FOOD AND DRUG ADMINISTRATION

WORKSHOP ON REFURBISHING, RECONDITIONING, REBUILDING, REMARKETING, REMANUFACTURING, AND SERVICING OF MEDICAL DEVICES

Friday, October 28, 2016

8:16 a.m.

FDA White Oak Campus

10903 New Hampshire Avenue

Building 31, Room 1503 B & C

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Jim Goldner	Alex Robinson
Thomas Green	Astin Ross
Stephen Grimes	Jeff Semone
Dennis Hahn	Greg Sharp
Heidi Horn	Patricia Shrader

A P P E A R A N C E S (Continued)

Jim Spearman
Stephen Spiegelberg
Richard Springer
Robert Steldt
Brian Szeremeta
Salvatore Tatta
Tori Wagman
Peter Weems
Nicole Williams
Diane Wurzburger
Benjamin Zegarelli

A G E N D A

P R O C E E D I N G S

DR. BITTLEMAN: Please take your seat. We're going to get started.

(Brief pause). So welcome to Day 2 of the Workshop for Rebuilding, Reconditioning, Remarketing, Remanufacturing, and Servicing of Medical Devices.

So we have the overflow -- overflow rooms are still open if you would like to use them. We also have luggage holding in the back if you -- if you have luggage here.

We also encourage you again to preorder lunch. We tried to get Sodexo to open up a little earlier today and it looks like that worked so yay.

The working definitions that we discussed yesterday they will still remain in effect till the end of the day. And, as a reminder, the FDA has put together these definitions of the common R words which can be seen on the monitors on the wall in the back and the handouts outside to avoid confusion during the workshop. These are in no way final and they're just for -- to avoid confusion today.

If any of the speakers would like to use any

different definitions than what we have set out, just make sure you explain that clearly during your talks.

Yesterday we heard from a multiple of stakeholders and discussed benefits and risks associated with activities in this industry. Some of the major themes that were discussed yesterday and Captain Sean Boyd talked about last night is safety and health for patients is the number one priority. And that's really why we're all here today.

We also want to make sure that the transparency and visibility for FDA and all of the stakeholders really shined through. We really want to exchange information as much as possible. And in saying that, gathering data and information to really understand the scope of this issue is really important.

We also heard yesterday that quality system can be -- could be applied to not only OEMs, but other -- other parts of other stakeholders and it might be an idea to look at that for implementation.

But we also want to say that there's no -- we -- the FDA, themselves, have no preconceived

notions of regulatory for -- for multiple stakeholders. Really today and yesterday is designed to gather that information and try to make an educated decision onto what, if any, next steps are coming to light.

So I just want to also thank the -- everyone on the webcast. We have received all of your comments. The comments that you -- that you go -- e-mailed to the third-party servicer's mailbox.

The comments will be added to the transcription and your questions will be asked during the appropriate panels.

So this morning we have two more panel discussions. The first -- first being discussing the characteristics of good refurbishers, reconditioners, rebuilders, remanufacturers, and servicers. And Panel 3 will discuss challenges of stakeholders that stakeholders face when performing these activities.

The form of the panels will be the same as yesterday afternoon. Each stakeholder group will present their viewpoints regarding the topic of the panel and the floor will open to questions from the

audience and in person and online.

So one thing we do want to change slightly from yesterday, when you -- when we are doing the panel discussions we're going to try to stay on topic of the panel. And if you have comments, this afternoon we have the stakeholder -- the presentations by participants. We'd like to -- you to hold your comments till then. But we would like to have a great discussion about the specific topic for the panels.

I just want to reiterate that our number one priority is safety and that's really what we're focused on here today. So I'm going to hand it over to Diane Mitchell who will moderate the next session.

CAPT. MITCHELL: Good morning and thank you for being here on Day 2. I'm going to ask the panelists to please come to the table.

And the structure this morning will be just a little bit different than what is on the agenda. So we'll begin now and then the panelists will present for an hour and then there'll be 30 minutes of questions -- open for questions, and then there'll be a break, and then we'll move onto the next panel.

So, again, to repeat this panel now is discussing the characteristics of good refurbishing, reconditioning, rebuilding, remarketing, remanufacturing, and servicing entities.

And before we begin I'm going to introduce the panel members not necessarily in the order that they are sitting at the table.

So yesterday I was sitting in the back and it was just a little teeny bit difficult to see the people who are sitting up front so when I do say your name if you would just be so polite as to stand up for just a second and then sit back down again so everybody can see you. I think that would be great. Thank you.

So I'm going to begin with Dennis Hahn. Dennis Hahn is the Director of Regulatory Policy and Innovation at Johnson & Johnson Medical Devices. He is responsible for ensuring global regulatory policies are appropriately interpreted, effectively communicated, and efficiently implemented in the Ethicon surgical device businesses.

He has worked in the medical device industry

for over 30 years. The past 23 in regulatory affairs.

Next, Richard Eliason. Richard joined Crothall Healthcare in March of 2011. He began his clinical engineering career over 25 years ago working in a hospital environment and has held various technical, supervisory, and managerial roles with in-house OEM and ISO clinical engineering organizations.

He is the former chair of the International Certification Commission for Clinical Engineering and Biomedical Technology, the past chair of the United States Certification Commission, and a past chair of the United States BMET Board of Examiners.

Jason Dominitz is the National Program Director for Gastroenterology in the Veteran’s Health Administration. He is also the gastroenterology section chief at the VA Puget Sound Healthcare System and a professor in the Department of Medicine at the University of Washington.

Jason completed his residency in gastroenterology fellowship at Duke University and was a fellow in health services research at the Durham Virginia. And received his master’s degree in

clinical research from Duke concurrent with his fellowship.

Mark Leahey is the President and CEO for the Medical Device Manufacturer's Association, MDMA, a national trade association representing hundreds of research-driven medical technology companies.

Mr. Leahey is a member of the Massachusetts Bar.

Dennis Durmis serves as the Head of Commercial Operations Americas for Bayer Pharmaceuticals, Radiology Business, since 2013. Dennis has been at Bayer for 16 years. Prior to Bayer Dennis held various positions at CONSOL Energy, a coal company.

Dennis holds a BS in electrical engineering from the University of Pittsburgh and a master's in business administration from the Tepper School of Business Carnegie Mellon University.

David Anbari. David is the Vice President and General Manager for National Sales and Operations at Mobile Instrument Service and Repair, Incorporated. The nation's largest company focused exclusively on

surgical equipment repair and maintenance services for virtually all OEMs.

David began his career with the Federal Reserve Bank and worked as a consultant in finance and supply chain operations for a variety of firms before founding a software company that served billion dollar medical device suppliers in the U.S. Department of Health and Human Services.

Barbara Maguire is -- as Vice President of Quality and Geisinger Clinical Engineering, Barbara oversees all aspects of the clinical engineering line of business quality, compliance, CMMS, vendor partnerships, and negotiations as well as central dispatch functions and oversees the delivery of clinical engineering services to ISS Solutions parent organization, Geisinger House Systems.

Ms. Maguire has over 25 years of experience in biomedical engineering.

Salvatore Tatta is a Certified Clinical Engineer with over 24 years of hands-on experience in a complex tertiary care Veteran’s Administration Medical Center comprising 300 and safety -- -78 beds

research and community living based out-patient centers.

He received his BS in engineering from Manhattan College.

Greg Sharp, VP and GM of IMS Steris Corporation. IMS is an independent-source organization focusing on repair of surgical devices and instruments.

Greg has spent the majority of his career in the medical device space. He worked at Philips Medical and Hill Rom and has also worked at Echo Engineering and T&G Management.

He holds a bachelor's degree in business administration and a master's in organizational management.

So now we'll move onto the presentations. For hospital end users and engineers it looks like Barbara is presenting.

MS. MAGUIRE: Good morning. The three of us are representing the point of view of clinical engineers and hospitals, the end users of the patient care equipment. So Sal is going to be begin.

MR. TATTA: Good morning. Oh, sorry. Thank you. Good morning. You want to say your information?

MS. MAGUIRE: So I'm here representing the American College of Clinical Engineering. They have a mission to establish a standard of competence and promote excellence in clinical engineering.

We have just over 750 members and were established in 1990.

MR. TATTA: A little background on the VA. The VA's the largest integrated healthcare system. We have over 1,700 sites of care, over 1,500 biomedical engineering professionals, and we do have a disclaimer that this presentation reflects our views and does not represent the views of the VA.

The focus of our presentation will be briefly focused on a clinical engineering perspective and the interactions with ISOs and the OEMs pertaining to service, repair, and parts. And then Dr. Dominitz will discuss his perspective.

First I'd like to clarify the roles of the stakeholders where clinical engineering was included with the third party. What is essential is that we --

of the essence that we are considered as a second party or the medical device system owner.

So what do we do? Clinical engineering does just not fix medical devices. We provide comprehensive support by interacting with the entire medical center.

We are highly-trained professionals who support and advance patient care by applying engineering skills to healthcare technology where are mission is to ensure the safety and performance of medical devices.

Clinical engineering breaks down to these nine disciplines all of which we do each and every day.

In-house clinical engineering departments are responsible for the lifecycle management for thousands of medical devices. We perform and conduct risk analysis all the time. We start at the pre-procurement stage looking at system quality and efficiency, serviceability, reliability, system integration, and interoperability, you name it.

Once the devices arrive we continue into the

equipment installation implementation. We establish emergency procedures and educate clinical staff. This all requires substantial coordination with multiple departments.

We then systematically review performance, safety, and effectiveness throughout the medical device's entire lifecycle. At the end of the day we have intimate knowledge of all the medical devices under our care. In yesterday's panel on presentation, Scot Mackeil, was a perfect demonstration of this.

To accomplish all that we do doesn't come cheap. Some OEM organizations suggested yesterday to not talk about cost. What I do agree is that it's all about safety; however, as you can see the cost after procurement far greatly exceed the purchase cost hidden under the visible iceberg. It's quite substantially where there actually should be more than one chart present.

Now Barbara's going to talk about ensuring quality of services. Thank you.

MS. MAGUIRE: So in keeping with the topic of the panel, I wanted to talk about some of the

characteristics of good clinical engineering programs and how they already meet the quality standards.

When partnering with ISOs or receiving services from manufacturers there are several steps that good clinical engineering programs take to ensure quality. So we have a responsibility that the CMS requirements are followed no matter who is providing the service.

So we diligently check for the qualifications of the service engineers who are performing the service. We include terms in our contracts and in our terms and conditions which require that trained individuals are used, require the use of calibrated test equipment, and require the provision of detailed field service reports which we then include in our maintenance records so that we have a complete maintenance record no matter who's performed the service.

For high-risk equipment we require that any servicers follow the manufacturer's recommendations and we ask them for documentation of this. So we provide this oversight on behalf of the hospital.

There are many other regulations that we're required to follow as part of the in-house program. Some of those are listed here for reference.

In regards to the quality systems regulations, though, I wanted to touch on a few specific ones and how they overlap with the Joint Commission requirements already in place.

So for management responsibility Joint Commission already requires oversight of the Medical Equipment Program by hospital leadership.

For quality audits the performance improvement sections of Joint Commission require collection of data related to device failures, analysis of this data, trending of this data, and that corrective actions be put into place.

Regarding personnel, Joint Commission human resources sections require hospitals to establish qualifications to hire, orient, train, and monitor the competency and performance of the staff that's used for medical equipment service.

For document control we're already required to document incidents as well as all maintenance

activities and to analyze these records for trends. Thank you.

Regarding inspection, Joint Commission requires that we specify the procedures that we're going to use for the inspection, that we calibrate our test equipment, and that we document the test equipment that's used in those processes.

For acceptance activities all equipment that comes into the hospital must be inspected prior to use on patients.

And for records, the hospitals are required per Joint Commission and CMS regulations to maintain documentation related to medical equipment maintenance throughout the life of the equipment.

So we already have policies in place. We train our staff to these policies and then we audit that or processes are following these policies and that's how we ensure quality in what we do.

I'm also including for reference some more detailed aspects of the Joint Commission requirements in addition to the quality regulations. Thank you.

So I also wanted to mention regarding

characteristics of good clinical engineering, as part of the ACC we do have a code of ethics that is expected of all clinical engineers who are working in hospitals. And this covers many aspects of providing quality service, keeping the patient first, and ensuring safety.

MR. TATTA: Okay. So clinical engineering is jam packed with highly qualified and skilled clinical nerds -- I mean, engineers. We actually hire -- we actually hire the best training BMETs from the Air Force or the Army that have technical and engineering degrees.

When we hire them, especially from the OEM, we have to train them on the basics and by setting high educational standards to increase their knowledge base. So we provide them with lots of specialized training.

As a matter of fact, many clinical engineering departments have over at least 150 years of cumulative experience.

Okay. And to also ensure their qualifications, yesterday somebody mentioned that they

wanted us to test the device again after a clinical engineering repair to verify it again that it works property.

We do already do that with ongoing supervisor oversight and clinical review -- clinical operation -- excuse me -- review of clinical operation with our dedicated clinical staff. We simply do not work in a vacuum.

We also have successful OEM partnerships on multiple levels. For example, there is basically not one OEM service engineer that comes into my facility that I do not know.

Having successful OEM partnerships, especially wherein the VA where all contracted manufacturers need to comply with our VAAR Regulation A52.211070, where the OEM must supply our facilities with service manuals equivalent to the service manuals that they provide to their OEM field service biomedical technicians.

Toward all the healthcare facilities that are out there a bit of advice. If not done so already, you can easily search this Reg and include a

similar clause in all of your equipment contracts. It's not up to the FDA to encourage the OEM to provide us service manuals. It is up to us to enforce it.

The OEMs also provide us with quality service schools. Some are covered at no additional charge in our equipment purchase contracts, others, I have to say, are quite costly. And they also provide us resourceful technical support and discounted parts.

We provide incoming and safety inspection testing, preventative maintenance, repairs, information technology expertise, data integration, system integration, consultation documentation on all our medical equipment in a safe and effective environment for patient care.

We have oversight by our local environment care committees via periodic reports where we analyze our work orders for tracking issues and failure trends. This feedback of excellent information is essential to all the clinical EOC members.

And how would you think we would become subject matter experts if not trending on all our repairs and knowing what we do?

We also have an effective equipment control via centralized inventory assets and maintain and effective work order documentation system to record all the work performed.

We also provide excellent customer service and are heavily relied upon by clinical staff for our on-site quick and first-call response to the patient bedside. We are called upon by clinical staff and our vast -- for our vast, multimodality knowledge base and experience.

We are the ones users rely upon to go into the OR in the middle of surgery to fix something or for troubleshooting a lost PAX connection or an EKG not transmitting. We are the ones replacing the MLC motors on our spare parts -- from our spare parts stockpile on a linear accelerator within 15 minutes so that the patient care -- can get care without delay or getting called at 2 o'clock in the morning coming in to resolve issues the physiological monitoring system in the ICU.

It is our strong dedication that we are constantly going above and beyond our normal call of

duty.

I would also like to point out that in-house clinical engineering manages and supervises all repairs performed by the OEM and the third party and we make the determination of when to utilize each party.

So when it comes to parts, on average almost all of our repair parts are procured by the OEM. We ensure the quality of parts by vetting out part suppliers, but I have to say what's missing. And labels on approved parts is what's lacking.

Everything we do is about safety. We have an effective medical device hazard recall procedure plan. We work closely with all the medical center staff for medical device incidents, safety notices, and recalls because all -- we all share considerable knowledge about the devices under our care.

We also have access to the equipment histories and repair documentation, OEM and ISO service reports, they're sign-in sheets when they walk in my door to perform work, to each part we order and replaced.

During hazard recall we are essential during all -- all the phases. Clinical engineers most often conduct the investigations. We preserve evidence, organize a rapid response so that it can be properly analyzed and translated to the end user.

We also work closely with our patient risk managers by performing RCAs and FMEAs.

So, in summary, of the concerns reported to the FDA, as a system owner we treat medical devices as if they were our own. And we like to stress that we do not adulterate our medical devices.

OEM service does not mean better service than the in-house clinical engineering service. We are patient-driven and not profit-driven and we have vested interest in our patients.

In conclusion, I overheard a comment made in the crowd yesterday, “Nothing to hide, nothing to fear.” We have nothing to hide. This is so not the issue.

The real issue is clinical engineering already is subject to many inspections like the Joint Commission and to the numerous standards and

regulations that Barbara mentioned which overlap the QSR.

Imposing further service regulation would burden clinical engineering making them cost prohibitive and increase cost for healthcare organizations with no improvement in patient care.

