance specifications of a device - Activities that significantly change the performance or safety specifications, or intended use of the device, are remanufacturing and are not servicing. Activities that are not intended to significantly change the performance or safety or specifications, or intended use of a device, however, should still be evaluated to determine whether the change significantly affects device performance and safety specifications, or intended use.

Number 2: Evaluate whether any changes to a device require a 510(k) - Regardless of whether changes made to a cleared device are servicing or remanufacturing, such changes should be considered pursuant to 21 C.F.R. 807.81(a)(3) and the concepts in the FDA guidances Deciding When to Submit a 510(k) for a Change to an Existing Device and Deciding When to Submit a 510(k) for a Software Change to an Existing Device.

Number 3: Assess component/part/material dimensional and performance specifications - Assessment of changes to dimensional and performance specifications can inform whether the activity performed is servicing or remanufacturing. Consequences of component/part/material changes can be evaluated by comparison to OEM component/part/material specifications and/or through testing. Deviations in component/part/material specifications from the OEM counterpart may result in significant changes to the legally marketed device's performance or safety specifications, or intended use, and may necessitate closer evaluation. When there are no deviations in component/part/material dimensional or performance specifications from the OEM counterpart, there would likely be no significant changes to the legally marketed device's performance and safety specifications, or intended use, in the absence of other types of changes.

Number 4: Employ a risk-based approach - FDA is considering recommending that

entities employ a risk-based approach, such as one that conforms to or is consistent with ISO 14971: Medical devices - Application of risk management to medical devices, when assessing whether an activity they perform is servicing or remanufacturing. A risk-based assessment, as referred to throughout this document, is based on the combination of multiple risk concepts that are important for managing the risks of medical devices. Risk estimation, risk acceptability, risk control, risk-benefit analysis, assessment of hazards and hazardous situations, and overall risk evaluation are all concepts that can be applied during servicing and remanufacturing activities. The concept of risk, as defined in ISO 14971, is the combination of the probability of occurrence of harm and the severity of that harm. Although the risk terminology used in the white paper is primarily derived from ISO 14971, we recognize that an individual entity's terminology may differ.

And for the purposes of this white paper, an activity performed on a device is likely remanufacturing when a risk-based assessment identifies any new risks or significantly increases known risks and thus significantly changes performance or safety specifications, or intended use, in comparison to the legally marketed device.

Adequately document decision-making - When deciding whether an activity is servicing or remanufacturing, FDA is considering recommending that the rationale for the determination be documented with sufficient detail to explain why the determination was made. Specifically, FDA is considering proposing that the documentation specify why the activities performed on the device do or do not significantly change the performance or safety specifications or intended use of the legally marketed device. Effective documentation can facilitate sound decision making and evaluation of adverse events and provide necessary information for an entity to justify their decision making in the event that an inspection is conducted by FDA or this information is otherwise requested.

I'm going to shift in a minute to join our panelists, and I'd like for those who were

invited to the panel to start making their way to the front of the room. But I'd like to start off just with a brief introduction with instructions for our panelists and participants in the room.

And so this session will be a semi-moderated panel discussion by invited stakeholders. If you were invited to be a panelist, please come to the table. We do have assigned seating.

And so the panel will be asked to provide brief summaries of their thoughts regarding the guiding principles indentified in this white paper. FDA also has targeted questions that we will ask of the panel.

And during this panel that will last 60 minutes, I'll offer the audience an opportunity to ask the panel a question or to make a brief comment during the session.

And just to go over the questions that FDA was requesting feedback for regarding the guiding principles, there are three questions:

1. Are there additional considerations that may help entities distinguish between servicing and remanufacturing activities?
2. What are acceptable methods of assessing component/part/material specifications during servicing or remanufacturing? And then
3. What are the pros and cons of the risk-based approach discussed in this white paper?

So for panelists' knowledge, you have to press the red button in order to talk.

And so, first, I'm going to start off on the far side of my right with introducing our panelists. So first we have Binseng Wang, who's representing the American College of Clinical Engineering; we have Wayne Moore, who is from Acertara Acoustic Laboratories; we have Rob Jensen from AAMI; Dave Anbari from Mobile Instrument Service and Repair; we have Pat Baird from Philips; and to my left, we have Rob Kerwin from IAMERS; Jeff

Lersch from Karl Storz; Scott Trevino from TriMedx; and Steve Niedelman from King and Spalding.

And so I'd like to welcome our panelists to discuss the guiding principles. We have broad representation from different stakeholders in the servicing and remanufacturing sphere, and so we spent the day already discussing the white paper through pressure testing and discussing software, and we also talked about access to information. And so now that we've traversed through most of the white paper, we'd like to discuss the guiding principles that were already discussed this morning that are really the philosophy surrounding the distinction between servicing and remanufacturing.

And so this session is semi-moderated. We held a pre-meeting during which we asked for two volunteers from the panel to help start our discussion, and I'll call on those folks first, and after that time, I'll open up the discussion to the rest of the panel.

And so Number 1 was are there additional considerations that may help entities distinguish between servicing and remanufacturing activities? And, Binseng, I'd like to start with you, if you're ready.

DR. WANG: Thank you, Dr. Silverstein, for the invitation. Again, my name is Binseng Wang representing the American College of Clinical Engineering.

The short answer to the question is no. However, my colleagues and I at the American College of Clinical Engineering are very concerned about overwhelming the front line staff of all kinds of service organizations, including the manufacturers as well as the FDA staff, with a number of very good but very complex tools. It would be almost like trying to kill cancer with simultaneous application of massive doses of chemotherapy, radiation therapy, gene therapy, etc., with the end result of curing the cancer but killing the patient. The reason we are concerned about this process is that, as you folks thought this morning, when you try to apply the five principles as well as the flowchart, it took quite a bit of time,

and the phone line people that we have out there, again, it doesn't matter whether it's from the manufacturers or a third party or hospital staff, are not typically trained to do this kind of analysis, and if they have to do this after every single service opportunity, we are really taking a huge risk. What's going to happen, most likely, is that they would either choose to cheat or they try to do this with some mistakes. You could say that the reason I say that is because I'm not a very smart person, which there might be a colleague here -- Wayne Moore would certainly agree and attest to that.

(Laughter.)