Allowing OEMs complete control over service activities does not ensure the safety and effective CM medical devices and eliminating in-house clinical engineering would jeopardize patient care and patient safety.

We have to keep our successful in-house clinical engineering, third-party clinical engineering service, and OEM partnerships alive because if we are successful our patients will have also successful pat-- positive outcomes.

The think to remember -- excuse me. The thing to remember is we do it well and we do it right. Now, I introduce Dr. Dominitz. Thank you.

DR. DOMINITZ: Sorry. My microphone's not working. I hope that's not intentional.

So it's interesting being on this panel.

I'm not a clinical engineer. I'm a physician. And we've heard a lot from OEMs, ISOs, and engineers. And the -- I know the FDA was interested in having and end-user perspective and so I was offered this opportunity. I'll be brief.

CAPT. MITCHELL: So I just -- your 20 minutes is up.

DR. DOMINITZ: I guess I'll be very brief. Well, let me just say that --

CAPT. MITCHELL: I've had a couple people yield to you. So --

DR. DOMINITZ: Okay.

CAPT. MITCHELL: -- a couple of the other speakers have yielded to you so.

DR. DOMINITZ: Oh, thanks. I just have two slides.

So, as you all know, physicians and patients expect the equipment to be safe and effective and we've had a number of events in GI endoscopy where I work that have raised concerns about the safety and effectiveness of our equipment.

I've been doing endoscopy for 20-something

years and, you know, sometimes the equipment doesn't work quite as you would expect. And just minor deviations on how the scope works can really impact your ability to deliver the care that you want to give to your patient.

And there are challenges in these devices. They're highly complex and the repairs need to be done exactly right and they're not always done right. We also need to be able to track our equipment for look backs for infection control purposes.

Next slide, please.

So, as I said, these events have heightened our awareness. Patient distrust is a real concern. We had many patients cancelling their endoscopy over all of that super bug stuff you heard on the news over the last couple of years. And that's a real problem because the procedure are lifesaving in many cases so we need to be vigilant.

And we need help from the manufacturers, engineers, vendors, repair vendors, regulators to design them safely from the outset to ensure ongoing safety especially at the time of repair, to offer

correct preventative maintenance guidance. And cost is always an issue because it can lead to delays in repair and replacement of equipment. Thank you very much.

CAPT. MITCHELL: Thank you very much. So the next group of speakers will be the independent service organizations. I do not have a speaker identified so…okay. Greg Sharp.

MR. SHARP: Thank you. I didn't want to cut this group short. You did such a great job. So we deal with the clinical engineering team on a daily basis and really respect what they do and what they offer to the industry so it was good to hear that.

In our panel we're the independent service providers and we want to talk about, you know, what we believe good service, good refurbishing is, all the R words that we've seen.

Our views are consolidated into -- into what I'll be speaking about so we won't be passing the mic along.

Our belief is that good servicing entities share certain core characteristics. The first is

patient safety focus, so that's first and foremost of everyone and I think everyone in this room. The next is a strong quality management system. The third one is alignment within users of the equipment that is serviced. So maybe a little bit unique from other folks, but we truly believe that's very important. The fourth one is commitment to proactive device management utilizing scheduled and preventative maintenance and the fifth one is local presence.

So we also believe that the current multi-layered oversight framework on provider organizations is adequate to ensure the devices remain in excellent working condition. And I think you've heard that time and time again either from the ISOs or from the clinical engineering group.

There are multiple organizations out there that are managing and overseeing what's going on in the industry and to introduce another oversight such as the FDA is unnecessary and drives unnecessary cost. No one's afraid of it. It just doesn't make sense.

And so, you know, as we move forward there's other things that we can do to create a better

environment for the patient and for outcomes, but it's not creating more oversight.

So if we look at, you know, what we would say from an FDA perspective if they were going to -- you know, what do they take away from this. And really it's creating better collaboration between clinical engineering, between third-party service organizations, and between OEMs. If we can work better together, then ultimately the patient's going to win.

So we'd like to explore each of the five characteristics of good servicing that we just spoke about. The first is that patient safety.

You know, safety is the top priority whether you're an ISO or whether you're an OEM and -- or whether you're clinical engineering. And we all focus around the things that we do to make sure that we have the right outcomes.

From an ISO perspective, you know, our goal is to repair everything back to OEM specification. So whatever the released specifications that the OEMs give us is what we repair that device back to. And if

you're not giving enough specifications, then give more. But don't complain about we're not doing the right thing to the right specifications if you're not giving those or releasing those to the industry.

And, you know, the other thing is everything that we do is 100 percent inspected before it goes out from ISO perspective and then it's inspected again when it gets to the facility.

So you heard the clinical engineering group talk about that. They don't accept things back into the building unless it's gone through their testing. And that's just another safety check and secondary inspection area for us.

And then the end users, themselves, will make sure that the product is functional before they introduce it to a patient. So there's multiple layers within the already existing system to monitor the safety and efficacy of these products.

We believe in strong quality management systems and we have a strong commitment to quality management. And, you know, today we use ISO as our -- as our quality system of choice and it fits really,

really well for us and it's worked for many years. And more and more companies are getting better and better at how they manage their quality systems.

And I would argue that today -- and I know myself and probably everyone else on our team here would look at our quality systems almost mirror what the FDA would be looking for if they were to regulate us.

And so, you know, we're there or very close to there today. We have a quality system that is really focused around a service environment, not a manufacturing environment. So it's already been skewed to an area where it's what we do on a day-to-day basis and it's not an oversight of manufacturing because that's not what we do.

We focus on returning the device to its original operating condition. There is not functionality changes, there are no changes to performance, safety, or intended use. We just repair.

And you can look at the R words and from our perspective, you know, refurbish is just some level of repair. All we do is repair so you can use all the R

words you want, but from our perspective we're repair organizations, all right. And refurbishment and all these other things, other than remanufacturing and we don't do that, are all just a certain level of repair so it really doesn't matter what you call it. In our vernacular it's we repair surgical devices.

There are many things in the QSR that do not apply to independent service organizations. So to say that we're just going to slap the QSR over to service, there are so many things in there that don't apply because we're not manufacturers.

So it would be very costly to rewrite the Regs to focus on what service should be -- or should be compliant with in the Regs if that were to happen. And, again, we're just going to argue why would you go through that expense?

And that expense isn't my expense, that's tax dollars expenses where you have to write that, then you have to create a field organization that can oversee that. There's over 5,500 hospitals, there's thousands of service organizations, and there's limited field inspectors with the agency. And so to

focus them on areas where there doesn't appear to be a major problem doesn't make sense of using good tax -- good tax dollars to, you know, help increase the outcomes of the patients. So, you know, from our perspective regulations is not required.

And then training is very important to every independent service organization. And we document our training. We have skill levels that we test to. And just like you saw with the clinical folks over there, it's very important to us.

And the other thing is we do not have hand devices to our technicians, our engineers that they've not been trained on. All right. So it's not the wild, wild west out there. It's very, very disciplined.

Number three is alignment with end users. Now we partner with those who are closest to patients and the device used to allow real-time feedback. And that's one of the advantages you get by being local is that day-to-day interaction with those caregivers and those end users and talking about any problems that they're going to have.

You know, we can tell -- I know there was a comment about endoscopes down there by the doctor that's on the committee there. What we find and we track every single repair on an endoscope for our customers and then we trend that for them based on what percentage we say were preventable versus which ones were not.

That's something we do at no charge for our customers because we find that 60 to 70 percent of all repairs on endoscopes could have been prevented. Not because it was a bad repair, because of care and handling.

So you talk about patient safety, it's us helping the customer with that day-to-day how do I do the care and handling of the endoscope to prevent the repair. That's much more important than the repair, itself, because we do -- we do a quality repair, but yet these scopes continue to get broke and broke and not because of the parts or the repair previously, but because of the care and handling in the environment that that endoscope is in on a daily basis.

We're committed to help our customers solve

their device repair issues. And, again, every type of repair we do, whether it's surgical instruments, whether it's surgical devices, we focus around how we can help that customer solve problems that are inhibiting them from giving better patient care.

Number four, proven track record of promoting proactive preventative maintenance. So, you know, there's lots of equipment we work on where the OEMs have not even put out a preventative maintenance schedule. And so based on our history and what we have in our repair history files we can show the customer that these are the kinds of things that we should be looking for with you so that we can prevent a repair from happening during a procedure.

And so we help them with that and help them understand where the failures are coming from so that hopefully we can put plans in place that can help them out and help prevent repairs before they happen with a patient in the room.

Let's see, the other thing is, you know, this proactive care and preventative maintenance is reducing the total cost of ownership by prolonging the

useful life. And I know I always get OEMs shaking their head, well, you can't prolong the useful life.

And I'm saying, yes, we can. And we're doing that by not changing anything on those devices, but just replacing worn parts that can be replaced easily, right.

And OEM they certainly -- and, you know, I'm in a unique advantage -- in a unique situation where the owner of IMS is Steris Corporation which is an OEM. Most of my career I've been an OEM service executive so I know both sides of the fence.

And from a capital equipment OEM they're very incentived to sell project, which they should be, and they're very incentived to drive new technologies, which is great. Look what's happened in the healthcare environment over the last 20, 30 years.

But sometimes technology comes at such a pace that customers can't afford to keep up with it and there's not enough financial outcome information to say I should have to replace this device today because my patient will be better for it.

And in those situations the customers need a

choice. And that choice may not be that the OEM is discontinuing service on that device. It may be they need a provider to keep that device going a little longer till they have money to invest in new technology when appropriate. So that's one of the advantages that we can offer, as well.

And our continued customer support is really, you know, demonstrated by the ongoing demand for our services. So if we were the bad boys out there and if ISOs were the people that are causing all the problems, I don't think hospitals would be using us because hospitals are all about patient care and patient outcomes. So why in the world would they keep using us over and over and over again? It makes no sense to me. I don't think there's an issue.

Local presence, number given. To be effective, service must be responsive and convenient. All right. So the better and closer you can get to that hospital, to that incident, or that repair the more quicker we can get the problem resolved.

You know, there's really no substitute for onsite expert personnel to support that device

performance, ensuring quick response to emergent issues. And you heard just from the clinical folks, as well, that's what they do every single day. They're onsite taking care of their devices.

And, you know, our local technicians have ongoing training and education programs that we do for the customer so that we can help them out locally. So we may have a truck up there doing instrument repair, surgical instrument repair and they find things on that device -- it could be bioburden, it could be micro cracks that you can't see with the naked eye but you have to have magnification -- they immediately bring that into the facility, show that caregiver what's going on so -- and offer training programs about how to inspect better and more efficiently and effectively. So we're partners with them in preventing and taking care of patient safety.

So how can the FDA and OEMs and hospitals help augment all these good characteristics?

You know, first of all, OEMs making available all service manuals and parts. And I heard the comments yesterday from some of the OEMs about

let's make regulation across all -- across all third parties, therefore, we'll have visibility to repairs.

No, you won't. I mean, that's insane because there's millions of repairs done every year and there's a few MDRs filed. You'll have visibility to MDRs, but the majority of all repairs would never get reported nor would they be -- nor will they be public information.

The only way you can get better visibility is to sell parts. And just like Steris does, we trend our parts sales that our service people don't consume and then we know what's failing out there in the field and we can track and trend that.

So if you really want to get visibility, you know, do what's right and sell parts and service manuals and help support the environment that's out there.

The FDA could change the MDRs to include an identification of service provider to track performance of both ISO and OEM. So there's no reason -- we're not opposed to that. So if there's a portion of the MDR where the service provider can be

identified, great. And if there's a trend of certain service providers that are causing problems, then the agency has all the right in the world to go in and look at those folks. And we think that makes more sense than putting regulation across the entire industry.

And then hospitals to utilize qualification procedures for all services providers. And you've heard from many of them most of them have very, very good ones. And if they could standardize, that would be awesome so everyone could have the same.

But today we see that every facility we go into we go through a qualification process and it's rigorous. And most of them require them coming onsite to one of our repair facilities to see what we do and make sure that we have all the systems in place to support that.

And the other is as ISOs when we come across a device that may get shipped to us that we cannot do the repair on we ship it back. And for us we either ship it to the customer or we call the customer and say do you want us to send it to the OEM.

And about 5 to 6 percent of the parts that IMS gets we don't repair because we're not qualified to do that repair and we sent it off to the OEM or back to the customer and let them deal with it at that point in time. So we're not going to do repairs that we're not qualified to do and that's part of our process, everyone's process from an ISO perspective.

So, again, with all the evidence that you've seen so far during the little bit over a day there's been no evidence that says that there is an issue out there, that there's a difference between OEM and ISO or clinical engineering.

You know, Aclaries (phonetic) analysis I think is accurate. And even if it were 100 percent off the amount of repairs that you're talking about is less -- is still .000 something, right. It's still a very, very low number.

And there is plenty of oversight in the industry today to drive what we're looking for, which is patient safety and patient outcomes. So thank you.

CAPT. MITCHELL: Thank you. Next we will hear from the OEMs. And I have as the speaker Dennis

Hahn.

MR. HAHN: It's Dennis Durmis, but that's okay.

CAPT. MITCHELL: Sorry.

MR. DURMIS: Hi. I'm Dennis Durmis. I do appreciate the opportunity to be here and present to the FDA. And I'm the head of commercial operations for Bayer's radiology business. I was the head of the global service business for two years. I also was a founding member of Bayer's multivendor service business. So like Greg, I've kind of been on both sides of the aisle, as well.

With me today is Dennis Hahn with the Ethicon Division of J&J and Mark Leahey with the Medical Device Manufacturer's Association. So we can go to the -- we can go to the next slide, as well.

So today I'm representing members of AdvaMed, the Advanced Medical -- I knew I was going to screw it up, but we'll go here. So the Advanced Medical Technology Association and MITA, the Medical Imaging and Technology Alliance and obviously MDMA.

Obviously we're representing OEMs who spend

a lot of time designing, manufacturing, and servicing and putting quality standards in place to do just that. There are a large number of us, as well, who have multivendor or third-party service businesses within our organizations.

What I'd like to touch upon today is -- and at the end I think you'll agree and it's great that we're in violent agreement with lots of what was said yesterday and what was said today which is that quality management systems are the right approach with regards to helping drive patient safety, which is what we're here first and foremost for.

Interestingly enough, when I hear an OEM speak and say we believe in quality management systems, they're speaking truly on behalf of the entire OEM organization.

Unfortunately, when we hear an ISO say we believe in quality management systems, they're speaking on behalf of their individual company. There are many ISOs out there who do not have quality management systems so it's unfair to compare and contrast to say that ISOs believe in quality

managements systems when they're only representing a portion of the thousands of companies that are out there performing third-party service.

So with regards to what's important to us, clearly patient safety is what we're here for today. It is -- it is what's most important to us. In my particular business we have equipment that's used 20 million times on an annual basis. So 20 million patients that are using and receiving procedures that are enabled by our equipment so safety is top of mind and first and foremost for us.

Clearly, we follow the quality, safety, and regulatory requirements, but they're limited to original equipment manufacturers today. The FDA already has guidelines around what -- you know, what should be done. And we believe that should just be extended more broadly both from a functional perspective and process perspective as well from an oversight perspective. And those are enabled or described in 21 CFR 820.

Obviously consistent requirements proper servicing supports device performance enabling patient

care and patient medical staff safety. At the end of the day we're trying to enable a patient outcome and doing it in the most safe and effective way. And a good quality system really is what's going to drive that approach.

So keys to good service and a quality management system that provides a framework that operates assigns responsibility and demands accountability starting with management.

Dictates consistent practices such as procedures, training processes where quality can be controlled, provides traceability, so the device history file, documentation records of what service was performed. Addresses customer feedback and complaint handling and customer feedback.

So it's a closed-loop process from start to finish that allows us to evaluate and assess everything from manufacturing to service, get feedback, and then take it back to the beginning and improve either our manufacturing processes or improve our services processes.

I think that's certainly important in

something that is required for a successful service operation. And it minimizes the risk of incomplete knowledge and use of non-qualified parts.

So I want to state that we believe that there are exceptional service providers out there some which potentially could be at the table. And we don't want to imply that as an OEM that we are perfect nor do we, you know, do things always right.

But what we do have is a closed-loop process that enables us to build upon the mistakes that we make or improve upon the service capabilities that we have out there. And it's a continuous improvement process versus somebody or someone who's performing a repair and going back and doesn't get the feedback and doesn't build upon what's out there today.

So I appreciate the FDA's given me two hours to go through this list in painstaking detail. We will understand in-depth each and every one of these. I'm just kidding.

We did want to just highlight, you know, in 21 CRF 820 from a service perspective so that certain other things apply with regards to the

remanufacturing. So design controls would be an example of something that would be included in -- in here from a design controls perspective for remanufacturing.

But you see everything from, you know, quality audits, documentation controls, purchasing controls, process controls, device packaging distribution, quality system records, complaint file, servicing. So, again, I think it's a very good foundation. And as an OEM we believe it's a very good foundation to build upon your service approach and leverage the language. And it's already been defined, you know, with the FDA.

In my experience we manufacture vascular injectors. We received a call a couple years ago where a vascular injector was used in the MRI environment. It was causing there to be image artifact or image quality distortion issues.

So we went in, looked at the vascular injector and found that someone else -- somebody else had performed service on that and they used standard wood screws, or ferrous screws, in an MRI environment.

So as a result that caused image distortion. Also could have caused patient or user safety so ferrous materials can be sucked into the magnet, if you will.

And, you know, this is an example of where a quality management system would have helped prevent that type of situation through training, through supplier inspection, through supplier audit, through procedural controls that are in place.

So when you take a look at all the things that could have or did go wrong in that instance, a quality management system would have helped create a foundation which would have prevented that type of situation.

With regards to the most important thing -- and, again, we were asked to address, you know, what does good quality service look like. But at the end of the day, we do go back to patient risk.

You know, the patient has the most at stake. They shouldn't be worried about who performed their service. They're worried about, you know, their personal situation when they're receiving and using our equipment or having our equipment used on them.

Performance of these activities within a quality system, you know, should enable and allow for best in class safety and efficacy with regards to medical devices, as well.

Healthcare professionals have an interesting stake, as well. The operator of the device obviously is trying to make sure that the patient receives the best care in a safe and effective environment, but there's also risk to them with regards to whether or not a piece of equipment is serviced and maintained in an appropriate fashion.

It's interesting and somewhat unfortunate in my mind that the panel discussion that we have today we've had two physicians. One spoke yesterday and we had one today. I think you spoke yesterday, as well. But both of which said the same thing which is they believe that we have a problem contrary to what I believe parts of what we're hearing today is that we don't have a problem.

So the fact that we don't have more physicians or user groups or patients speaking at this panel and articulating what their beliefs are and what

their thoughts are when they have the biggest stake in the discussions is a little bit unfortunately, but hopefully in future discussions we'll be able to -- we'll be able to get them involved.

Finally, again, a minimum set of requirements on all entities participating in these activities is what we're asking for. And we would encourage the FDA to provide some level of oversight with regards to servicing.

And I think we heard yesterday from the first OEM panel that, you know, that doesn't mean that it's all things to all people. It means that we need to take a look at what makes sense from an oversight perspective.

We hear that there's regulation and regulatory guidelines all over the place, but there's not a consistent regulatory oversight with regards to servicing. And we think that makes sense moving forward.

So with that, thank you very much.

CAPT. MITCHELL: Great. Thank you. This is a panel discussion and we're talking about

characteristics of good servicing, to summarize it. So what I'd like to do now is open the floor to questions about what are the characteristics of good servicing.

And so please with your comments try and frame it as a question.

MR. POWERS: Good morning. I have one question. As a clinical engineer in a --

CAPT. MITCHELL: I'm sorry. Could you introduce you name and your affiliation?

MR. POWERS: My name is -- my name is Mike Powers. I work at Christiana Care Hospital in Delaware. We're 1,000-bed hospital. And I'm in-house service, a clinical engineer.

And one of the largest things that I like to do every day is not only repair equipment, but repair the relationship between the physician and the equipment. I'd just like to hear you guys kind of address that because it seems like, hey, yeah, we all fix equipment, but it seems like the physician is really concerned maybe my relationship with the equipment hasn't been addressed.

DR. DOMINITZ: Well, can you expand on what you mean by the relationship between the physician and the equipment?

MR. POWERS: If the equipment has been repaired and the physicians are concerned, hey, how do I go to my patient and say, look, you know, everything breaks. But when our stuff is fixed or the last time you were here and it broke while you were experiencing care, how does that physician then alleviate that concern with the patient?

How -- because that's where the point of care is. There's, you know, the patient, the physician, and the equipment that make kind of a triangle in patient care. And if we're talking about this one leg of it, then, well, we have to make sure that the physicians and the patient both trust that equipment.

So repairing that relationship seems to be as important as repairing the equipment, itself.

DR. DOMINITZ: You know, I think it's interesting. I -- excuse me. I've had equipment fail on me a handful of times in the middle of a procedure.

Usually my patients are asleep and not really aware of it and, you know, I have to swap out a scope, you know. So, you know, it happens.

And I'll say and the procedure took longer than we expected, the cable snapped in the middle of the procedure and -- but it's usually not a big deal-- we're able to couch it in terms for the patient that it's not a big deal. But, I mean, obviously it's quite upsetting in the middle of a procedure to have your device fail.

And, you know, I have to say I think physicians are very naive about this whole field. I consider myself incredible naive even after attending this conference yesterday and doing some reading in advance because we just expect that things are being done right. I had no idea about the level of oversight or lack thereof on these processes. And I think that's probably true of most physicians.

What's happening -- you know, we hear from, you know, my colleagues here from the VA where it's the largest integrated healthcare system in the U.S. we have excellent clinical engineering departments,

but what happens in small, you know, private practices, office-based endoscopy units? How do they assure the safe handling of their equipment?

I'm not sure exactly how to answer your question except to say that, you know, I think it is an important relationship between the physicians, the patients, and the engineers. We all rely on each other to get the things done right.

MR. TATTA: That is the right answer actually.

MR. POWERS: Are you experiencing clinical engineers that contact you and explain to you how the service repaired any deficiencies in your equipment?

DR. DOMINITZ: You know, if I see -- I have had those discussions. I'm the chief of GI at my local hospital and so I know our engineering department. But I think most of my frontline staff do not have the relationship with the engineers. It's usually the nursing staff and myself. Mostly the nursing staff actually.

MR. TATTA: To answer your question and to tag what he said is building a working relationship

with the physicians, you know. It's exposure, constantly being there when they need you and meeting their needs. I mean, if they have an issue and constantly, you know, working with them for that entire issue and, you know, follow up. They love follow up, you know.

Like go there like -- if you can go every day, go every day. If you're in the facility it's just constant exposure with them. That's basically what it is it's building a working relationship with your customers.

The more you do for them the better it's going to become. I mean, you have your troublesome clients, you know, some of these physicians out there, but the more and more, again, exposure you have with them the better they are with you in saying, hey, you helped us out on that day. Great. And then they start relying on you and that's where you're building that, you know, rapport with them so.

MR. POWERS: Thank you.

MR. ZEGARELLI: Hi. My name is Ben Zegarelli. I'm an attorney and I'm representing Karl

Storz.

So I want to bring up a theme that we've heard a lot the last two days. We've heard a lot of collaboration and breaking down the walls between all the entities here and how that will affect good servicing and promote the qualities that we're looking for.

However, what I want to bring up as relevant is that it's the process that's going on in each house. And it applies to ISOs, it applies to OEMs, and applies to clinical engineers. What is the process that you are using to repair and service these devices to get them back to the physicians?

And Dr. Dominitz made a couple of really good points yesterday and today about the super bug issue and endoscopes. And, you know, I know we're not talking about reprocessing here, but it does relate to other latent defects that can happen through suboptimal servicing.

So really these issues should not be happening. These seminal events should not be happening. And part of what prevents this is

oversight.

So my question to you is how less oversight serves the good characteristics of servicing when something like this happens and how does collaboration step in where oversight isn't present?

And then to the clinical engineers I want to address another specific question. I can repeat it if after the first answer, but how do the Joint Commission standards address -- address this issue and all the quality system regulations that Mr. Durmis showed upon the screen there?

MR. SHARP: Well, I know we're not talking about reprocessing, but you brought it up. And the question back to you is do you have evidence that there's cross contamination caused by a bad repair?

And, you know, we look at the endoscopes out there and at least all the ones that I know of where we've had patient deaths they were -- they were maintained by the OEM.

So I would push back saying, geez, is that an issue? If it is, then bring it forward and with evidence because we do testing on completed devices to

make sure that they meet the sterilization requirements.

And so, you know, let's talk about things where we really have information and relevance around and not, again, anecdotal information. So if that is an issue, then let's address it. And if not, then let's keep moving forward so.

MR. ZEGARELLI: My point more is that oversight serves to prevent these issues and it provides an established process by which each in-house process can be overseen.

And I think Mr. Durmis brought up a great point which is that OEMs have that standard of oversight where the process is reviewed on a regular basis and checked. And I'm just -- the point I'm making is why is oversight a bad thing if it standardizes the process?

MR. ANBARI: And just real briefly. The example you bring up is probably not the right one --

MR. ZEGARELLI: Fair enough, yes.

MR. ANBARI: -- because a design defect by a manufacturer is something that we don't -- we're not

going to correct that. Having said that, you know, how does -- your fundamental question is how does less oversight promote these good characteristics in servicing organizations.

And I think the short answer is we're not arguing for less oversight. We're arguing that the oversight that's in place today is adequate and it's demonstrated in the facts of the performance of ISOs and OEMs both in the quality of the repairs and the service that's provided to the marketplace. And that the risk of unintended consequences of oversight that's too great would reduce a lot of the good things that the independent service organizations bring to the marketplace.

And that that could result in greater spend by hospitals from a cost perspective and a lower -- and actually, in effect, reduce patient safety by reducing the amount of support that independent service organizations can provide to healthcare facilities.

And that'd be the -- that'd be my quick way of answering it.

CAPT MITHCELL: So I'm just going to pause, take sort of an FDA privilege here. And I'm going to reset the conversation.

Let me start at the beginning. So what we need to know is what are the problems that we're facing. We need that in terms of what's your sense, what's the perception, and what's the data.

Then what we need to understand is what -- what -- what makes good servicing, right? What are the things that need to happen or that we now know that happen that make servicing the kind of stuff where it's so good that the doctors don't even know that something is being serviced because every time they get handed something it works exactly the way they're supposed to the minute they touch it?

And after that we need to be able to figure out, okay, how do we make this happen? And that's going to happen maybe with the FDA, maybe not. We don't know. We're not at that point. We're far away from that right now because we're still trying to sort out what exactly is the problem and then what exactly is going to make these devices perfect in the hands of

the -- of the surgeons and the other providers that use them.

So that's where we are right now is what are the characteristics of good servicing. So during this question and answer session I'm going to ask that everyone please focus on questions that identify characteristics of good servicing.

And I even am probably going to be assertive enough to say I'm sorry, you are not addressing the issue that we have here for Panel 2 today.

So I have -- I have some questions online and I have people in the room and I'm going to ask you to please stay focused on the characteristics of good servicing.

Now, I have some questions that I can ask and they're right here and I may ask them, but I know we have people standing up so I'm going to just let this go a little bit longer and see if we can stay focused where we need to focus.

And I'm doing this because this is what we really need and I think this is what the group needs to really move forward in this space. Okay. So thank

you.

MR. ZEGARELLI: I can be done and we can wrap this up and move on. I just want to respond briefly and say with all due respect I think I am addressing the issue because from an OEMs perspective, our perspective of what good servicing characteristics are we're up on the board when Mr. Durmis put up all the QSRs.

And we believe the roadmap is right there for good servicing characteristics. So I can be done.

CAPT. MITCHELL: Okay.

MR. ZEGARELLI: Thank you.

CAPT. MITCHELL: Thank you. No. I'm sorry. There was a lady in the back.

MS. BUTLER: Okay. I'm the lady in the back. My name -- my name is Penny Butler and I'm with the American College of Radiology. And by training and experience, I'm also a medical Physicist. Worked many years in a hospital.

I was very impressed with all the speakers and especially the in-house service and the independent providers because I think they're really

-- our members feel very strongly that they're an important part of service and making sure their equipment is working correctly.

And I was particularly impressed with the systems that the in-house and the independent folks have -- many of the systems that they have in place to ensure quality.

So I guess my question is how can we take some of the systems that you have and make sure everybody that's providing this kind of service is providing quality service?

Because in my experience that's not always the case.

CAPT. MITCHELL: So I think that's an excellent question. It speaks more to a later panel so I think we'll just hold onto that question. Thank you.

MR. LIVENGOOD: Hi. I'm Keith Livengood from -- I'm the CEO and President of Livengood Laser. I've been around for a long time. I've been working on las- -- I've been working on all medical equipment since 1980.

I've worked for the federal government as far as I was in the United States Air Force. I was a certified biomedical equipment technician and I worked for ISS. I've worked for hospitals, I've worked for CEOs for 13 years with Coherent and now I've been an independent service organization, three guys, for the past 15 years.

So I can see where everybody is at in trying to solve the problem which is how can we work together to provide quality service, okay. We don't -- we don't -- at my company we don't reinvent the machine. The FDA says, okay, corporations, you can build this within these specifications. You do all your documentation, you make everything perfect for the FDA.

We, as an ISO, we maintain that. We make sure that -- like when I look in the service manual I can follow the manufacturer's recommendations, boom, boom, boom, right down it must perform within this tolerance, this tolerance, this tolerance, this tolerance. We record everything.

Working for independent companies like

Fontona they give us this lengthy service report that we have to certify, boom, boom, boom, every checklist so that the C- -- I mean, so that the OEMs can then report back to the FDA.

We go to hospitals. If we do a poor job, they fire us, you know. You don't come back a second time, okay. Same thing with doctor's offices. The doctor's offices if you don't do quality work they fire you, okay.

So I'm glad I haven't been fired a lot, maybe once or twice, you know. Those are lessons you learned. But trying to get us all to work together for one common good, I mean, I've worked with OEMs that, well, the sales people say that the service department's not doing their job. The service department says the sales people aren't helping them.

Well, my first year working for the OEM I was the number one top in service sales, okay, service contract sales. I understand how to work with customers. They know me. They've -- a lot of them have seen me. I've been working with lasers since '89. They know me, they see my face.

The mistake that OEMs make is by excluding people like ISOs from getting all the service updates if you're excluding future sales because my customers know me, they trust me, they know I'm going to be their quickly. Some OEMs it takes two to three weeks to get an OEM to show up.

CAPT. MITCHELL: Excuse me.

MR. LIVENGOOD: I could be there.

CAPT. MITCHELL: I'm just going to interrupt.

MR. LIVENGOOD: Sorry.

CAPT. MITCHELL: And your question about characteristics for good servicing is?

MR. LIVENGOOD: Well, what I'm getting to -- it takes a little while to get there, okay, is -- well, I wanted -- I wanted to see what the background was just to show you how I'm seeing all these different areas.

OEMs want more sales and they want everything to be safe. They have to follow the FDA rules, they want us to follow the regulations the same as they do, okay.

If you bring us in and you train us, we certify off once a year, we come in, we do this, okay. We become an independent service contractor for you. When you are too busy to meet your customer's needs you can hire us. We can sign a non-compete clause where we come in and we only work within your timeframe and your -- I'm sorry. I'm going on and on

CAPT. MITCHELL: Yeah. So I think what I'm hearing is that you think that a good -- that a characteristic of good servicing is an excellent working relationship between OEMs, hospitals, and ISOs.

MR. LIVENGOOD: Well, that was -- that was really quick --

CAPT. MITCHELL: Would that be a fair --

MR. LIVENGOOD: -- to get to the point, wasn't it?

CAPT. MITCHELL: -- characterization?

MR. LIVENGOOD: Yes. I think it was. And I think that we can all work together and we can all -- you know, like I said, we will do what they ask us to do as far as paperwork. I don't think we need to

reinvent new rules. We can just follow their rules, but use us instead of excluding us.

CAPT. MITCHELL: Thank you.

MR. LIVENGOOD: Sorry.

CAPT. MITCHELL: I'm going to just take a quick -- I'm going to again take prerogative and just direct a couple of questions myself.

So the first question I have -- and it's directed towards the ISOs, but I invite anyone of the panel to answer it -- is that during the presentations we have heard some aspects of good services.

Can you speak to how you demonstrate to your customers these qualities?

MR. ELIASON: Sure. I'll take that. It struck me listening to the CE group, at least from my perspective --

CAPT. MITCHELL: Can you -- first of all, I'm going to ask you to state your name for the transcriptionist and then speak a little closer to the microphone.

MR. ELIASON: Okay. Thank you. Can you hear -- hear me now? Okay. I'm Richard Eliason. I'm

with Crothall Healthcare Services.