DR. WANG: However, I did make an effort to check this with a line person who works day in and day out in a major teaching hospital in the United States, and he confirmed that it's not a trivial task for him to do this kind of analysis every day on every piece of equipment that he services, and it doesn't matter whether it's repair or scheduled maintenance.

So I would like to propose that we try to give the front line people a simple and clear question to ask themselves after they service a piece of equipment, and the question is very simple. It's based on the first principle: Has the device performance or safety specifications or intended use been significantly changed? If the answer is no, then it was servicing, and you just document that and you'd be done with it. If it's not, then we have a whole lot more work to do. And being a very simple person, I would like all this to be a cardinal principle instead of five principles, etc. We just need one principle and train our people in the future to do that. And this has precedence. For example, in the imaging area, we have AIAT. Okay, the other types of devices, very often we have a power-on self-test that is applicated -- I mean used -- designed by the manufacturer and used by the users to determine whether a piece of equipment is safe to use when they first turn on that piece of equipment. So this kind of basic simple rules are easy to instruct, easy to be obeyed and

performed, and we all can then be fairly assured there's no additional safety performance issues that we need to worry about.

Now, coming back to the question, if the question of whether any significant changes happened is no, then okay. Now, if you did detect some type of significant changes, then you need to stop and consult your supervisor or somebody who has a little more knowledge, experience, to give you a little more appropriate answers should you proceed with this or not. This person then would be a person that's better trained, has a little more time to do this kind of analysis, and then we can have a reasonable answer. So, in essence, we really would like to recommend that we give people clear, simple questions, protocols, train them well, and require them to perform it, and that is what basically we need. Thank you.

DR. SILVERSTEIN: Okay, so now I'd like to go to Steve to the end of the table, other end.

MR. NIEDELMAN: Thanks, Josh, and thanks to FDA for pulling together this conference because I think it's a topical issue and it's been a difficult issue for the industry to tackle and the Agency to tackle for the last decade or more. I think a good part of it, I think the guiding principles that have been developed, the five of them are as good as you're going to get from a practical application perspective. From somebody who sees many of you, deals with many of you, you know, as a consultant -- I am from King and Spalding. I am not an attorney; I am their lead quality system and compliance consultant, and my experience is based upon my career at FDA. I think the practical application of these principles, if they're followed, would be great. What I'm seeing is all too often servicing becomes the umbrella for doing an awful lot of things. From devices that have been cleared with software that's locked out and approved for only one indication but it's capable of doing six or seven or eight other things that may be approved in foreign

countries, how do you handle the release of the next version? That software is already in your device. At the next service visit, unlock the next indication. How do you deal with that? Is that a service call, or is that a remanufacturing process?

I think the practical application of some of these things, loaners that come back that have been sent out to address, as a customer service, units that are in for service, when they come back, how are those handled? Are those handled as service units? Are they refurbished, or are they remanufactured and sold as new? We see all sorts of things that go along with this. I think somebody raised end-of-life issues earlier today. I think that's a consideration that needs to take place as well. When does servicing stop for end-of-life devices?

And I think, you know, is end of life really end of life or is it, yeah, we still have parts available so we'll keep servicing it? So, you know, again, it's the practical application. I think the trickiest part of this is going to be, and Josh and I briefly chatted about it, is the software side of it, and I think the -- if you follow the rubric that was developed for the flowchart, I think everybody -- there may be some fine-tuning that needs to take place, and it may need a little bit more definition around the term "significant," but I think software is the trickiest issue for industry, is how do you deal with that? It's not as clean cut as hardware. Many manufacturers, as we had this discussion, do make service manuals available, some refuse to make service manuals available, some will make service manuals available for a charge along with training, and that's important. I mean, just handing out a service manual might not be an appropriate approach for all industries. So in my opinion, I think the five guiding principles are very good. I think, sure, we can fine-tune here or there. It's all about the practical application and the industry's decision to follow them and follow their guidance.

DR. SILVERSTEIN: So I'd like to open it up for the rest of the panel. I'm not sure, let's

say, Scott, if you would like to chime in about these guiding principles.

MR. TREVINO: Thank you, Josh. Scott Trevino from TriMedx.

A number of good points here. I think what I'd like to share, one point of view here, I think the guiding principles are adequate with a number of things. I think one thing that I think is important to look at and understand is how do we measure the problem we're solving? Certainly, there's a reference in the report from FDA made to the data, and the data, I think, shows a few events out of the MAUDE database as well as the ECRI data, and I think it would be very important to establish a baseline for the problem we're solving utilizing data. I think that way we can address the problem we're solving through these guiding principles and determine whether or not those principles, when put into place in forthcoming guidance, are effective in solving that problem.

I think it's also a good exercise for us as we continue this discussion, which I applaud and I think it's a very good effort, to say do those guiding principles address the problem we're solving and how so? And where can we hone in and focus more appropriately? I would also say that with regard to these guiding principles -- and we've had this discussion this afternoon. It's imperative, if not absolutely required, that there's access to service materials, and I use that term in a generic sense to refer to all those, the tools, parts, training instruction, and so forth that's necessary and required to actually fulfill assessments of specifications. You can't assess specifications if you don't have the specifications, for instance. So I think that's quite important. So service materials as well as specifications for performance and safety. I would also say that there are a number of details, the devil is in the details as they say, with regard to how these are implemented, when and where. And I did mention earlier today, as part of the discussion this morning, that with regard to the flowchart, for instance, if something is already deemed as a design output for the service instruction from the OEM, I don't see how the flowchart and those

steps are necessary as that is already followed, all of these principles as well as all the other principles under the current regulation. I would see that as unnecessary and creating a burden without benefit, again, going back to my first point, which I think data, there is data, we can continue to drive for more data, and I think that's an important way to look at guidance in this area because, as one of my colleagues here mentioned earlier, this debate has been ongoing, not just for the past couple years, not even the last decade, but multiple decades, and I think that would be very important. Thank you.

DR. SILVERSTEIN: So I'd like to open it up to any member of the panel if they'd like to just comment on whether there were additional guiding principles that we think need to be addressed or any specific comments that you have on them.

MR. ANBARI: So David Anbari with Mobile Instrument Service and Repair. We're an independent surgical equipment maintenance and repair company.