But as I was saying, when it struck me when I listened to the CE or second party, third party in-house what we do from an ISO perspective is -- is you could have from a Crothall perspective, for other third parties that serve as acute care accounts, we look just like the in-house program.

We're there, our staff is there. We're under the same CMS guidelines, Joint Commission, entities with deem status. We follow the same standards that Barbara put up there whether -- that are governed by CMS. We're following the EQ56 standard through AAMI for clinical engineering parties and other standards through NFPA 99.

But we're required through that process to prove or demonstrate that our programs are effective. So we use measures of quality, customer satisfaction surveys, internal audits. We use evidenced-based data from our PM procedures and servicing to go back to show the things that we do.

We have key performance indicators, KPI, or metrics with our clients that we track daily, weekly,

monthly, quarterly. We have joint reviews, we have annual reviews. But at the end of all that we have to show through performance improvement initiatives what we have done to have an effective program which is making equipment safe and reliable. So we do that by reporting -- documented reporting reviews.

CAPT. MITCHELL: Thank you.

MR. ANBARI: I mean, and similarly, I think, in the repair side -- oh, sorry. David Anbari with Mobile Instrument Service and Repair.

On the repair side of the business for surgical devices we find that most, if not all, of our customers and in competitive situations with my colleague to my left they do inquire pretty extensively about our training programs for our repair personnel, they inquire pretty extensively about our supply chain for parts and replacement items.

But ultimately I think the main point of focus that they want information on are the quality control protocols that we use during and at the conclusion of a repair process. Those are very specific to each individual device that has different

parameters that we have essentially developed from or have taken from manufacturer's specifications.

That dictates the quality controls checks that take place at the time of the receipt of a damaged piece of equipment, it dictates the interim quality control checks that we take against the device as we're repairing it, and it also dictates the checks that we perform at the conclusion.

And I think one of the things that is clear is that simply using good parts and good technicians doesn't always assure a good repair. It still has to be checked for sterility assurance, it still has to be check for its ability to be reprocessed, and it still has to be checked for how it would perform in a clinical setting.

The last piece of that is probably the most difficult thing for anybody to simulate, ISO or OEM, so we rely on a lot of scientific measurements and measuring technologies to ensure that we're meeting the specifications for the device.

But that's really the piece that I think most of the provider organizations are focused on when

they ask us tell me about how you're good or what your good means.

CAPT. MITCHELL: Thank you. Does anybody else on the panel want to comment?

MR. HAHN: Certainly. Dennis Hahn, Johnson & Johnson. Just as background, as part of this conversation we heard definitions yesterday that cover a very wide range of activities ranging from what are called routing service and repair all the way through refurbishment and remanufacture of medical devices.

And from the OEM perspective I'd like -- you know, today we -- or last two days we've been discussing it from the perspective of routine service and repair. My comment really wants to begin from the other end of that spectrum and that's remanufacturing because, you know, for -- because the range of these activities that we're discussing cover this full range, you know, remanufacturing is providing a device -- a new device that has a new indication or a new intended use.

And from the regulatory spectrum it's important to understand that the quality system

regulation also covers those aspects. And so OEMs or any manufacturer of a device defined as a manufacturer who's providing product with a new intended use would also have to follow design controls.

And so I think it's important to show that from the OEM perspective the quality system regulation really is scalable and risk-based and those elements appropriate to those activities that are being conducted are covered within the quality system regulation.

CAPT. MITCHELL: Thank you. And at the end of the table can you tell us what you might be looking for that would tell you that good servicing has been done?

MS. MAGUIRE: So from an in-house clinical engineer --

CAPT. MITCHELL: Barbara Maguire.

MS. MAGUIRE: Oh, sorry. Barbara Maguire with ISS Solutions.

So from an in-house clinical engineering perspective what we would be looking for from the vendors that we use -- is that what you're asking?

So we question them as to what quality standards they follow, we ask for copies of their policies and procedures, and we ask them to report back to us regarding equipment failures. We ask them for qualifications of the employees that they're going to use for service. And then we review with them regularly the performance as far as response time, up time of equipment, and any repeat failures that they might have.

So asking them, you know, if they have -- if they're ISO certified or have a quality system in place really tells us how important quality is to them. And it's interesting that we do get a variety of answers where some, you know, have that in place and have no problem answering those questions and others less so. And where we don't get positive answers to that right away it definitely raises a red flag to us that that's a vendor we may not consider using.

CAPT. MITCHELL: Thank you. We'll go to the back microphone.

MR. SPEARMAN: Hi. My name is Jim Spearman.

I'm President and CEO of Consensys Imaging Service. Officially we are an independent service organization, but we're also a hybrid. We are an approved service provider to the big three OEMs and in two additional instances we represent to OEMs during the warranty period.

In response to your question, in addition to the panel responses, from an objective standpoint though the ISO 1345 2016 version, which we just recertified to this week successfully, specifically calls out regulatory reporting. It's a mandate in the new standard which is great. We think that's awesome. We have a regulatory alert notice program that has been activated at least four times over the last five years.

Something as simple as a technologist plugged in a cell phone jack into the front of an MRI, the loaded software and drivers onto the MRI. That's a violation of 21 CRF 820.

We've heard questions about customer satisfaction and what metrics do we provide to customers. ISO 1345 requires objective evidence in

all categories. Two clear categories specifically are called out -- customer satisfaction as well as regulatory compliance.

So for those who say QSR is too complex, we are a service organization. We do zero manufacturing, but there are portions of the 21 CRF 820 that are directly applicable to every portion of these medical devices.

So my question for the panel -- I've heard a lot about in-house service organizations, hospitals -- what do you address from a best practice perspective for out-patient imaging centers at physician's offices which is what we cover nationally including the large health systems and networks?

MS. MAGUIRE: This is Barbara Maguire from ISS Solutions.

So I think your question is for what do we use to address the quality for out-patient facilities. So the out-patient facilities that are part of our health systems or that we service we apply the same policies and procedures whether it's for in-house or for an out-patient facility.

So if we were maintaining imaging equipment at those facilities or contracting with a vendor to maintain that equipment, we would subject them to the same policies and requirements as we do within our hospitals.

MR. SPEARMAN: Can we also expand that to out-patient free-standing imaging centers that are not attached to a hospital? Does anyone have any best practices there?

MS. MAGUIRE: So address those in the same way no matter where we're providing the service so we don't differentiate, you know, with the patients in an in-house environment or in an out-patient facility. We apply the same stan- -- same policies for service and the same quality standards in any environment.

MR. SPEARMAN: I mean, outside of your health network for the panel speaking of, as folks have referenced, we've got stakeholders who are not present here in the room. A free standing out-patient imaging center are there any best practices if they're not attached to a large health network that has the resources that your facility does?

MR. TATTA: I mean, it's hard to speak for entities that we, you know, don't -- are not responsible for. I mean, if we have an out-patient clinic that's part of our facility, our rules and our policies and procedures do apply.

I mean, we can't speak for an entity that we -- I'm sorry, this is Salvatore Tatta.

We can't speak for somebody, you know, that we don't have any relationship with. I mean, a recommendation would be to look at the different publications that are out there, look at AAMI standards, you know, the Joint Commission.

A lot of these facilities are Joint Commission accredited so they would look at those standards and regulations and then follow those and come up with their own policies and procedures.

MS. MAGUIRE: And I think if you're looking for a recommendation as far as a best practice or a good characteristic, I would recommend to them that they require of all of their vendors that they follow some kind of ISO or quality standard.

MR. SPEARMAN: Thank you.

CAPT. MITCHELL: Thank you. I have a question from online. Actually I have a couple and I'm going to turn them into one.

There have been -- quality has been talked about and yet there's -- the question online is can it be a good characteristic if the way that you determine quality is not uniform for everyone?

In other words, when there's no overarching regulation you can sort of pick which quality standard you're going to follow or which pieces you'll use or you won't. And can you still assure that these are good practices when there's that much variability in how you determine what you're going to do in terms of quality?

MR. TATTA: This is Salvatore Tatta. In speaking for the VA, we have a lot of -- we have a lot of policies and procedures that we do share with each other. So, you know, we ensure quality because we do pretty much almost the same exact thing, you know.

We have the same standards, same policies, medical equipment management plans. We follow the same practices. We network, we communicate with each

other, we talk about best practices amongst ourselves, hey, how did you do this, what'd you do that, and that's how we build up our experience on, you know, the -- you know, going into the field and, you know, training. We rely on our laurels of all the different aspects of what we do.

But our policies and procedures, you know, we keep it consistent. Whether we procure equipment there's a lot of standardization going on in the VA. We have a lot of best practices on how we handle everything. We take a team approach. We talk to all our end users. We talk to the clinicians.

If I'm working for Dr. Dominitz over there, I'm going to meet with him on a regular basis for a project that we're working on. It's not going to be like me making the decision in a silo. It's us making a decision together as a team.

So working on that together and working out these policies and procedures that's how you build quality. And, you know, knowing the rules and the Regs of the FDA and the quality assurance regulations, that's what we are here.

And, again, when I said we're the clinical nerds. We study all this stuff. We read the regulations. Oh, that's what we're supposed to do. So when a vendor comes in we tell them, no, you can't do this.

Do you know how many times I told the vendor, OEM's, don't do something? So when they come into my facility I'm the one in charge. I tell them what we need to have done and the outcome is for best patient care. I hope I answered the question.

CAPT. MITCHELL: Thank you. Anyone else?

MR. ANBARI: I mean, you know, the interesting thing about --

CAPT. MITCHELL: David Anbari.

MR. ANBARI: Sorry. David Anbari with Mobile Instrument Service and Repair.

The interesting thing about ISO standards, quality systems, et cetera, is that despite the fact that we're not all working from the exact same set of procedures and process -- granted, we're held to the same standards, but the processes and the documentation each company uses to achieve those

varies.

Yet we can still produce reliable, quality equipment that functions the way that it was supposed to when it was first put into service. And I think that's really the ultimate measure.

So despite the fact that there's variability in the quality systems that companies use working on the exact same piece of equipment, provided that the final product works functionally and holds up just the same as it did the day that it was first put into service, that's the ultimate test that quality system can do it -- is functioning provided it does it on a reliable basis.

MS. MAGUIRE: Barbara Maguire, ISS Solutions.

I think what the question is getting at also is how can we say that the quality is the same if we're not all subject to the same regulations? But what we're maintaining is that any of the parts of the QSR that cover service are already covered under other existing regulations that we're subject to so that the quality is, in fact, the same under the existing

requirements.

CAPT. MITCHELL: Thank you. From the front mic, please?

MR. AGOSTON: Yes. Hi. My name is Greg Agoston. I work for Stryker Corporation. I have a very quick comment and then a couple very quick questions.

One is I think that the data that we've been referring to throughout --

CAPT. MITCHELL: Can you speak a little louder, Greg?

MR. AGOSTON: Yes. Is this on? I think it's off. Is it on? Is that better? Okay. Sorry. Sorry about that. How's this?

Okay. Okay. So my name is Greg Agoston. I work for Stryker Corporation. Very quick comment and a couple questions.

First, I think with regard to the data that's been presented sizing the problem I think it's very much underreported because I think what's missing are the incidents in the hospitals operating room, in particular, related to delays, surgeon frustration,

patient exposure to anesthesia. I think those are very real things that are never reported or very rarely reported because no hospital wants to say we've got problems, right?

Similar to issues, if you're familiar with the Detroit Medical Center, front page newspaper ten years of problems just finally came out related to reprocessing instruments.

So my first questions is is that when you're looking at this issue related to service and quality from an overall perspective from we're looking at equipment represented here on the board from MRI, CAT scan, x-ray, all the way down to a Met scissor, stainless steel instrument. And included in there are rigid scopes, flexible scopes, video equipment, anesthesia equipment, pumps, et cetera.

To the panel, is it possible to address this globally or shouldn't we be looking at this as segments related to risk?

MR. SHARP: I think you make some good points there. This is Greg Sharp, IMS Steris.

And certainly it's a large topic, huge

scope, right? And should it be risk oriented? Maybe. But, you know, the first issue -- just addressing the first question you had about hospitals not reporting.

Well, regulating the entire environment doesn't get you there either so, you know, they're either going to report or they're not so it doesn't matter who did service. It's a question of are we not doing it correctly in the hospitals and that's a whole nother kind of topic.

But I think from a standpoint of certainly we need more data and we need more understanding about what's going on out there and if there is a difference between OEMs and if there is a difference between the risk of equipment and what it provides in encounters with that particular patient or that care that they're giving that patient.

So, I mean, I wouldn't be opposed to that. But, again, it's how do you identify risk and how do you classify devices differently because today I'm not sure that they're in a classification that would fit that neatly, right.

So it's an interesting topic. I don't know

how you get there without a lot more investigation.

DR. DOMINITZ: This is Jason Dominitz from the VA. I think you raise some good points. And, you know, in the VA we do have systems now to report near misses and other issues that come up. Any patient safety concerns Dr. Hemphill, who spoke yesterday, oversees that process. And so we do actually report those kinds of things internally within the VA, which is a -- you know, a very large healthcare system.

I don't know if that kind of reporting happens in other settings. But, you know, I do think we can, to some extent, stratify by risk. And, you know, your point about anesthesia exposure, et cetera, I think is spot on.

MR. AGOSTON: Thank you. Second question to the ISOs. So one of the issues is related to parts. Parts has come up commonly, instruction manuals has come up commonly. But parts are just a small piece of the repair equation.

You know, at some level it has to do with the fixtures, the biocompatibility of materials used, and also the sterility. I would contend that running

a product through a Sterrad machine or Steris machine and saying it came through, it came out, it wasn't full of water or had some other major problem with it, it didn't explode does not -- is not to the same level of validation that an OEM is required to test to, to prove that that has been tested against a known amount of contaminate and run repeatedly, you know, hundreds of times through sterilization to prove validation.

So my question to the ISOs is, you know, what do you do to verify sterility integrity for all of the equipment? Because you're dealing with multiple pieces of equipment, various manufacturers, different components.

From my side, from the OEM side, we've seen all types of things be included into some of these products, including Teflon tape that plumbers typically use, we've seen parts that have been remanufactured, we've seen parts that are supposed to be flexible be welded, materials that are supposed to be of certain thickness be much thicker, et cetera.

So can you address that?

MR. SHARP: Well, again, we've all seen

things out there in the environment, right, and we've seen them from OEM repair guys and third party and biomed. So, I mean, my years and years of experience as an OEM and the thousands of service professionals that have reported to me I wish I could say I've never had an incident where they made a mistake and they did something incorrectly, but that's not the case.

So, yes, you've probably seen some things that we would not, you know, condone and things that we would not do from that perspective.

I guess my take on sterilization is I know from our organization, yes, we have done validation of sterilization through the same protocols that you use. And that, you know, if we're using the same components, the same adhesives, and the same processes then the outcomes going to be the same. And the OEMs don't test their repaired items, right?

So you go through, you manufacture, and you get your 510(k), you have your sterilization validation. But you don't sit there and redo every service item and do validation again.

And so what we're saying is we're following

the same service procedures, the same components and compatibility so there's not a need to go through and do sterility validation every time we go through the process.

MR. AGOSTON: But do you validate, though, through outside third-party sources as far as being tested against known concentrations of contaminants and then validate to the level?

And, again, it's a general comment. I'm not being particular to you because --

MR. SHARP: Right. No, no. And --

MR. AGOSTON: -- because your company may do something to that level, but the challenge I think here is is that there's, you know, hundreds of independent service organizations and how do we know that they're all to the same level of standard as Mobile or IMS?

CAPT. MITCHELL: So let me just refocus the question a bit. I understand that there's a concern with, you know, different types of ISO organizations. But when we get back to what are the characteristics of good quality services, servicers, if you're looking

at sterilization as part of the what you need to do to ensure that a device is ready to go back into the hands of a doctor what would be the characteristics of a process to determine that that would be good?

MR. ANBARI: So a good -- a good -- David Anbari with Mobile Instrument Service and Repair.

Characteristics of a good process to ensure the sterility of a device that has been proven by a manufacturer to be able to maintain sterility as a part of their clearance process would include ensuring that the materials that we -- that we use or that are used by one of our suppliers to create a part are sterility assured.

And the raw material, meaning the plastic, the metal, whatever the case may be that we can be a sterility assurance on that. And then once the part is in the form that it needs to be in from that material ensuring that that part is sterility assured, and then finally making sure that after a repair's completed that the device can be sterility assured.