Just to follow on Scott's comment briefly, I think one of the guiding principles really needs to continue what the FDA has done to date in this area, which is to make the process evidence based. Aside from just making sure that we have a way to measure have we impacted the problem, let's make sure we have a good dimension on what the problem is to begin with, and I think that really just is continuing the work that the Agency has done to date. I think in terms of the five principles that are proposed, they're all the right things. I think in some respects, the risk-based approach really ends up encompassing some of the other principles. The risk-based approach really -- if you're operating a good quality and risk management system, you're going to be appropriately documenting your decision making, you're going to be assessing the impact of any component that you're purchasing, having manufactured or custom building. But I think the risk-based approach is really one of the most critical elements of this because, for the flowchart to work, it has to be risk sensitized at every portion, every one of the decision points. In terms of additional

potential guiding principles, I think one that is fairly, I guess, implied in much of what we're talking about is the presence of a quality system. You know, whether it be an internationally recognized one, 13485 or, you know, certainly adherence with QSR, I think you've got to have a quality system in order to make sure that the output from servicing or remanufacturing activities is what is intended.

And then just to echo Scott's other point, I think, you know, whether it's access to servicing information or really promoting cooperation and engagement, I know that's a big part of why we're all here today and I know that's part of what, you know, what you guys have been trying to promote in general, but I think the more that that can be a guiding principle to lead us to the right answers for servicing and remanufacturing, I think that's key as well.

MR. KERWIN: So I think one of the general themes we're hearing is that this is a 40-year problem in terms of getting adequate documentation and the healthcare community needs to have choices. And one recent report I saw, we're talking about the last 9% of the market, and in order to really compete effectively and to offer choices for lower-cost healthcare, which ought to be a goal, we need access to that information, and maybe looking to what the VA offers might be a good goal as sort of a best of breed in terms of getting the information on their pre-procurement assessments. How the department gets that information might be a good first step in terms of making sure there's adequate information.

MR. LERSCH: Thanks, Josh. This is Jeff Lersch, Karl Storz, a manufacturer of endoscopes and other devices used for minimally invasive procedures. So we appreciate the leadership of the Agency continuing the discussion on this topic.

I personally found this conference today very insightful. I have an interesting group at Table 13, who we had some spirited discussions, but everybody was very professional

and tactful, which was nice, and I think it ended up, you know, I learned from them, which was important. Relative to the guiding principles, my takeaway from the discussions today and where things sit is the FDA has more insight than they had before the day started, in particular, regarding risk-based assessments. You know, from where I sat and from listening to the conversation, I think there was consensus that risk-based assessments across the board, servicers, manufacturers, made sense and the question is how can we incorporate those better into a flowchart or a decision tree, whatever decision is made towards that end? But those are my comments on the guiding principles.

DR. SILVERSTEIN: So Rob. Wayne.

MR. MOORE: Well, my understanding of the conference was that we're trying to draw a definitive line as best we can between what constitutes servicing and what constitutes remanufacturing. So a lot of things are being discussed up here, but getting back to that, and do the five principles shine any more light on that line of distinction, I'd be in agreement that the risk-based approach is the best way to start.

For a third-party service entity who, for example, wants to determine whether or not it's smart to get into a particular business and repair business, being able to understand what he or she will have to do in order to ensure they're doing servicing and not remanufacturing, to be clearly understood and evaluated. There were some people that said that there's a gray area between servicing and remanufacturing and maybe a Venn component where there's some gray, and how do you get the answers for that? Well, you get the answers from that by going to the FDA and asking if this constitutes remanufacturing or servicing, maybe through a Q-sub or a pre-submission, and get some definitive analysis on whether or not what you plan on doing to a finished medical device is, in fact, a repair or is a remanufacturing process. And in Guiding Principle Number 2, it talked about are there other resources available to make that distinction. There are. You

know, the Agency has one, you know, when to determine if a change in a medical device constitutes remanufacturing or triggers a new 510(k), but there are a lot of other documentations, from the safety documentations that are applicable to a particular medical device; from general, like IEC 60601-1 and others specific to a particular product like ISO 60601-2-37, which is specific to diagnostic ultrasound devices. Go to those, buy those documents, analyze them in context with what you plan on doing as part of a repair, and see if that actually is going to cross the line.

And "significant," speaking as an engineer now, "significant" has specific meaning within the context of safety, and "significant" means that you fall within the parameters that specification or standard calls out. If you go outside those, those are unexplained variances that need to be accounted for.

And there are other documents that you can go to. I would always counsel on doing patent research to make sure that something you're planning on doing is a repair; is it stepping over somebody's intellectual property, and that happens from time to time. So there are a lot of documents that are available. If anybody wants to contact me, I can give you a whole list of how to go out and how to determine if you're going to cross the line and what other documents you should look at in your risk-based analysis of whether or not you should go into that business.

MR. JENSEN: So in the interest of full disclosure, AAMI is responsible for 14971 and 13485, and I want to make sure that everybody knows I'm not exactly agnostic on the use of standards for these kinds of things. I was asked to say some more about the risk-based approach, and of course, in the documentation, it really talks about the intersection of severity of an event and the probability of that occurrence. I think, though, it's worth considering when you think about a Rubik's cube or think about a Rubik's puzzle that has five sides, this is really a multifactor risk situation, and these are only the ones that I've

been able to come up with so far, and I may be the least informed person in the room. So let me just say that if there are others, you should consider those as well.

There's the reason for the non-availability. What exactly happened? How did the device get to this point that makes risk at the point of care? There's the urgency of the need for speed. How quickly does this have to be repaired? There's a lot of reasons why speed may be necessary in the clinical environment, and all opportunities for servicing do not necessarily provide the same amount of speed. The device itself contains certain risks based on its class, whether it requires reprocessing after servicing, that sort of thing. So those are inherent. There's also the servicing information tools, etc., risk. Do the folks that have the opportunity to provide service have the items that they need to actually do it?

And I would just generally say, and I think it was relatively solid consensus today, that no matter who the servicer is, less information is more risk. So it's pretty obvious that at the end of the day, if there's somebody qualified and competent there, regardless of the source, that less information automatically equals more risk.

There's personnel risks. Are they OEM or are they non-OEM? Are they trained? Are they trained OEM or not trained OEM? Are they certified OEM or not? And do they have specific device experience or not? So those are just five things that we could consider as we look at employing a risk-based approach.

There are some other types of risks that kept cropping up today and in other discussions in the past. One is the cyber compromise. Now, that could be the device, but it could also be the intranet of things inside the clinical environment, or it could be the internet depending on the connections and the security devices from there. Privacy, the same way. It could be the device -- it could be a compromise there and also could be the intranet of things inside the hospital or the internet. One thing that came up as a repeated kind of theme is the whole idea of liability, and I know that I don't believe that the

regulation will necessarily solve who the eventual finger gets pointed at if something goes wrong, but it would be in our community's best interest to at least keep that in mind as we continue this positive conversation. Another one is business brand reputation. With the kinds of things that happen today on the internet, there's no one in this room, I think, that wants to have whoever they represent as a stakeholder appear and get shared on Facebook three million times before the end of the day. Nobody wants that.

The business model or market share, that comes up frequently, and I don't think the FDA is here to level any playing field, but there are models in business that emphasize the device sales, there's models that emphasize servicing, there's models that emphasize part sales, there's models that emphasize training and every combination of the above. And I think that one of the pieces of the Gordian knot here is to try to solve some of that or at least speak openly about what can be positive and what won't. I think if the community can solve some of this on its own with agreements, less will be solved in a regulatory or legislative manner.

Costs for all stakeholders are always big. And this sort of idea about some of the cons, there's this idea of there's no data yet for the baseline models. I think we learned as we went back and looked in the past about what research was out there and what wasn't and how certain we all could be in agreeing in it. So NEST, if it's developed, I saw the FDA's recent announcement on the 27th, I think NEST can help us understand that those risk-based evaluations are what we're doing in the trench is actually useful and getting to the right assessment of risk. Or are we seeing risk that's pulling one way or the other, down or up?

Another con is this takes time and it's not free in any company. The risk evaluation takes training; it takes knowledge; it takes repetition until it becomes part of the corporate culture of wherever the user is. So we just need to go into it, and I think we've heard that

over and over.

My favorite part about employing a risk-based approach is really that it forces the thinking necessary to drive yourself to what we all hope is a right decision. And I think that I told you I wasn't agnostic about this subject, but I think if we can continue along those lines with our eye on the whole canvas of risks for everyone, we may be able to reach a better understanding of how to do this better.

DR. SILVERSTEIN: So I think you just provided an excellent segue to our third question, which is -- I'm going to go to Pat now. And so, you know, what are the pros and cons of the risk-based approach discussed in this white paper? And we'd kind of like to -- you know, I think we've already received a lot of specific comments, but we'd also like to hear sort of a higher-level comment about the philosophy around it.

MR. BAIRD: Thank you. So folks that already know me in the room know that I have a passion for risk management. Folks that know me even better know that that passion comes because I get things wrong a lot, okay; I make a lot of mistakes. And so this is why I care about risk management because you predict those mistakes you're going to do.

I wanted to share a couple of stories with you. One is actually from several years ago when I was working on revising a risk management process, and we brought a clinician in to take and help us out with some of these processes and procedures, and she really didn't know, you know, some of the engineering concepts behind doing proper risk management, but she really got into it. She really, really liked it. And she liked it so much that she said, you know, if you really care about the outcome, you'll do risk management. Whether it's required, you know, by an agency or not, if you care about the outcome, you do risk management. And she meant this because when her daughter got married, she did a process failure modes and effective analysis on the marriage ceremony and the reception. I'm not kidding. And she wasn't an engineering geek; she was just a clinician that really was

into this. And it actually was good that she did because the DJ ended up not having the song for the first dance, and she had predicted that might happen, and so the first dance was streamed to Bluetooth from the best man's telephone and to a remote speaker. Okay. And so I understand why people are reluctant to invest some of the time into doing some of these processes, but I keep going back to what she taught me, which was if you care about the outcome, you'll do risk management.

And then the second story I wanted to share I was thinking on the flight here of, wow, remanufacturing and the definitions of remanufacturing. I wonder what was my first exposure to that, and I wonder if there was any risk involved with that. And so I actually had a flashback. About 30 years ago, okay, one of my best friends in college liked to restore old cars, and he had bought this 1930 Ford Model A, okay, that someone had already started modifying, and he wanted to finish working on it. This car had already been modified, someone had chopped out the doors, moved the chassis up, and you got into the car from the back. Okay, kind of strange, but that was a different kind of car.

He wanted to swap out the engine; he wanted to replace the old original engine with a Chevy 350 V8 4-bolt. Folks that know what that engine is, you know, I'm hoping you're nodding your heads of, ooh, that provides some extra horsepower, right? Oh, by the way, it's going to be more reliable than the original engine, given the age of that original engine. It's going to be easier to find parts, and it's going to be cheaper. So to me, as I'm looking at, you know, the description of remanufacturing, I'm like wow, there's extra features, there's extra performance specs, it ends up being cheaper to maintain in the long run, this is an example of remanufacturing. I remember helping him put this in, and I mentioned before that the doors got chopped out. Okay, so the wheelbase of this car was 88 inches long, so about 7 feet, so it was really kind of a short kind of car. The driveshaft itself was only 12 inches, okay, so this is very short. I'm bringing all of this up because I was there as he was

backing it out of the driveway and into the alley and going to take it for the first spin ever. He hit the accelerator pedal; the front end flips up in the air, okay. The wheelbase is so short and it has so much power, the thing, unless you were very gentle with the accelerator, always kept lifting off the ground. He sometimes almost flipped over the car.

So added new features improved the performance and improved the spec, introduced new risks. Okay, so tying this all the way back to that. So, overall, totally in support of risk management, particularly when you're changing things, needing to look for things you didn't think about before. Absolutely in support of that.

Some of the challenges that I see, and it was alluded to a couple times before, was I think we need some education. I think that, to an outsider, someone who isn't a risk management geek like me, hazard versus hazardous situation versus harm, those can be scary words. They sound like a lot of work. They're actually simple concepts, and the way that we write things in the standards and regulations can be off-putting if you're not intimately familiar with these things.