And to your earlier question, I can tell you that our organization does use independent testing

laboratories to validate the sterility of our repairs on -- on an initial basis when we first begin repairing an item and putting it into our circuit and then on a routine basis intermittently to ensure sterility.

MR. AGOSTON: One other quick question --

CAPT. MITCHELL: No. I'm going --

MR. AGOSTON: -- if I may?

CAPT. MITCHELL: Thank you. But there is four, five people back --

MR. AGOSTON: Okay.

CAPT. MITCHELL: -- so I'm --

MR. AGOSTON: Thank you very much.

CAPT. MITCHELL: Back microphone, please.

MS. GEORGE: Yes. I'm Elisabeth George. I'm the head of Global Regulations and Standards and Philips. We're an OEM. We're a third-party servicer and we have lots of relationships with ISOs, the clinical engineering, and other third-party service providers.

I'm really happy to hear the very positive best practices of trending data by the clinical

engineering teams. I'm also happy to hear the ISOs do that. I know that some of that's driven by regulation, some of it is driven by contract expectations.

As an OEM, we have to do total global trending of all of our devices and the product issues on service and on complaints and on parts replacement. Those are input into our determination for continuous improvement and for recalls.

The clinical engineering groups you're doing it based on the 2, 3, 10, 20 devices of that type from us. The ISOs are doing it maybe on the 200 that they're servicing in a region or in the U.S. We're doing it on the hundreds of thousands that we have distributed globally.

So my question to you guys is is that -- and obviously we have products that are used in doctor's offices, small clinics, remote regions that don't have the wonderful clinical engineering groups and ISOs that are as competent as the ones that we've been hearing from today.

So my question for you guys is is what are

your thoughts of what would be a best practice for the OEMs to be able to capture all of that information in an effective way to support our continuous improvements so that we can help to make sure that the patients and the clinicians get what they deserve is high quality and patient safety?

MS. MAGUIRE: Barbara Maguire, ISS Solutions.

So I thought about this a lot because several of the manufacturers had brought this up yesterday, as well, is that how can they get access to our repair data.

And there have been several efforts underway to try to standardize data in the computerized maintenance management systems that in-house clinical engineering organizations use.

So I think one way that the manufacturers might be able to get better access to that data is to work with the existing standard organizations such as within AAMI to come up with standard definitions for what we call different service activities.

Because I think without a standard for that

it would be nearly impossible to get meaningful data transferred from the in-house clinical engineering maintainers to the manufacturers to enable you to do any kind of trending on that.

MR. SHARP: Greg Sharp with IMS. And I agree, without some kind of standardization we'd be happy to share the information and the repair history, there's absolutely nothing to hide there. It's just how do you physically do it? It's enormous, enormous amount of data all configured a little bit differently on how we have our repair system set up and our asset management systems set up.

So it's a novel idea that I think we would all support. I think it's just figuring out the logistics and format around how do you do that. But it would be -- it would be a best practice if we could get it done sometime.

MR. ANBARI: As a -- David Anbari with Mobile Instrument Service and Repair.

As a practical matter, most devices when they first come out on the market due to the warranties that are provided by manufacturers stay in

the hands of the manufacturer for most servicing activities. And I think that's a fairly accurate statement across all different modalities of devices.

But having said that, I think one of the questions the manufacturers have to ask themselves is whether the data that they have on repair events and service events is statistically significant to indicate whether there's a design problem or some form of a systemic issue with one of their devices.

And practically speaking, if they know that during the first year of release after a device is the most likely probability time period to see a problem that's systemic with one of their devices and they're tracking that information and they're the primary servicing entity, I would expect a characteristic of a good manufacturer would be capturing that data, statistically analyzing it. And it sounds like that already happens today.

CAPT. MITCHELL: Okay. Thank you. I'm going to go to the back mic again.

MR. ONGIRSKI: My name is Raymond Ongirski. I'm with UNC Healthcare in North Carolina.

My question is actually specific to the VA clinical engineering person. In terms of quality service, it's a two-part question, can you confirm for me is it factual that the federal government with -- and under the VA specifically has access to all service manuals, all software diagnostics, all availability of training for every medical device?

MR. TATTA: Okay. So when it comes to service manuals we do have it in our contracts that we get the service manuals. And we have a large supply of service manuals for all the medical devices.

There are times where it's very difficult to get OEMs to provide us service manuals. And bottom line comes down to contracting to resolve those issues and us working with the OEMs.

It's not the first time that I've signed confidentiality agreements with OEMs that they would provide the data to us because I was like, hey, you're not getting paid until you provide us the service manual. That's what the contract states.

There are other -- were other times where the OEMs it took them a couple of months, but they

actually developed their own service manuals to meet with that VAAR regulation.

So we have another organization called CEOSH. It's a group of clinical engineers that we actually have been for many, many, many years we have gathered service manual data. We have such a large repository I don't know how many we have, but almost every piece of medical equipment in the VA system we have a service manual for.

So if I get, let's say, one piece of equipment, one anesthesia unit at my facility, no one else has it, it'll go into their database. And if let's say another facility has we can go -- has that service manual, we go and we tap into that service manual and we get that service manual.

CAPT. MITCHELL: So I think you've identified some very interesting best practices.

MR. TATTA: Thank you.

MR. ONGIRSKI: The second part of my question, if I may, is without that ability to get those service manuals could you provide the same quality of service you are today?

MR. TATTA: You would need the service manual to do specific work. There are times where you can have the general comparable knowledge if you don't have the service manual, but you do need the service manual that we do study.

I mean, I have some -- some of my technicians that when a new piece of equipment comes in they study that service manual. They actually read it like a novel and they learn from it. And then that's how they provide good, quality service.

And we don't just know the technical aspects of the manual, we have the user manual, as well. We get two user manuals with our service manuals. One goes to the clinicians, one goes to us. And we actually learn all the different clinical aspects of that medical device.

CAPT. MITCHELL: Thank you. Front mic?

MR. MACKEIL: Scot Mackeil. I'm a regular biomed guy. My question follows onto that and, you know, that was right on, Salvatore.

One of the essential elements of providing good, quality service -- and especially in my shoes

when I'm right there on the front lines -- is having high quality service information that's comprehensive and has good, quality repair and maintenance procedures in it, parts, information about parts and supplies.

One of the roles in my department -- and this is the question that's going to be directed at the OEMs. One of my roles in my departments is as our department's technical librarian. I've literally seen and archived hundreds of technical manuals, service manuals, and operator's manuals.

The OEMs have touted their quality systems, yet there is huge variability in what's called the service manual. The variability ranges from, well, I'm sorry, we don't have a service manual to an operator's manual that has service tacked into the title to satisfy a requirement, to some of the outstanding and excellent service manuals that I've gotten from Steris on our sterilizations and the absolutely brilliant service manual I got on the Ethicon harmonic scalpel.

So based on that, will the medical device

manufacturers go back to the drawing board after they leave this meeting and look at quality service -- quality systems and apply them to service manuals so that every service manual that I get from a medical device manufacturer is as good as the best ones that I've seen like the manual for my Drager Apollo or the Steris sterilizers of the Valley Lab ESUs.

You know, I can -- I know what a great service manual looks like and I know what a bad one is. So, medical device manufacturers, please tell me about service manuals and how you're going to renew your approach to increasing the quality of them across the board from all the organizations. Thank you.

MR. DURMIS: So I think that -- I think it's a good question. I think every OEMs going to have a different approach so I can't speak on behalf of all of them with regards to what their approach will be with service manuals.

Personally for our group it's tied to training at some level. If we look at the 120 field service engineers that we have in my company, we have five major fluid delivery injection systems. And even

within those five -- those five systems we don't have everyone trained to do everything because the complexity associated with each one is slightly different and we don't want to have a generalist doing specialized work in a specialized area.

So depending on the level of training and depending on the complexity of the product, that would indicate at what level the service manual may be or at what level we'd be comfortable with different people working on the equipment. So it depends on really the complexity of the product and how it -- how it's -- you know, how it's designed and what the service requirements are before we can say, look, you know, everything from going in and allowing companies to or biomeds to actually look at software code and change software code, I mean, where do you draw the line I think is the question with regards to what is a good service manual.

Everybody's going to have a slightly different interpretation of what that is. You know, I think is, you know, with MITA and AdvaMed we can definitely take a look at trying to address the answer

probably in a collective way if that makes sense.

CAPT. MITCHELL: Great. Thank you. We have two more questions and we're going to end at 10:15 so I think this works out perfect.

I'm sorry. One more comment.

MR. TATTA: This is Salvatore Tatta. I just wanted to add one thing. To help you with that I would actually look at the VAAR regulations that we have that I mentioned, 852.211-70, that tells you exactly what we're looking for in a service manual. Thank you.

MR. NANNEY: All right. Hi. I'm Courtney Nanney with Quality for Catholic Health Initiatives, clinical engineering. And I'm actually looking for best practices in this area.

I investigate incidences, patient safety issues. And service to me is not just fixing, it's preventing it and it's especially preventing patients from getting hurt.

So I would like to know what the best practices are with the different OEMs and ISOs and in-house on addressing use error and abuse. Because from

my investigations the number one cause of patient injury or death is use error, not equipment malfunction.

Let me just do a little survey here. Who would agree with me on that? Okay. I think we're in good company here.

So I especially think we at least ought to work together on this because it may seem out of scope, but we're the only ones that are going to see this. No one's going to hold up their hand and say I don't know how to use this thing or I screwed up.

So how do we address that if we really want to save patient lives?

MR. SHARP: So Greg Sharp with IMS. You know, for us and many of the ISOs we track every device that comes in. And in the initial assessment that we do on that is what caused the damage.

And so if it was user error that caused that damage then we code it that way and then we trend that for that customer and we review that on a periodic basis, typically quarterly. Some customers want it monthly by department by device.

And then we sit down and we talk about what they can do to prevent those types of failures because those are critical, right. Those are the things you don't want to happen.

So, you know, we attempt to do it. We don't catch all of them. We don't code them all correctly. But we have a trend and it's pretty accurate. And when we go and focus with the customer on those particular areas we see great improvements over the coming months when we do that.

MS. MAGUIRE: This is Barbara Maguire from ISS Solutions. So one of the good practices that we employ to look at use errors is to review them and trend them, as you said. And then we meet with the education department to review those to identify the cause and how they could adjust their training going forward to try to better address those.

MR. ANBARI: David Anbari with Mobile Instrument Service and Repair. Just to echo what Greg said, that's precisely what virtually all of the third party repair companies for surgical equipment do is we track, we trend, we report back.

Often times when we detect what we believe to be a preventable care and handling issue that caused damage to a device we report that back on a much more frequent basis as soon as we detect that it's something we think is a common cause.

But I think the other thing that we do to help in the -- in just aggregate prevention goes to some of the consulting and educational programs that I had mentioned in previous discussions.

Specifically, you know, we do conduct assessments of surgical equipment care and handling that follows the device all the way through its lifecycle in a given case from sterile storage through its prep for a case, use in a case, return back to decontamination, the washing and decontam process, as well as assembly, sterilization, and restocking.

And through that process and through that assessment we can often identify common cause issues or mishandling issues that cause damage to devices. And with minor changes on the part of the customer's behaviors we can make pretty dramatic improvements in what we see.

And I know most of the companies in my space offer similar types of services with different names around them, but it's not just reactionary prevention. Meaning, we've seen damage that we think could have been prevented. It's also proactive by looking at where do we see deficiencies in the overall care and handling process.

And it's a service that really our kinds of organizations are uniquely positioned to provide because it's not focused on one manufacturer's type of one type of device, it's focused on that overall cycle of reprocessing surgical equipment which, you know, reflects devices of different modalities and different manufacturers origin.

CAPT. MITCHELL: So does anyone from OEMs want to comment?

MR. TATTA: So we perform in these situations like a root cause analysis. We find out how to use the device. We look at the event logs. We basically become detectives because when we walk into the situation, we have to say what happened? Is the patient hurt? What's going on, you know?

So we ask all the questions like a detective and then do our -- and we do our investigation like where were you last night at 10 o'clock, you know, questions like that.

Then we look at the event logs and say, hey, what actually happened at 10 o'clock last night for, let's say, an overdose of morphine or whatever it could be. You know, and then we look at the systematic issues, you know -- you know, how did it occur? You know, was it use error? Was it user error? Was it design flaw?

And then from there we make the determination and recommendation and, again, it's constant communication, constant, you know, meetings, you know, reports, file the reports, tracking, trending, the whole nine yards, the equipment history. We look at everything.

MR. HAHN: Dennis Hahn from Johnson & Johnson. Again, very similar to what Salvatore described the process, you know, within an OEM facility is very similar. You know, the user error report comes in, an investigation is conducted.

And depending upon the information provided it may be -- it may relate back to an investigation into labeling, it may relate back into was this actually designed. So we got an error, but it was actually designed -- the device was designed to stop to prevent further damage or all the way back to, you know, the design of the device. If the investigation shows that there may be a design issue, we would go back to through our design controls and be reevaluated.

But, again, a very similar process to what Salvatore described.

MR. NANNEY: I want to make one more statement- -- this is actually a statement. If any vendor -- OEM or third party -- has a problem with any of my equipment, feel free to call me and I will tell you exactly who worked on it last whether it was you guys, an in-house person, or the manufacturer because nobody wins if we don't find out who caused this problem.

CAPT. MITCHELL: Thank you. Last question.

MR. FISH: Hi. My name is Jon Fish and I'm

a National Director with Prezio Health.

We've heard a lot of discussion today in regards to -- and yesterday in regards to the biggest concerns being parts availability and not having manufacturer's guidelines and reference to repairing equipment properly.

My question is specific to the manufacturers. And that is from a characteristics of a good OEM/ISO relationship in specific regard to patient safety overall, because that's what we're focused here on was overall patient safety, what is the best practice and what are the good characteristics of an OEM/ISO relationship?

We've heard, you know, some companies like Steris that provide training and parts to individuals; we've heard other companies that don't share any manuals, any anything.

So my question is specific to the manufacturers. What are good characteristics of an OEM/ISO independent relationship specific to patient safety?

MR. DURMIS: The elephant in the room. No.

I mean, I think it's, you know, what's good practice so I can, you know, first and foremost say that, you know, we view the clinical engineering group and the hospital as our customer. And that's who, you know, our first and foremost priority is in driving patient safety, you know, with our inter-customer level.

With regard to the ISO I guess I would ask the question back are you looking for information around procedures and parts as a result of it being easier for the ISO organizations or to drive patient safety?

MR. FISH: I think it's ab- -- I mean, we're already doing it today. So the independent organizations already out there we already have documented quality processes, we have quality systems in place, we do independent testing of our parts.

But the OEMs biggest issue that we've continued to hear is that the parts aren't being used, they're not our parts, they don't have access to our testing processes or our manuals so how can they validate that they were doing that.

If the manufacturers that are out there --

you know, to me it seems like the best practice are some of the examples that we've seen by manufacturers that share that information openly to ensure that we have the highest quality patient safety overall.

MR. DURMIS: So, again, I guess I can stress that the hospital is our customer and that's who we focus on. And it's important for us to share information with them.

From a business perspective, I think a best practice would be to enter a relationship with a -- a business relationship with the OEM in some form or fashion.

I guess I don't think you've heard that at least in the last two days that the OEMs are talking about all the, you know, necessarily the bad things that are being done or the inappropriate parts or parts availability.

I think at the end of the day, you know, I would ask the question why are the ISOs asking for that information from the OEMs if they're already out there providing quality service in the health space?

MR. FISH: I'm just going to speak on my

behalf here. I'm not speaking for all ISOs. I would tell you we're asking for it because of the conversations that we're having today. There's -- we absolutely stand behind every one of our repairs. We follow ISO 1345 and 9001. We go through diligent testing on all our components. We've been in the industry for 20 years. We believe we have solid systems so we don't see a reason for additional oversight.

The argument that seems to be out there is that you don't have access to this stuff so how can you make sure that you're meeting those components?

Well, if we had access to it there would be no question so no reason for additional oversight.

MR. DURMIS: Well, I think the argument today was that we believe that the quality management system is the right tool that should be used by all people providing service in the healthcare space. And, you know, that's first and foremost.

I think that what you're hearing at least from the OEMs is that not everybody is doing that and that's the area where I think there is concern versus

saying individuals and companies who do have quality management systems are performing good service. Those aren't -- those aren't where we have concerns with regards to patient safety. It's the ones that are not doing that.

With regards to the multi-vendor service side, I mean, I was foundational in starting our multi-vendor service business. And, you know, I can speak that, you know, we started with a quality management system. We had ISO certification in our multi-vendor service side.