So I think one thing that we can do, and I'll talk a little more about this at collaborative tomorrow, is I think some training material, I think some plain English kind of explanations, right, and some of these stories such as weddings and 1930 Ford A's help ease and remove some of those fears, having some of those educational opportunities. I had mentioned before when we were talking about the infusion pump door and saying that I had a concern that the example that was in here suggested that perhaps you just test it for accuracy, and I was worried that they only tested for accuracy, say, at a slow flow rate at room temperature. But some of the testing, some of the verification activities aren't just the normal use case. We need to, you know, test it, and does this thing still perform at high temperature, low temperature, etc. So not just a concern. A way that I've seen risk management fail in the past has been that people just did one simple test, "Look, it passed;

there, I'm done, we did a great job," and not actually thinking through.

And then the final thing, and it's sort of related to that, folks that travel through airports, you might have heard -- I follow some travel bloggers, but sometimes they have a reference to the security being provided by TSA, and they don't have a lot of confidence that TSA is actually keeping us safe. They call it the security theater, right, where it's not real; it just has, you know, the dressings and going through the motions but it's not real. One thing that I always want to caution about when talking about risk management is making sure that it isn't just a check box, that people aren't implementing just risk management theater. "There, look, I did a test; it passed, we're done." Actually showing that people took a thoughtful approach and doing something meaningful, something value-added, I'm always on the lookout for that. I think that's it.

DR. SILVERSTEIN: Thank you.

So I'm not sure if Dave or Rob would like to sort of take us through your own sort of like risk management philosophy. I don't know, Dave, if you'd like to start. You know, Pat just expanded upon, you know, what happens in his practice. and so I'm just curious.

MR. ANBARI: So the model that we use for risk management at our company is the absolute classic example of what, you know, risk management is, 14971, with a probability of occurrence and a severity of harm perspective matrix. And we actually use three rating scales on each of those: a low, a medium, and a high; and a low, a medium, and a high, and then the action that's guided through that takes us through our corrective or preventative action process or the process specifically that we go through based on whatever the event is. You know, I think, historically, our perspective has been there had to be an event, there had to be a failure, there had to be something bad that happened, and I think what our quality system has evolved to in the past 5 years has been, no, we're really being proactive with it and trying to use it to assess everything from -- we use our risk model to assess

everything from our parts suppliers, our internal work processes, our work environment. I mean, we have literally wrapped our entire quality system around risk management as the principle for how we make those decisions.

And it literally guides us through all of our management review process; it guides us through -- you know, down at the individual technician level if there's -- you know, we've kind of adopted the mass transit philosophy of if you see something, say something, and if something seems -- even if it's already been approved as in spec on receipt and in spec when it's been transferred to the point of application, if it doesn't seem right, it's your job to say something. Now, we have other quality systems in process to be able to detect those errors downstream, but we think it's more important to detect them upstream as quickly as we can for the obvious reasons of our own internal efficiency and things along those lines.

But, realistically, our -- you know, when I look at the flowchart contained in the white paper, I instantly go to the risk wrapper that sits around it. And when we talk about terms like, you know -- I mean, I'll go out on a limb here and say, you know, the FDA's done a very good job of teaching everybody in this room that specifics matter, that getting clear, concise definitions for things is critical. I guess I'll go out on a limb here and say I don't think we're going to ever get a definition of what "significant" is across the wide range of devices and services and everything that goes on among the companies and businesses represented in this room. I think what "significant" is defined as is what your entire risk management program is intended to do. You know, until as an industry we recognize that risk management is inherent to that quality system and that we use the principles of risk management to determine significance at the individual repair level, at the parts sourcing level, at the way we train people, at our facility level, at how we transport product, until we look at it that way, I think, you know, "significant" is going to be elusive for us.

DR. SILVERSTEIN: And so, Steve, I wonder, you know, you interact with a lot of

clients, and I wonder, for those who are kind of on the border of whether they think they might be remanufacturing or if they're still in servicing, you know, what role does risk management play in that?

MR. NIEDELMAN: So there are many firms that do risk management very well, and they're very objective and they take a very agnostic approach to it, and it is what it is, and they really thoroughly go through it. Other firms, based upon my experience, that harm is impossible, it's so rare, it's so infrequent, there's no way we're going to build or consider that. There's a tendency to downplay the risks that are associated with risk -- following 14971 and the risks associated with that have been identified.

And so, as a result of that, they sort of start shortcutting, and they start cutting corners here and there, and before you know it, they don't come up with the risk management that they should be coming up with. They should have a harms list. They should be up front about it in the design of their device, not after the fact but in the design of the device; risk management plays an active role in determining what design characteristics you need to build into your device.

But often the case -- what I have been seeing is firms don't know how to do it well, and some firms, you know, I applaud everybody that's in this room that you found it important enough to come to this conference, but there are many others that don't place that same level of importance on it. And this is, you know, to Pat's point, training, getting people to understand it, getting it to a grassroots approach to get people to be able to embrace. There are risks. I mean, we're in a heavily regulated industry, and healthcare is dependent on it. So my experience is there are many, many, many, many firms in the industry that do it extremely well. The small amount of top firms, sometimes they need to have some handholding and they need some assistance. And some of those devices that they're manufacturing are just as critical as the large firms. So, you know, I guess it

depends where you sit in the industry and your approach to it, your level of education and sophistication.

MR. JENSEN: So just to piggyback for a second off what Steven said. So most of my risk management was originally learned in the Marine Corps as a logistician, and so the culture around this risk management becomes, you know, quite important. The consequences of failing to manage risk management or to do risk management are pretty severe. But that cultural element, kind of what Steven was alluding to, is extremely important, and that culture will trump your strategy every time if you're not careful.

The other thing I wanted to say just as -- this is not necessarily with my AAMI hat on, but just my engineering hat on. A lot of other sectors are really out ahead of us in terms of the use of AI on large-scale data, the aviation community, the financial community, etc., and the "see something, say something," like David pointed out, that's a great way to do it now, but I would open yourself up to the possibility that we may never see it at all and we may need computers to dig through some of that and find some things that we need to take action on.

DR. WANG: Thank you. First, I want to preface by saying that I'm not trying to downplay the importance of risk assessment, but also we need to be aware that it is not a perfect tool, as mentioned before. Not everyone knows how to do it, and it requires a lot of training, time, etc., etc. Specifically, I'm referring to the concept of risk that a lot of people unfortunately are still mixing the severity of a risk with the risk. As defined by 14971, risk is a combination of probability and severity. The problem is that the probability is often not available as hard data. The majority of times it is a best guess at best, if not simply just an off-the-top-of-my-head type of guess. The real data only comes out after the device is on the market for some time, and through the postmarket surveillance you get actual data, and by that time you should actually perform a reassessment of your risk and etc. I have

seldomly seen anyone doing that, and this is a major concern that I have.

Another one is something that we also tend to forget is that something that is not in the 14971 at all is what I call scope. It's very different when you analyze a single piece of infusion pump that you fix because of the door problem, etc. Okay, you may have made a mistake, and maybe you made a mistake another 10 times, 50 times, or maybe even 100 times. However, when you're talking about software that is built into a device that has significant problems, that problem propagates to a few million pieces of infusion pumps out there. So the scope is very different. You cannot just think, oh, I did my risk assessment and therefore I'm okay. No, think about the repercussion out there. Okay, this scope is not considered currently in the standards, and it's completely ignored, intentionally or not, by most people.

To rest my case, I don't think risk assessment is an end all, be all solution. It's the number of recalls that we have seen in the last 15 years on infusion pumps, the so-called smart pumps. How many recalls have we seen? In theory, all of those companies did their risk assessment; they all followed 13485 or 9001 or C.F.R. 820, etc. Why do we have so many recalls? So that proves, in my mind, that risk assessment regulation is not enough.

At the end of the day, what was said by Rob is that the culture is the important thing. In our reality, for the people who are in the front line, the reality is that they care for the patient; they care about the end result, the impact on the patient. That is the driver that we really need to get. The rest are only tools. Tools are only good if they are used by the right people at the right time with the right training. Otherwise, we could give them all the tools we want, but if they are not really able to use it properly or they are overwhelmed by the overwhelming number of tools, complexity of the tools, then we're still not achieving anything.

Thank you.

DR. SILVERSTEIN: Great, thank you.

Okay, so I'd like to pivot a little bit and talk about what are acceptable methods of assessing component/part/material specifications during servicing or remanufacturing, and I'd like to start with Wayne.

MR. MOORE: Are they still out there? I see these bright lights and dead relatives seated back --

UNIDENTIFIED SPEAKER: They all left.

MR. MOORE: They all left, okay. So could you ask that again?

DR. SILVERSTEIN: Absolutely. So the question is, and this is coming from Guiding Principle 3, what are acceptable methods of assessing component/part/material specifications during servicing or remanufacturing?

MR. MOORE: Yeah, it really is going to, once again, be device specific, and what you're actually looking at changing, I think, is really key in this whole area. So analyzing, again, going back to the guidance documents for the initial entry of a product into the 510(k) process and see what its intended use is, what materials it's going to be using, what sort of standards that it's held accountable to, biocompatibility and other areas, and then determining from there what you're going to need to do in order to make your own part, fabricate your own part or do a repair using materials or components that may not have come from the original equipment manufacturer. There are a lot of techniques in reverse engineering. Again, I'm talking about third-party service, not somebody in a hospital. And I agree with you. I was in the Marine Corps as well, and if I'm injured in a foxhole, I don't need the corpsman doing all kinds of in-depth risk analysis. Put the tourniquet on and get me out of here. But I'm talking about third-party service, people who are specifically and consciously making a decision to embark on a process that's going to affect multiple instruments as they go through the repair process. So it's extremely important to make

sure that, again, all of the issues related to getting a part certified are carried out, all the materials that are being used are appropriate, and not just the materials. I'll bring up a point.

Somebody or a couple people had mentioned medical-grade epoxy. Well, that doesn't tell me anything about how it's going to behave once it's adhered to something and once it undergoes a process that may or may not be appropriate for medical-grade epoxy and render it useless or inert or even hazardous. So you need to understand what you're doing, and this comes about through rigorous engineering analysis and, again, going back through the risk assessment process and having a good, well-defined risk assessment process and qualifying those processes.

DR. SILVERSTEIN: Great, thank you.

And so, Jeff, we also asked you to consider this question as well, which is what are acceptable methods of assessing component/part/material specifications during servicing or remanufacturing? And so I was just kind of wondering, I mean, I think you're coming from the endoscope realm, and I think that some of the parts are not always exposed, and so, you know, can you just kind of walk us through your high-level philosophy of how Karl Storz does that during their servicing?

MR. LERSCH: Let me just clarify to make sure I know what your question is, Josh. So you're asking me to provide you Karl Storz's approach towards selecting components for use within manufacturing and servicing of endoscopes?

DR. SILVERSTEIN: So, yeah, setting aside trade secrets, confidential information, I'm just talking sort of like a high-level philosophy of, you know, how you own -- you do your own assessments in house.

MR. LERSCH: Yes. I must confess, I'm not a manufacturing expert, but I am pretty familiar with the processes that go on at Karl Storz. So some of the members of the FDA

have been invited to visit our manufacturing facility in Massachusetts, so they've actually witnessed it themselves. You know, Karl Storz, for those who don't know, is a family owned, privately held company. Very, very passionate. I think the culture piece that was mentioned is readily apparent in -- the same people that manufacture new scopes also do the remanufacturing of scopes that come in for repair, so the same exact people.

The other thing that culturally, I think, is very interesting for people to see is all the people in the manufacturing process contribute to process improvement on a daily basis, and they have a wall of ideas, literally, that people just run and put stickers up, I had this quick idea on how to improve something, and it really is very, very beneficial. All the scopes go through, you know, the same exact quality management system process and validation process. All the components that are selected for use obviously adhere to all the guidelines that are in place. So it's pretty particular on what is done relative to manufacturing and/or remanufacturing of scopes that are sent back to Karl Storz by customers.

So, you know, like others, we validate everything we do from a component standpoint. You know, with endoscopes, it's very, very important to understand the properties of, for example, adhesives and how they're going to not only perform their function but how are they going to hold up through reprocessing and the different sterilization modalities that are utilized. Relative to, you know, optics, that is an area of expertise we have had for many, many years and continue to have. So we make, for example, our own glass for our fiber optic scopes, and we do that because we're pretty particular about the image, and we want that to be as good as can possibly be, and so we do things that others may not do. That doesn't make us better or worse; that's just how we operate. So I don't know if I answered your question or not, but --

DR. SILVERSTEIN: You did very eloquently.