We've reversed engineered the competitive products, you know, and/or hired people with institutional knowledge around what those best practices were.

You know, we came -- we identified what equivalent parts where. Biocompatibility testing, component level testing, incoming inspections. So there are ways that service can be performed and, you know, as a third party that doesn't require lots of involvement with -- you know, with the OEM, but at the same token --

MR. FISH: I guess -- I guess I'm --

MR. DURMIS: -- engaging with the OEM in a business relationship is probably the best -- the best way to do it where there's win win. And there are lots of examples where that's happening.

MR. FISH: I guess respectively I'm going to go back to the question and ask what are the characteristics of a best practice OEM/ISO relationship in regards --

MR. SHARP: You know, I --

MR. FISH: -- to ensuring patient safety?

MR. SHARP: Greg Sharp with Steris IMS. And I'll put my Steris hat on so I am OEM right now. And, you know, our best practice that we truly believe in as an OEM is to share service manuals, parts, and technical support.

Our name is on that equipment. We live and die by that brand and we want to make sure that whoever is servicing it has what they need to do it correctly so.

And we don't ever believe that we will or should have 100 percent of the market share for

service. It should be determined by the customer and who they want to use. And we just want to make sure that we can facilitate that in the safest way.

MR. FISH: Thank you.

CAPT. MITCHELL: I'm sorry. So thank you all for coming and for attending. I think this ended up being really helpful certainly to the FDA to better understand best practices.

We -- just for your information, we are looking at expanding the dialog to include patients and more physicians. And we did not include all the web comments, but they will all be made available to the FDA later.

Finally, right now it is -- if you could all reassemble by my computer it would be in 13 minutes, 10:30 that would be terrific. Thank you very much.

(Whereupon, at 10:18 a.m., a recess was taken and reconvened at 10:32 a.m.)

MS. ROSS: The second panel for today, which is actually the third panel overall, is going to be on challenges stakeholders face in performing high quality refurbishing, reconditioning, rebuilding,

remarketing, remanufacturing, and service activities.

So we have several panel members. My name is Astin Ross. I'm going to be the moderator for this panel. And I'm going to start by just giving a brief introduction to our various panelists that, of course, are representing the OEM perspective, the ISO perspective, as well as the clinical environment. And I also am not necessarily presenting the panelist in any particular order.

So our first panelist is Jason Dominitz. So you've heard from him previously. He is, you know, the National Program Director for Gastroenterology in the Veteran's Health Administration. And he's also the section chief for the VA Puget Sound Healthcare and a professor in the Department of Medicine at the University of Washington.

He does have obviously a medical degree as well as a master's degree in clinical research from Duke concurrent with his gastroenterology fellowship.

We also have Mark Leahey. Mark Leahey is the President and CEO of the Medical Device Manufacturer's Association, MDMA, a National Trade

Association representing hundreds of research-driven technology companies. He is also a member of the Massachusetts Bar and a graduate of Georgetown University. Particularly, the Georgetown Law Center and the Georgetown McDonough School of Business.

We also have Mary Logan. Mary Logan -- no.

UNKNOWN SPEAKER: Mary Logan's not on this panel.

MS. ROSS: Oh, I'm sorry. That's Panel 4. I do apologize. We also have Richard Springer and he's an experienced executive who has proven growth and turnaround experience.

He is currently the Chief Operating Officer at Alpha Source, Inc., an independent service organization who provides innovative solutions and procurement in manufacturing of medical equipment, servicing for healthcare customers around the world.

He has a BS in electronics engineering technology from DeVry Institute of Technology and an MBA from Nova Southeastern University. He also participates in a lot of advisory and board positions for startup industry associations and client

partnerships.

We also have Patricia Shrader. She is the Vice President of Global Regulatory Affairs at Medtronic, a position she has held since 2011. In this role her key areas of focus are global regulatory requirements and processes and regulatory policy.

She also supports Medtronic's quality organization on compliance matters. She's a graduate of Georgetown Law where she spent -- afterwards she spent eight years in private practice with the firm of Hogan and Hartson, now Hogan Lovells, and advised clients on both pre and post-market issues and strategies.

In her various role in the medical device industry Patrician has worked across the spectrum in medical devices and has first-hand experience with device servicing and refurbishing.

We also have Jim -- or James Nestel who's a licensed professional engineer and has been working in the medical imaging industry for over a decade.

He has a record of directing teams nationally and internationally while continuing to

achieve goals in various industries in imaging, pharma, lighting, retail, and in a host of others.

Currently, he's the projects and installation manager at Hitachi Medical Systems America and the Service Committee Chair for the Medical Imaging Technology Alliance.

In additional panel member is Jim Goldner. Jim started in the imaging industry with his own independent service business. When the business grew and the opportunity came to merge his company with a large independent dealer he eventually became part of a nationwide distributor.

With hisown business in these dealings, alternative service has already been a focus and laid the foundation for his company First Source, Inc. They are currently in the process of upgrading their mobile technology and x-ray equipment to provide it at affordable prices by using rising partnerships with OEMs for distributions channels.

Thomas Green is an additional panelist. He started Paragon Service in 1991 after ten years of anesthesia equipment sales and service. They are

based in Michigan and Northwest Ohio as an independent service organization and he also serves as a member of the Anesthesia Patient Safety Foundation, a Subsidiary of the American Society of Anesthesiologists, since 2006.

An additional panel member Scot Mackeil. He's a senior anesthesia biomed at Massachusetts General Hospital in Boston. He's also an active member in several organizations related to clinical engineering and he has been a very good panelist in some of our previous panels so we look forward to hearing from him, as well.

Yes. And Alan -- and Alan Lipschultz. So Alan Lipschultz is a professional engineer. He currently is an expert consultant from Healthcare Technology Consulting, LLC. And he has primarily responsible -- responsibilities for biomedical, clinical, and forensic engineering support to clients that do include a gambit from investigations to reporting findings as well as expert witness testimony.

He has degrees in electrical engineering, a

master's degree in Washington St. Louis University in St. Louis as well as his certificate in health -- technology healthcare.

So we'll go ahead and get started and we'll have first the speaker from the OEM or, I'm sorry, the ISO. Thank you.

No. I know the ISOs. I'm sorry. I misread.

MR. GREEN: My name is Thomas Green of Paragon Service and I'm here with Jim Goldner, First Source, Inc., and Rich Springer of Alpha Source, Inc., to discuss the challenges facing independent service organizations and refurbishers in the United States in their quest to efficiently protect healthcare patients.

First of all, we'd like to say that other than desire by the OEMs to have little or no competition, there's little or no evidence suggesting that ISOs or refurbishers should be further regulated by the FDA. That is documented by the ECRI Institute study showing there are only 96 incidents in over 2.1 million reports over a ten-year period.

While we applaud the efforts -- the efforts of the FDA to create a safe environment for patient safety, we disagree with the claim by OEMs that ISOs or refurbishers create an unsafe environment for patients in the United States imposing more regulation; therefore, increasing the cost to ISOs and refurbishers simply eliminates competition for the OEMs, which is good for them, but drives up the cost to the patient and could reduce the quality of patient care by eliminating competition.

As Greg Sharp stated earlier today, ISOs offer very high quality service which is performed at a 40 to 50 percent lower cost than the OEM can offer with generally faster response times; therefore, benefitting the healthcare industry and patients.

Mark Bruley of the ECRI Institute has testified earlier that 96 incidences over a ten-year period causing patient harm or death from over 2.1 million total incidents involve refurbishers and service issues -- servicers; however, I'd like to point out that nobody has, that also includes OEMs. So it's 96 incidences which also OEMs are included in

that including at least one report where an OEM misserviced a device causing death.

There was also people who have talked about underreporting. And it would -- be my opinion that if there's underreporting, as Scot talked about yesterday, it would be on minor issues but not involving patient harm or death. And 96 probably is an accurate number.

There are many obstacles and challenges facing ISOs and refurbishers. OEMs -- OEMs limit training seminars to eliminate ISOs and their competitive status in the marketplace, therefore, decreasing patient safety.

For example, quote, "Effective March 31, 2015, to register for a, redacted name, clinical systems technical training course an independent service organization individual must be endorsed by a, redacted name, customer using a standardized endorsement form enclosed. And ISO individual is endorsed if the, redacted name, customer verifies the ISO individual performed services at the customers, redacted name, equipment that is the subject of the

requested class and does so exclusively at their site or network of sites. The enclosed form must be completed by the, redacted name, customer healthcare provider providing the endorsement. ISO individuals not endorsed by a, redacted name, customer healthcare provider are not eligible for enrollment," end quote.

In other words, an ISO employee and only an ISO employee must be endorsed by a hospital in order to attend a $15,000 seminar, but can only service that account, okay, and no others. Not even the account down the street.

That is totally unreasonable to the ISO. Even MITA stated in their June 3rd, 2016, letter to the FDA, quote, "Proper service training is essential to the performance of these activities in a way that results in safe and effective operation of the medical device. Training is an ongoing process intended to develop the skills and knowledge necessary for competent performance of a task. Given the complexity of the medical image devices, a high level of training is necessary to perform any of these activities. This training also needs to be constantly updated to

reflect knowledge of the latest products including software, hardware, and versions thereof and understanding of current best practices," unquote.

Even MITA agrees in principle, but some of their members disagree in practice especially when dealing with their competitors, the ISOs and refurbishers, where some OEMs will not allow ISOs to be serviced, trained which is contrary to the goal of patient safety.

OEMs charge exorbitant fees for training when they are -- when the school is available, therefore, eliminating competition. Service schools ten years ago were about $3,000 for a four-day seminar. Today that same school's about $15,000 and does not include expenses. That is for one model of one brand for one technician.

Parts are sometimes not available to ISOs or may only be available at pricing much higher than even less price, therefore, harming ISOs and the consumer. Certain manufacturers restrict part sales. This is a very effective way to control service and parts access.

For example, an OEM will not sell parts directly to an ISO at list price forcing them to buy from another source at a 20 to 25 percent list price. There is an increased chance that there will be delays in getting the part from an alternative source. All of this affects patient safety and cost to the consumer.

Software is frequently not available to ISOs in order to service or upgrade equipment. Certain manufacturers employ service software that's password protected and not available to the ISO for the proper service and calibration of the medical equipment.

Service software access is controlled by the OEM and access to the software is done in a very discriminatory manner. The newest software is also controlled by the OEMs and also frequently not offered to the ISOs thereby limiting access to the newest and best version to the user.

This also applies to refurbishers who -- refurbishers who want to sell equipment with the newest software it is often not available.

All the issues facing ISOs are the same

issues for refurbishers. Access to reasonably-priced training, access to parts, access to service software, and access to software upgrades these are all obstacles to increase patient safety created by the OEMs.

The previous FDA standards as talked about yesterday, which were set from 1987 to 2000, require the refurbishers to register with the FDA at no charge, agree to refurbish to manufacturer specifications, put a sticker on the rear of the machine identifying who the refurbisher is, and have traceability reports.

The current regulations for ISOs and refurbishers -- this is not an inclusive list -- but we all want to protect the patient, number one; satisfy the medical end user, number two; avoid an incident and a lawsuit of course. There are state regulations, there are other regulations, and there are current regulations that ISOs and refurbishers must follow.

Our panel is making the following recommendations if there's going to be any further FDA

regulation. Number one, require the OEMs to provide access for all entities to service training seminars for medical devices and increase patient safety.

Number two, require the OEMs to provide access to service parts at a reasonable cost to properly service medical devices and increase patient safety. We've seen examples, we'll hear examples of someone put in the wrong part. Maybe they didn't have access to the right part because the OEM wouldn't sell it to them.

Require -- number three, require the OEMs to provide service software to properly service medical devices and for calibration and increase patient safety.

Number five, require the OEMs access to leasing software to extend the life of the medical device.

Number six, require the OEMs to directly provide recalls and safety information directly to the service providers, ISOs, and third parties to properly service medical devices and increase patient safety.

Seven, require the OEMs to eliminate the

ability of the OEM to remove service certification of a former employee. Briefly what sometimes happens is you have an OEM service rep, they're fully certified, they resign, the go to work for an ISO and the company says they're no longer qualified to work on equipment.

Number eight, enforce 21 CFR Section 1020.30G.

In conclusion, we believe there is no evidence suggesting that ISOs or refurbishers should be further regulated by the FDA. We further believe that if the FDA followed our recommendations that patient safety would be increased and healthcare costs could be contained. Thank you.

MS. ROSS: Now we hear from the OEM group.

MR. NESTEL: Good morning. My name is Jim Nestel. I'm with Hitachi Medical Systems. I'll be presenting today for the OEM group. Participating with me in the discussion panel here and also contributing to the slides was Pat Shrader, Vice President of Global Regulatory Affairs at Medtronic, and Mark Leahey, who we've seen a couple times before already through this workshop with MDMA.

It was mentioned earlier this morning, I think we might have seen a similar slide yesterday, again the OEM panel is primar- -- is made up of members of AdvaMed, MITA, and MDMA. We are manufacturers of medical equipment. We support this equipment in a variety of different ways and many of the OEM organizations are also third-party servicers or provide multi-vendor service.

A disclaimer as I get started in the presentation. As I make a reference to service, I'm kind of encompassing the five different Rs we've been talking about through the workshop.

So what I'd like to do today is discuss we've been challenged -- or asked to talk about the challenges of providing good service. And when -- as an OEM one of the biggest challenges we run into is dealing with incidents of poor service.

So there is a wide variety of service that's provided out there by a wide variety of service providers. Those providers are OEM and non-OEMs that do -- there are several of them that do good service. We've met them, we've heard from them, they are here

in the meeting today.

We also, though, do encounter poor service and that creates a variety of challenges for us. It does create concerns for an OEM of patient safety and operator safety. It creates issues or concerns for the owners and operators who have been left with poor or non-functional equipment and service providers that will even refuse to return to correct the equipment.

It places a cloud over the entire industry. I mean, we're here today and we're listening to the ISOs that do provide good, quality service; yet, there are concerns that the OEMs are raising over the poor service.

So they're providing good service, but they're being drawn into the question because of others that provide poor service. And it creates a need to find a way to provide or prevent poor service. Provide good, quality service or prevent poor service.

So I'll do a couple of quick examples here based off of some things. I know there's a common -- the anecdotal concern that keeps coming up.

First one I have here quickly is a wire that

was repaired in a system by soldering a grounding wire back together and then just wrapping it in some electrical tape. It's a simple example in that, you know, the comment came up yesterday put a green light on the system that tells us when it's been repaired right.

I can put every green light in the world on the system, it's not going to tell you when a poor quality repair like this has been done. And this creates safety concerns for grounding, for people in contact with the equipment. It certainly violates manufacturing practices and it certainly violates the UL or ETL style rating that a piece of equipment may have.

Another example is an ultrasound probe. Here his probe was repaired by a third party and they replaced the material on the end of the probe with a material that may look compatible, it may be biocompatible, but the material, itself, impacted the operation of the probe and impacted the transmission loss.

So if this probe had been used or is being

used or was used, the image would have been degraded, it would have been darker, the signal would have been lost, the detail would not have been there. You know, this is a vaginal probe so I can't speak to, you know, experiences with this, but I can't imagine a woman out there that would okay with a third-party probe that, well, maybe we'll have to run the scan a little bit longer or maybe we're going to have to repeat the process again because the probe wasn't repaired to proper specifications.

And the final example I have this morning today, I believe we saw this also yesterday in Peter Williams's presentation, was a nuclear medicine camera where the service on it had been degrading to the point to where several of the pixels were masked in the image. And the result would be an image that could be undiagnosable, could cause things to be missed, may require additional scan time.

And in this example the third-party servicer just refused to return and correct the problems with the system. And the customer finally had to call in the OEM to correct the issue.

So, you know, how do we prevent this? How do we try to avoid this? You know, and this is where you've heard it a couple several times now the OEMs believe that a quality control system will prevent this. And the ISOs that are here said they have quality control systems to prevent this.

The problem today our concern is that only the OEM providers are required to have a quality control system across the industry, across all areas. We've heard that there are quality systems required in some of the hospital environments.

But I believe in the previous panel the question came up what about when we're dealing with an out-patient environment, a standalone imaging center that doesn't fall under some of those requirements, how do we assure that patient care is matched in those environments?

So there are, you know, ISOs out there that are not operating with a quality system today. And the challenges that we see with that is it does create this lack of recordkeeping, it does result in lack of training requirements or maybe no training at all.

There may or may not be documented work procedures. There's, you know, very questionable parts qualifications at that point where are the parts sources, how are they qualified, how are they verified.

And there's a lack of industry standards that makes it more difficult for customers to sometimes differentiate between suppliers. You know, is their quality system good? Does it meet what would be required, you know, by the FDA?

So diving a little bit deeper into the -- some of the items within that list. The device service history. What type of challenges does that represent to us as an OEM?

Again, it's not required today for third parties. Some of them do maintain that. We've heard from the hospitals that they maintain that, but it's not maintained everywhere.

When a customer ends up with a resolved -- an unresolved issue the OEM will get called in, for example, in that -- that nuclear med camera. So we may walk in and we don't know what was done with the

device in the past. Finding the root cause of the problem could be much more challenging.

It may be difficult or at times not even possible to repair the equipment. We might have to say that the equipment can't be repaired and, therefore, take it out of service and then we're unable to meet the lifecycle expectation of that piece of equipment because of what's been done to it.

Labeling is a common concern. When a piece of equipment is serviced by a third party there's no requirement for it to be identified that way. And concerns we found is that patients may wrongly believe that the OEM maintains the full knowledge or the responsibility for the performance of the device.

The devices could be modified or altered without indicating that they no longer meet the OEM specifications. And, you know, what type of impact might this have on that equipment operation?

The OEMs may be unable to return or repair -- repair or return that piece of equipment to service. If it's been modified an OEM would be in a position where if can we -- can we repair and return

that piece of equipment to service and know that that modification is acceptable if we don't have the standards and expectations for that modification.

And in the long run it could result in a decrease in brand name value when poor services cause poor performance.

The complaints and medical device reporting you've heard a lot about the reporting that has been done and/or the lack thereof. Some of the non-OEM service providers may not be familiar with the requirements of both complaints and significant events.

And that's one thing there's been a lot of discussion about, significant events. We haven't talked much about complaints, when a customer files a complaint about the performance of a piece of equipment, the deficiency of the piece of equipment. Is that complaint documented, tracked, investigated, and kept on record?

So those complaints and other issues they're not necessarily reported to the OEM. Many of the examples we have right now are after we're called in

after the problems the existed. We don't know what all has occurred in the past.

Device issues may be unknown or unresolved for an extended amount of time due to the lack of the performance data. Maybe there is something going on out there but we're not aware of it.

Problem could be attributed to the device or it could be more related to poor service. The operator, the doctor that's using that piece of equipment, may not know that the reason it's not performing well is because it's the service that's being done on the equipment verse the device, itself.

And the scope of the improper services is relatively unknown. It's difficult to document. Again, the reporting has been limited. We have examples of it and there's more and more coming in every week to each one of the OEMs. But the overall scope and scale and how long it's occurring out there is difficult to get our hands around.

The recalls, corrections, and removals. And it falls on the responsibility of the OEMs to get this done. And the challenges we bump into here is when

equipment is resold, relocated, or moved around it's not traceable and we lose track of that and it's more difficult to notify people that own that equipment if they might have something that has a pending recall on it.

Operating a non-repaired piece of equipment can present a safety issue for the patients or for the owners and operators. And in the long run it could end up impacting the reputation or the liability or the financials of the OEM or the owner operator if they have a problem with that device.

Product liability. Again, adverse events can -- will significantly involve the OEM when they occur and when they are filed even if the events not caused by OEM activity.

It could be difficult, then, once we're called in to do the investigation to determine if the -- what party's responsible for the previous work that was done on that device if there's no clear service history on it.

A lack of a detailed service history can impact the root cause investigation and prevent

failures -- or prevent future failures from occurring. Even if the non-EOM party can be identified, we may not be able to separate ourselves from the event and still be kind of drawn into it to the extent that if it's -- if there's a harm and you know there's going to be a lawsuit and eventually the OEM kind of gets drawn into it as the deep pockets in the process.

Incorrect parts. We've observed a variety of incorrect parts. We've seen used parts, 3D parts, or parts that clearly haven't been tested or validated before they've been put into a piece of equipment.

Yesterday the example of a wood screw used inside an injector and the safety, you know, issues that presented. Again, there's a question of access to parts have been brought up, but, you know, using something that's just severely deficient, you know, and questionable in an MRI environment, too, brings up a concern.

These do present safety risks to the patients and to the operators. They can violate the nationally recognized testing laboratory such as a UL or an ETL listing on that piece of equipment. And in

the end run they can cause poor or incorrect system performance, such as the probe we were talking about earlier, resulting in a failure, delayed, or incorrect patient care.

UDIs been brought up as something to help improve service process and there will be some benefits to that, but we also believe that when we're looking at third-party service it also still presents some challenges.

UDI identifies the original device source and the information from production, but it doesn't always go to the part level of the system so non -- where the non-OEM work can often occur on a device.

Traceability can be lost as soon as that device is serviced by non-OEM file -- or a non-OEM service provider if there's not a detailed history requirement. And there's no requirement of a non-OEM organization to modify or remove the UDI from a piece of altered equipment.

So kind of summarizing everything here I've covered a lot of points very quickly to try to stay within our time limit. But when we look at the five

Rs here, this work requires adequate employee training for the work being performed. How are we assuring that that's being provided across the industry?

The work procedures, the documentation and recordkeeping are needed. How, again, are we assuring across the industry that that is being done?

How are we assuring that properly sourced parts are being provided and validated parts and how are we assuring that we're adhering to the defined quality systems adequate to the work that's being performed?

So, again, as the OEMs have said, we believe that the QSR system covers this from front to back end completely and that's why we believe that that should be investigated as an opportunity going forward. Thank you.

MR. LIPSHULTZ: so can we start?

MS. ROSS: Yes, go ahead.

MR. LIPSHULTZ: So my name is Alan Lipshultz and I'm an expert consultant for Healthcare Technology Consulting, but my background is in clinical engineering. I'm going to give a brief introduction,

but then Scot is going to take over after that.

My -- the biggest challenge that I think the whole group faces is a lack of good information about what would be the benefits from regulation that will reduce the issues and the risk raised by the ISO community and the OEM community.

And without more information, I don't think we'll begin to -- ready to even think about beginning to say that regulation is going to solve those problems until we get more data.

Specifically, I would like to see the OEMs really start to stratify what are the high-risk devices that we're really concerned about. There's a whole wide variety.

I suspect if we look at the representation of the OEMs here in the group that there's certain industry segments that are highly represented and they're the ones where the issues are really coming up.

And there have also been discussions that it's the good or the better ISOs, the better hospital organizations that are represented. I think that's a

fair assessment. But we need to get more data about what's really happening out there. The OEMs are in a very good position to gather that data in terms of really starting to build a database of what is going on and so we can start looking for patterns.

I would like to see the manufacturers, as I say, identify whatever the high-risk devices, but even within the high-risk devices I think the manufacturer already has their risk assessment where they've gone down and done something like a failure modes and affects analysis where they know what are the high-risk safety critical components for which if someone were to put an improper parts replacement in there or do a poor service maneuver regarding that device, then there was a risk induced.

And as a manufacturer given they have overall responsibility to reduce that risk I'd like to see if you structure this whole thing in an FMEA type manner and then bring it to the user industry in hospitals, if you bring it to the ISO organizations, they know what an FMEA is, they know how to talk in that type of language in terms of here's the

situation, here's the risk, here's the probability and list the different ways of mitigating the risk and let's have a discussion about that as an organ- -- as an institution -- as, I'm sorry, as an industry before deciding necessarily that regulation is the way to go.

For -- and I'm just tossing out one example, but I could think of many. There was discussion about why do ISOs, why do hospitals substitute parts.

One very valid reason is they don't have access to parts, another valid rea- -- or valid reason at least in their mind is that it's cheaper to buy what they believe to an equivalent part from an alternate source.

Give them some information as to, A, why it is better to spend the more money to get it directly and get the OEM part. That might motivate them. The other thing to do is possibly from a manufacturer if you really want to reduce risk maybe it's worthwhile cutting the price on the parts that you're charging.

Even if it's at a loss, that's still mitigating a risk. You'd be spending other ways -- money other ways to reduce risk. Maybe there's some

tradeoffs there and maybe the different OEMs really need to address that.

But I think there's lots of opportunities to try and close the gap before we start jumping to solutions. And with that, I'm going to turn it over to Scot.

MR. MACKEIL: All right. Thank you very much. My name's Scot Mackeil. I'm a biomed in the OR at Mass General Hospital.

And I'm going to put out this disclaimer here. I did not come here as a representative of Mass General Hospital nor do I speak for them or represent their interest. I came here because I read that this was happening in the biomedical journals and I decided that I needed to do what I needed to do to be here and bring the point of view of biomeds from the workbench to the panel.

Panel 3 speaks to challenges stakeholders face. In light of today and Thursday's spirited dialog my outlook as a stakeholder has changed dramatically.

Quite a few of my beliefs about our industry

were quite seriously challenged in the discussions. As a panelist in this conference I hope by contribution is relevant and the value to the FDA, my colleagues, and the OEMs in the room.

For me, the good news is that when the big picture is considered things are relatively good for hospital-based services like myself. In spite of even the biggest challenges I face in the course of my job, I'm able to service the needs of my caregivers and deliver safe, effective support services with excellence.

But there are more than a few challenging cases that equipment manufacturers do not support me as I would like them to in terms of service manuals, software, and parts. This is some of the areas that the FDA could take action on and have a great deal of positive impact and benefit to our industry and improve the quality and safety by removing these serious challenges.

In light of the stories I heard from many third-party services, my support issues are pale in comparison. And I hope, as the FDA moves forward,

they will find the right remedies.

The past is past and tomorrow is the future. Some of the big picture issues we discussed define our future challenges. Thursday there was a lot of encouraging dialog as manufacturers and ISOs talked about being on the same page when patient safety was discussed. There was agreement on correlations between patient safety and collaboration between HTMs, ISO, and manufacturers.

The need for standards of performance and quality were obvious to all of us. The relationship between affordability of technology and the healthcare systems ability to delivery affordable care was discussed and acknowledged.

A few manufacturers and industry lobbyists expressed their frustration with cases where their products were serviced poorly by others and patient harm was possible or could have occurred.

My biomed ethical compass tells me this is never acceptable and there is no excuse. This never would have happened on my watch.

Sadly, every industry is undertaken by man,

including medicine and technology, will always have occurrences of unintended outcomes no matter how diligent and vigilant we all are. The airline industry is far ahead of us in safety management practices and still tragic accidents occur.

If the services that produced those bad examples had access to comprehensive service manuals, training, and parts would the results have been different? We may never know. And, by the way, again, those types of things wouldn't happen on my watch.

That same ethical compass tells me that the anti-competitive practices I heard examples of are not right either as Tom Green points out. But the single most impressive speaker that I heard yesterday was Katey Ambrogi from the FTC.

I heard her speak very clearly to challenge these fair trade issues and the issues of affordability, fairness, and competition that are very relevant in this discussion. Even more encouraging was how she said the federal agencies, including the FDA, had a general mandate to ensure the nation's

consumers are served by companies that do business in a fair and equitable manner.

Affordable healthcare is not just a national imperative, it was one of the -- it's one of the greatest challenges our nation has ever faced. Each of us is part of the solution.

This week's headlines have brought us news of projected 25 percent increases in affordable care insurance premiums and sharply rising deductibles in the coming years. There were also mentions of federal subsidies to soften the impact of the increases on lower income Americans.

The cost of technology, support, and service factor into the total cost of America's healthcare. In light of this, the FDA could consider this in its role as our regulator.

Our healthcare technology industries could rethink their approach to their third-party ISO counterparts in facilitating healthcare support services to be delivered more economically, again, Tom Green and the ISOs.

As a consumer of many of the healthcare

technology industries products and services I could see a lot of improvements for opportunities that would have a positive impact by benefit -- and benefit by eliminating these challenges on the overall affordability of healthcare and technology support services.

Not only as a biomed, but as a responsible citizen and taxpayer I would vigorously encourage the FDA to collaborate with the FTC in the manner Katey Ambrogi spoke of.

As a biomed whose number one priority is service to my caregivers and the safety of their patients, I do want to maximize the ability of myself and my colleagues to do our jobs to the highest standards while being mindful of and doing the job in an affordable manner in support of our nation’s goal of developing affordable -- excuse me, delivery affordable healthcare.

To meet this challenge, biomeds need access to comprehensive service models, as in the VA model presented by Sal Tatta. The job of a service manual is to provide knowledge and procedures so that the

biomed can read and study that manual and become qualified to service that device.

Service and repair procedure must be plainly described and utilize standard tools and test equipment. If the device delivers energy to a patient, the manual should describe how to measure and verify the energy output is accurate and how to calibrate it.

PMs (preventive maintenance) procedures should be written to sensible industry standards and help biomeds and healthcare institutions comply with CMS and TJC requirements.

Complete drawings, diagrams, schematics, including wire diagrams for patient cables and accessories, are essential because when you’re a biomed reading a service manual you want to develop an understanding of that device so when you’re standing there in the fire next to a surgeon who’s looking at you with that eye over his mask you can do your job.

Descriptions of how to access data, error codes, log files, and communication protocols are necessary for diagnostic and cybersecurity purposes.

Complete itemized parts lists and diagrams that include the manufacturer part number and part source and original part number is necessary to address the issues of sustainability after the manufacturer stops marketing the device.

I would challenge the FDA to very clearly define that any document labeled as a service manual be exactly that and apply a QSR to them as the manufacturers have requested.

Biomeds also need access to purchase repair and maintenance parts and device-specific service tools and fixtures at a fair market value without undue restrictions, as per Katey Ambrogi's comments.

Lastly, biomeds need access to complete comprehensive training that is no less rigorous than the manufacturer would provide to its own services.

So I hope the FDA will consider this and make it so for biomeds and third-party ISOs and the other five Rs. I have hope for the future based on what we all know is best practice as discussed yesterday and today. And I hope that the FDA and manufacturers will ask -- act in the best interest of

patient safety and affordable care. Thank you very much.

DR. DOMINITZ: This is Jason Dominitz from the VA. You know, I've learned a lot over the last 24 to 36 hours and, you know, I've been thinking a lot about this issue or what are the challenges here is what we're supposed to address.

And if I were to leave the VA where I'm very fortunate to have strong clinical engineers supporting my practice, if I go out into my own practice in an office-based endoscopy unit or ambulatory surgery center and I want to have somebody service my scopes, my electrical surgical unit, and my reprocessors, who do I know that the person who's going to do that service is qualified?

How do I know that they have access to the parts that they need?

How do I know that they've got the manuals, the training, and the ongoing training?

What processes are in place to assure that?

And that's my challenge to this group is to answer that question. How do you support the end user

to know that they're getting the right service?

That's all I have to say. Thanks.

MS. ROSS: Okay. At this point, since you've heard the presentations, we'll now take any questions from the floor. And just, you know, kind of a reiteration from the previous panel, you know, this is about challenges. So let's try to stay focused on that topic.

There is, you know, another session later that's talking maybe more directly about solutions.

MR. LIPSHULTZ: Can I ask a question?

MS. ROSS: Yes.

MR. LIPSHULTZ: So whenever you call it.

MS. ROSS: Sure. Well, what -- why don't you go ahead and start us off with your question, then.

MR. LIPSHULTZ: So my question is to --

MS. ROSS: Remember to please identify yourself for the transcription.

MR. LIPSHULTZ: Sure. My name is Alan Lipshultz from Healthcare Technology Consulting.

I wanted to ask the ISO group there was --

one of the bullet points was wanting the ability to get recalls and safety bulletins directly from manufacturers.

Wouldn't that imply a form of registration to be able to say I'm an ISO, I repair this manufacturer's product? Otherwise, how does -- there's got to be a database somewhere to be able to say that when a recall comes out on a particular product if it's going to go to these 50 ISOs around the country, then somebody's got to have a database to know who that is, where they are.

So call it official registration or not, it's some sort of communication to say I'm on the list which also gives the manufacturer, the OEM, the benefit of knowing just who it is that is actually providing the support because a lot of times they don't even know who the different ISOs are who think -- who are claiming to be supporting their product.

MR. GREEN: Thomas Green, Paragon Service. I don't think there's any ISO that wouldn't want to register with an OEM to say send me information if there's a registration process. I don't think anybody

would object to that.

However, there's a simpler way and that is obviously they have a database of individuals that have attended their service schools. They also have a database of who purchases parts.

And from that database they know that the individuals or the companies are servicing the equipment; therefore, they could contact the individuals or the companies. I don't think it's a difficult procedure.