And so, Scott, Rob, I'd just kind of like to get your impression. I mean, how is your

process the same or different from what Jeff just discussed when you're assessing component/part/materials?

MR. TREVINO: Sure. So, first off, what I would say is when we source parts, we have supplier quality prefs that's under our QMS, so it's a risk-based approach, and I know this isn't the risk question, but I think that's intrinsic to what we do and how we approach, you know, assessing components. I think, you know, maybe it's redundant or too simple to point out, but I'll go back again. I mean, the easiest is when you're sourcing parts from an already verified and validated source. From the OEM, those are already approved parts. And so those -- you know, it's sort of defined right in the white paper, which I would agree with and I'll go back to sort of the point before. In order to evaluate, you need to do a comparison, right, and ideally you have those specifications to compare to or what I just referred to as sourcing from a validated source essentially.

In the absence of that, there's other methods and approaches that you can take applying the risk methodology to determine, you know, those components that you source, do they significantly impact or create a new risk and, you know, by what method have you come to that determination. You know, one thing I would also point out here is critical to safety or, you know, parts that are -- not every part is equal, and I think that's part of how you assess risk as well, whether you're manufacturing a device or servicing it, and so, you know, not all parts are equal, and it's part of that risk methodology, and I say that's intrinsic in how we assess, you know, what we're doing and how we approach that. And I guess I'd hand it over to Rob to see if he wanted to answer as well.

DR. SILVERSTEIN: I'm going to give Rob a second to respond in a second, but if anyone would like to provide a comment, they're welcome to walk up to the microphones while Rob is talking, and then we're happy to take public comment, or you can also ask a question of the panel. So with that --

MR. KERWIN: Well, thank you very much. And we first want to thank the FDA for both this conference and for participating with us. We had a couple of our members in the experiential learning program, so FDA got to experience, first hand, the validation processes or at least get to know how that's being performed. We have as a condition of membership that our members agree to best practices, which includes inventory traceability issues. To address what's conforming and what's nonconforming kind of can be summed up to know what you must do, and do what you say you were going to do, and document what you did. And we think that while this is a continuing project of our best practices committee, we're very pleased to see the internal support for this and the number of members who are ISO qualified.

DR. SILVERSTEIN: You can leave it -- don't turn the microphone off.

UNIDENTIFIED SPEAKER: I'm just curious about the risk analysis part and the manufacturing and the certification parts. I guess I'm curious why the -- part of the risk analysis isn't brought up on root causes and how root cause of failures is reported back to the manufacturers. To me, any reoccurring failure should be reported back to the manufacturer somehow and a root cause analysis be done on what actually causes the failure. And I heard about recalls and so forth from some people, that they have products returning from recalls. I think a lot of that can be taken care of with appropriate root cause analysis of failures.

DR. SILVERSTEIN: Binseng, please.

DR. WANG: I'm going to answer this question based on my personal experience, so it has nothing to do with the American College of Clinical Engineering. I worked for two major companies, each one of them for over a decade. The first one was a major equipment rental company in the United States that had at that time about 100,000 pieces of equipment, mostly life-supporting ventilators, for example. The second company I

worked for was an independent service organization that had about 1.2 million pieces of equipment in the United States scattered in many hundreds of hospitals. And in both locations, a matter of fact, just never, ever ask us for service records. Actually, I offered them, and one of them came, when I was in the first job, looked at the records, and said thank you but no thank you, we don't want to look at them. The reason is very simple. By FDA regulation 820, they would have to review every single service report to determine whether it's a reportable incident or not. They realized very quickly that this would eat a huge number of hours of their labor, regulatory team. And so, for them, ignorance is bliss.

Thank you.

DR. SILVERSTEIN: Would anyone else on the panel like to respond also?

MR. TREVINO: I'll respond. I think this is an interesting point, and I referenced data earlier on, and there are a number of sources of data. On behalf of our customers, our customers do report events that occur, and you know, that data, as it's reported, the requirement is that the OEMs do root cause analysis of those causes. That's there today, and it does exist, and in fact, that's the data sources cited. And I think, in the report in May, I think there were over two million records assessed across multiple databases, not just the reporting database to the FDA, and those are the numbers that I referenced. And I don't want to be too precise here, but I think if you go and look at that data, that it's pretty clear if the, you know, root cause is done. I think of the 2.2 million records, there were about 100 or so that were identified as such, and I think it's well known, if you follow recalls and industry as well, what the -- you know, we have a record number of devices that have been recalled, I believe, this year, at least as of a quarter or so ago. Number one cause is software, you know, followed by design controls, manufacturing, and you combine those together, and I think you get the vast majority of root causes that are driving safety issues. I think servicing and remanufacturing, the delineation is important. But, again, I think if we

can get data which does exist today, I think we, you know, should grab that and see where we can get better, and I think that's one of the directives that we got to look at for collaborative community, which I know is a discussion for tomorrow.

DR. SILVERSTEIN: Okay, our next question or comment.

MR. BULGER: Hi. Yeah, this is Paul Bulger with Boston Scientific.

FDA currently expects OEMs to perform risk management of our servicing operations, and so it's encouraging to see, in the white paper, that this would be considered to be an activity for all servicers. My question really gets to the complexity of risk management where you have design FMEA and you have process FMEA, you have usability engineers, you have clinical evaluation, these are cross-functional teams that do this at an OEM, and I'm just wondering how -- the question's really for the FDA about how they would envision this information would be shared amongst the different parties that are servicing devices.

DR. SILVERSTEIN: Yeah, so --

(Off microphone comment.)

DR. SILVERSTEIN: So I'm on a separate part of the panel intentionally, so I'm just a moderator, and so I can't really speak to that, but --

(Off microphone comment.)

DR. SILVERSTEIN: Yeah. How about we're going to have Dave start to answer that question and then we go to Steve after that.

MR. ANBARI: Probably less of an answer to a question and more of a comment on a comment, I guess. You know, because we repair literally millions of surgical devices over the course of a year, we do accumulate a fairly robust dataset, and the other members of the trade association that I'm a part of, the Association for Medical Device Servicing Organizations, we're working on an initiative now where we want to try to start to share

that data across the multiple companies. We've historically not had a great -- we've had very little success in getting manufacturers to have interest in that data. I'm not entirely sure I know why. I think Binseng's comment is certainly one potential answer, and I'm sure there's others as well.

But regardless of the reason, we believe that the amount of data that we collect, particularly on more advanced devices, endoscopes, video equipment, fiber optic light cables, there's an enormous amount of information that we collect about root cause, about what components are failing, and about what we believe to be the reason for those failures. So we want to try and aggregate that data to try and start using it not only to inform research and development for replacement components, but hopefully because we'll reach a critical mass where from a manufacturer's perspective it's going to be information they're going to want and we're more than happy to share it.

And, frankly, from a public health perspective, you know, no sort of getting on a high horse or a soapbox or pointing fingers in one direction or the other, the bottom line is if that information is there and it can help improve the longevity, the efficacy, and the safety of a device, even if it's a 1-in-10 shot in a manufacturer's eyes, or 1 in 100, it's free data, it's available, we want to share it. It's hard to -- we want to make it available. You know, from that perspective, we've got it and we want to share.

MR. NIEDELMAN: So to respond to your question, within your firm, service records and service information should be evaluated both on the complaint side as well as feeders back to research and development to see how they can improve, through risk management, next-generation devices. Is there a need? Did you evaluate this correctly from the get-go? Did you do the initial risk assessment? Is it still accurate? These are all feeders that can be used on a continuous basis to see if you need to update your risk files. Do you have new harms you never even considered? Is it occurring at a rate that you never envisioned, or is

it much slower than you ever envisioned? It could work both ways.

But in any event, it's a feeder of information that should be fed not only on the complaint side and should be tracked as complaints, unless they're preventive maintenance-type service items, but they should be fed back into R&D to see whether or not you're meeting your goals. Is there an issue that needs to be addressed and you take a field action? No, it's fine, but for next gen, we need to consider these factors. So it's a constant and it's a fluid process that's important to make sure that it's tracked within your organization.

DR. SILVERSTEIN: Great, thank you.

Scot, did you want to make a comment?

MR. MACKEIL: Yes, sir. So I'm going to, you know, circle back to Pat, you know, talking about risk management and the other panelists who speak about the importance of risk, and we're going to tie that to the quality and extent and effectiveness of service information that's provided to servicers, and then we'll ask for a couple comments.

So when you enter a service call and you're presented with something that's broken, by the M.D., you know, the first thing that you have to do is you have to start making a series of risk assessments based on information that you have about the device which the M.D. is making the report to you. So the more extensive and robust service information that you've had access to, you've been able to read, you've been able to study -- for example, you know, a little skinny manual that's called the operator's and service manual that has little more than the instructions for use in it as opposed to a nice thick tome that you've read and it describes theory of operation, has exploded diagrams, comprehensive performance verification procedures. When you have that information and you had it going into that situation, you can make a much better determination of whether can I solve this now or do I have to tell the physician, well, we have to do something else, we have to get

you a replacement piece of equipment or proceed in another way. So information is tied to building a robust matrix to solve those and answer those risk questions.

So developing context is one thing. Having that information is another thing. Then you add your professional skills and ability, and then the important thing in that information matrix is once you've taken the action that your diagnosis has indicated, you can then test that device to a robust set of specifications and then in turn either make a decision again, well, this needs to go back for more work, or I can return it to the clinician, you know, in good conscience knowing that I tested it, accordingly mitigated any risks that lived in my mind, and explained the outcome to the physician, or again, you have to go back and say, I'm sorry, Doctor, but we have to bring in a replacement piece of equipment. You know, in my world, that's the value of having really comprehensive, effective, you know, complete information about a device versus not having that information. And I was wondering if our panelists can talk about that.

DR. SILVERSTEIN: So we actually are running short of time, and we have one other commenter. So I think this is going to be the last comment that we take. I'll briefly summarize our panel, and then I promise you that I'll also briefly adjourn us as well.

MR. MASTERS: I'll just go ahead and speak loudly. My name is Martin Masters, and I'm with Boston Scientific.

And one of the ongoing issues that I have in my mind is when you say no significant change in the safety or performance, but I can envision things that I could do by putting in a new power supply that's significantly safer, that I would make the safety significantly better but without changing the performance at all. It's still a 24 V power supply, 3 A, but now it's got much more creepage, much more clearance; it's safer, but I've got to tell FDA -- and this has got to be something that I've got to validate, which doesn't make any sense because it doesn't affect the performance of the final machine.

Another one might be if there's a one-in-a-million chance of this thing causing just a minor harm, really just a delay of procedure, it's no big deal. But if I make this slight change in components, it reduces my cost a ton and makes it two per million, which is still not significant but it's a 50% increase. So I'm saying there's danger in saying no significant change without being maybe significant degradation or an unacceptably significant change in safety or performance. See what I'm getting at?

DR. SILVERSTEIN: Thank you.

Okay, so I'd like to just briefly summarize what we heard, at least from the panel. And we appreciate the public comments as well.

And so in terms of just additional considerations that may help entities distinguish between servicing and remanufacturing, I think the panel's feedback was that these principles are generally okay, but I think we just need to make sure that we're still trying to address the problem that we're trying to solve here.

Number two, in terms of assessing component/part/material specifications, I heard that a process to do this assessment is extremely important and should be scalable depending on the specific component, part, or material.

Number three, in terms of the pros and cons of a risk-based approach, that risk management is extremely important with the right training and culture inside of the organization.

And so I'm going to ask the panel to hopefully bear with me while I briefly adjourn us because I won't make it over to the podium. We just wanted to thank you all for joining us for Day 1. We recognize that these table exercises were extremely interactive and in mixed groups, and really what we saw, which was very encouraging leading into Day 2, was all of the collaborative efforts that we saw between all of the stakeholders involved in this issue, and we look forward to discussing opportunities for collaboration tomorrow morning at

8:00 a.m. in this room. So thank you very much for coming, and this adjourns today's meeting. Thank you.

(Applause.)

(Whereupon, at 4:47 p.m., the meeting was continued, to resume the following day, Tuesday, December 11, 2018, at 8:00 a.m.)

C E R T I F I C A T E

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

PUBLIC WORKSHOP - MEDICAL DEVICE SERVICING AND REMANUFACTURING ACTIVITIES

December 10, 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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