MS. CONDON: My name is Linda Condon and I am an end user in a hospital setting. I'm the Director of Sterile Processing so I've got a different perspective. And I have listened over the last two days or day and a half to all these points of views.

I have a question, though, related to the parts. Because what I've heard is that there are many vendors and I don't know if it's like a total vendor that doesn't sell any of their parts or if there's just various parts that different vendors don't offer out for sale, but at the same token I've heard that the ISOs are indicating that they are using other

parts if they can't -- aren't available by the vendor. But is it always if they're not available?

So my question is is there any idea -- or any way to know what parts are actually available and what aren't?

Are you always purchasing from the OEM the part if they are actually selling those parts?

And is there a way to determine, you know, a database associated with that availability and is there any reporting associated with repairs that are being used with other parts?

MR. SPRINGER: Yeah. I'll take that. My name is Rick Springer with Alpha Source.

So a couple -- you had a bunch of things in that --

MS. CONDON: Yes.

MR. SPRINGER: -- question and I appreciate that very much. So in regards to always knowing whether or not parts are available, you know, often times it's very difficult to find that out. Even when you call into an OEM to try to get a description of a part or just an identification of a part or

availability of a part is very, very difficult.

If there is a part available often times what happens is there could be delays in getting that part. And you heard some of it echoed by what Tom put in the presentation. There are several gates in some respects in regards to training, individual qualifications, and those types of things that are available.

So generally what we will do is the inclination is to go to the OEM first because you want to go ahead and you want to use the right part in every single situation.

If in the event you cannot obtain that part, then you begin to look at other -- other sources, other ISO providers, some of the folks who are in the room here, as well, to go ahead and put the part in place.

But you begin to go through a process on qualifying those vendors, as well. It's not just opening up a magazine and finding what's available. You have suppliers that you've worked with. And speaking in regards to my company, we have a very

robust QMS system. We are 1345 2003 certified. We do qualify our vendors. So we will go down a list of suppliers on who can provide us that part and those services. So I hope that answers it.

MR. NESTEL: This is Jim Nestel. I'd like to respond to a couple parts of your question there.

You asked about if there's a database being used to track when non-OEM parts are being used. And to my knowledge, no, that doesn't exist. Now, each service provider probably has within their system what part they used or where they might have sourced that part, but there's no global database for that use.

There's not a requirement that I'm aware of right now that says that somebody you have -- that a service provider, be it OEM or a non-OEM, has to notify somebody if they're using non-OEM parts. You could require that of your service provider that you'd want them to do that.

And there's no requirement that it has to be done. And I've seen specific examples right now where even when you don't need the OEM part, the part that's inside the system is a -- is a power supply that you

can buy off the shelf.

Rather than buy that part off the shelf for $150 they bought a low-cost part and installed it literally. Rather than replace the parts by unit, they bought probably a $20 power supply at a Radio Shack and plugged it into the wall and connected it into the unit and violated all of the standards for maintaining that device when the OEM wasn't really needed in the process at all. They just went with the cheaper option.

MS. CONDON: Can I ask one more question? I think it's relatively simple. But we -- I've also heard in the last two days all the different reporting agencies, whether it be the ECRI or Joint Commission or whatever, as far as patient deaths and/or injury and that the category actually it being repair related wasn't in play.

But I was wondering as far as the classification of those deaths or injuries is there an unknown or other category and are we looking at those as in we didn't really determine what the root cause was about the medical device and looking at how that

may play into that there's actually -- I do believe this is very underreported, but ultimately those other classifications that may have been misclassified.

MS. ROSS: So that -- that question actually I'm going to hold for now because I think that goes a little bit more to reporting processes rather than challenges --

MS. CONDON: Okay.

MS. ROSS: -- that the -- that the system's facing. So thank you for your question. And we're going to go now to the back mic.

MS. WILLIAMS: Hello. Nicole Williams, microbiologist, Medical Optics, third-party repair company.

So I think we all can agree that patient safety's number one. All the ISOs that are -- have taken the time to come here today they do a very good job. We all use our raw ISO 9001 or 13485 compliant and we have our registers.

And as I sit here and listen to this I feel like we're still on a very separate OEMs, everybody else in the room. And I think it's very simple. I

don't think the challenges are very hard as that we make them out to be.

And just to the first question that was posed up on the panel, I think I -- we're very happy to register. We -- I -- we do some work for some companies where we're certified to do their repairs. And if we have a complaint because we have a robust complaint system, we send them the complaint on their items. We actually fill out their complaint form.

They have their quality management teams comes to our office, they certified that our complaint system is fine. There's -- there would be no problem with, hey, I call up Pentax and I say, you know, we repair your parts. We're -- we repair your scopes. We're 13485. We invite you to come over. We would like to be a qualified vendor, someone that you trust as opposed to Joe Smo's garages I like to say.

But you have to -- I don't think we need to make it as difficult as it seems. It would just be -- we would be like another vendor in your system. We have to be qualified, you know, meet your standards, your ISO standards. We're already meeting those

standards.

If you have another form in place, that way you're getting the same thing that we already do. We're providing you complaints. You can have our device histories if you want. And that way that's going to weed out all the others because now when we go to a hospital who doesn't maybe want to spend the money on an OEM and they want to use a third party, we can say, look, you have these devices. These OEMs say that they've inspected us, we do a good job, we can repair your devices.

You know, that holds a better weight and that's going to weed out those bad companies that use bubble gum to repair things. And hold us to -- that's going to hold us to a higher standard and help us keep -- you know, we're going to want to keep that certification from you.

And I think that might be a better way to go. And but, again, there has to be that collaboration. That I still feel like unless somebody forces some people's hands, it's not going to happen.

And would -- my question I guess would be

would the OEMs in the room be okay with doing something like that because you'd still be in control, but would the FDA or someone have to force your hand to do it?

MS. ROSS: Okay. Ma'am, I'm actually probably going to slightly just rephrase the question that you just had for the kind of potential solution that you just offer.

What would be the challenges to having a process like that allowing, you know, OEMs to certify ISOs or others to be certified repairers of their equipment?

MS. SHRADER: So I can address that question. I think those kinds of arrangements do already exist in some instances within the industry. As we've been talking over the last couple of days, first of all, I would point out that practices at different companies may be different. And in some cases there may be very good reasons for that so I'll speak as just one company.

We do not expect to be able to service all of the equipment that we provide to hospitals,

clinics, physician's offices. We're well aware that hospitals have biomeds who are quite well trained and can perform these services as well as we can and we try to make sure that they've got the information that they need to do that.

We are also supportive of independent organizations coming to us and saying, you know, we'd like to learn how to service this. We've -- I don't believe to date that we've actually then certified somebody to work on a particular type of equipment, but I think that's an idea that's definitely worth looking into if there's general agreement that that would be helpful.

MR. SPRINGER: I can add some comments, as well. This is Rich Springer with Alpha Source. So it's interesting, I work for an organization right now where we actually are what the -- what the question refers to.

So we provide services for end-of-life products and contemporary products for a major OEM right now. So I abide by all of their rules, all their regulations, I follow their procedures. There's

hand offs from their center to ours. We warehouse all their parts. I'm audited by them on a regular basis. I need to go ahead and fill out and comply with the compliance, do state registrations, 1279s.

We also make products as well not only for the aftermarket, but also for OEMs. So, again, I follow along with all of the FDA requirements in terms of making a Class II medical device, put everything in place in regards to that, follow the -- all the regulations associated with it.

And then we also act as an ISO, as well, where in some cases we provide services to outside and we go ahead and we do that on a regular basis. And we follow our own procedures, we abide by the QMS that we have in place, we follow by the ISO 13485 standards.

So I think it can work. It does take a little bit of work. It takes a little bit of cooperation, collaboration. But I think, you know, there are illustrations not only just to the company that I work for, but also in the room where that level of participation could be effective.

MR. GREEN: This is Thomas Green of Paragon

Service. I'd like to also address the question.

And that is in the last panel the last question was towards the OEMs about whether or not they would support ISOs. And the response twice was our customers are the hospitals and that was the end of the answer.

In other words, ISOs are our competitors. We don't like our competitors. We don't like competition and we don't plan on supporting them. And if we could get the attitude of the OEMs that ISOs are customers also of the OEMs -- purchasing parts, paying for schools, et cetera, et cetera -- then we could change that whole attitude that we're supporting their equipment.

And it goes back to our recommendations to the FDA from our committee.

MS. ROSS: Front mic?

MS. KLACIK: Hi. I'm Sue Klacik and I am with the International Association for Healthcare Central Service Materials Management.

And my question's very similar to Linda's. The last two days I've heard a lot of testimony about

shoddy workmanship, especially this morning. But all those stories, you know, and the pictures they don't seem to quite add up to what the ECRI is reporting.

So is there a disconnect? So this morning, James, you had talked a lot about shoddy workmanship. Was that reported through the ECRI that it would have shown up?

MR. NESTEL: So, no. I can't say that all those were reported because the question becomes when does it get reported into ECRI? And we're into those databases and we're looking.

Typically what trends up into those are the significant events. And if they haven't created a significant repent -- event, all of those are not going to report up.

The question becomes how many -- how long do we allow that questionable service, that poor service, that risky service to go on before we say, okay, we've got to, you know, find a better way to control and monitor this and regulate -- you know, regulate it, whatever term you want to use. How do we, you know, improve that quality and prevent those problems?

MS. KLACIK: Well, my two end users in here, Dr. Jason and Linda, we really want everything to be perfect each and every time for the doctors. When I give an item to the doctor I expect it to perform exactly as it was designed and intended to each and every time.

So you had shown pictures of the vag probe. I would never give that and I think that's something that should be reported because we would not accept that in a healthcare facility.

MS. ROSS: Okay. And so I'm just going --

MR. GREEN: Can I -- can I respond to that real quick?

MS. ROSS: Go ahead.

MR. GREEN: Okay. Great question also and it comes back to, as Jim was talking about. Here are medical devices that are being malserviced or perhaps was this person factory trained to work on this device.

If they weren't because the factory -- the OEM wouldn't allow them to be trained, shame on the OEM if the school's available, okay. And if the

school's available and the service provider didn't go to school, shame on them.

Does this service provider have access to OEM parts? It all comes back to the cooperation of the OEMs to the service providers. And do they have -- are they properly trained by the OEM? Can they get parts directly from the OEM?

And in short of that, we meet a year from now we're going to see more of those pictures.

MS. KLACIK: And like the doctor said earlier, as a user I want to be able to know for sure that when I give a medical device to a repair company that they do, in fact, have the competencies and the repair parts to repair the part so that it is back to new condition. That it is functionally equivalent to a brand new product.

MR. GREEN: So I'll do a follow up to that real quick. And that is when a service provider comes into your facility, make sure they're qualified to do it and make sure that they show you the certification, whether their company is certified by X, Y, Z company or that they have an individual that's gone through

the school. Where do you get your parts?

Do your due diligence. Find out are they qualified, where's your training, where do you get your parts from, do you have liability insurance, reference lists, the whole thing. Make sure that the company coming in is up to your standards.

MS. ROSS: And -- and -- yes.

MR. LIPSHULTZ: This is -- I --

MS. ROSS: Yes. We're going to let Alan have the last comment on this and then we're going to move onto another question.

MR. LIPSHULTZ: So I -- let's take the vaginal probe. In general when you're dealing with outside service or even in-house service through a clinical engineering group, there's no reason why user groups can't ask the service organization that's supporting them to say that you need to know -- and as part of your contract you need to know if they're going to use non-OEM parts at any point in the process as a disclosure so that -- and what process they went through to qualify those parts.

And that's a good question that user -- the

consumers, namely the healthcare providers, can use as a check that they're getting something that's adequate to show at least they are aware.

MS. KLACIK: Can I say one last comment?

MS. ROSS: We're going to need to move on, but thank you very much. So I have a question. This is from online and since we were talking about parts it's in that vein. And it is talking about, you know, how, you know -- I'm sorry.

What kind of special terms or things like that -- I think you were kind of referring that in your contracts you could have so that they do have to report, you know, whether they are using, you know, OEM parts or replacement parts and how -- what kind of processes are outlined for qualifying those parts.

So I would like, I guess, from the ISOs perspective I think this is going to is how do you qualify parts, one, when they're not OEM parts and then, two, you know, asking -- or having that in your contract about disclosing what types of parts are being used and how common that is.

MR. GOLDNER: Jim Goldner from First Source.

We have a very rigorous parts identification program and validation program. We have test bays in our offices and we quite often collect used parts. We buy equipment, break it down. But we also have equipment that's running to manufacturer's specification that we retest those parts. And we clearly sell those parts as used, tested and always with the same warranty as a new part.

Often we would prefer -- and there are certain parts like power supplies we never sell used. I mean, they have a life. They don't last that long. But other parts you can recycle and it can be effective.

A lot of times you're forced to do that because some new parts are just extremely, extremely expensive. Sometimes you can get into a machine that's kind of at end of life and a power supply can be $8,000. And you can buy a used machine, entire machine on the used market for $1,000. So, I mean, there's just some things where just the economics of it it's just the way it works out.

Most times we prefer in my business to use

OEM parts and often we are restricted. Certain manufacturers will call. First question, what's the serial number of the machine you're working on? Nothing about who I am, what my qualifications are. It's, nope, you're not on the list. You can't buy the part.

So they're -- they have very effective ways of discriminating about who they sell to and it is a challenge. And I think we've heard that over and over here yesterday and today access to service manuals, access to parts, and access to service software is critical for patient safety.

MS. ROSS: First mic?

MR. MCBRIDE: My question -- Jeff McBride from Red Lion Medical Safety. We service anesthesia machines, biomedical equipment, and medical gas systems.

My question is to Scot or first question. You mentioned that safety recall notices, product bulletins, and everything else are important to your operation.

Do you receive those on a regular basis?

MR. MACKEIL: Yes. I do receive product recalls and safety notices on a regular basis. And I have to give props to ECRI because I read their weekly alerts bulletin. And in doing so not only do I scan that for things that directly might affect me and my inventory that I'm responsible for, but it allow -- by seeing overall trends in medical devices in all segments of the industry it helps me better understand the challenges that I might be facing with dealing with equipment of similar types as I go about my duty supporting my caregivers.

MR. MCBRIDE: Do you get them from OEMs?

MR. MACKEIL: So we get specific device recall letters through our quality and safety office that has a dedicated staff members that do that and also from materials management.

You know, in a 1,000-bed hospital you can imagine the scale of that. And when I was in a 120-bed community hospital not only -- not only was I the biomed, I was the biomed director. I had to go to all the safety meetings, I had to report to the risk manager, and I had to maintain the product recall

notice book in conjunction with the risk manager. And that was a very small scale thing.

So we got those letters and we acted upon them as they required.

MR. MCBRIDE: We service -- or we've gone to OEM training classes, we've -- one of the manufacturers had up to five years ago three anesthesia machines out there that were on the market. We have received over those five years one product safety recall. One from OEM.

My next question is, Mr. Green, could you elaborate on you said the endorsement policy for the training? I didn't understand what you meant by you have to sign that or have somebody -- a facility sign that.

Can you only service that one facility?

MR. GREEN: I thought I -- you know, reading their pol- -- the company's policy, which is still in effect, and I did state after reading their policy that you can only service that one facility with that one service rep on that one device.

So if you send someone to the school and

five miles away there's another hospital that has the same exact brand with that model of machine, I can't send that service rep over there. I have to send another service rep to the same school to service account number B, which is anti-competitive.

MR. MCBRIDE: How many facilities in your area have that I guess one type machine? How many facilities would there be?

MR. GREEN: The one that comes into mind that -- the school that I want to go to but I just can't justify it economically, last count there were 800 of those machines in my geographic territory that I cannot service.

MR. MCBRIDE: But how many facilities do you --

MS. ROSS: Excuse me. So you're on question, I believe, number three at this point so I am going to ask in the interest of time before lunch that, you know, the people who are the mics now you ask one question so that everyone who is currently standing -- and we do still have one more online question that we'd like to get addressed can get

addressed before the break.

MR. LIPSHULTZ: I'd like to respond to his question.

MS. ROSS: Yes. You can finish responding to his question, but that really needs to be the end.

MR. LIPSHULTZ: It'll be quick. I was director of clinical engineering for a major institution that had thousands of manufacturers. So that if I looked at the number -- the volume of recall notices and alert notices coming in, yes, there were many of them over the year, but they were not necessarily if I took one manufacturer or two manufacturers I might not get any for five years from that manufacturer.

It's a question that when you're in-house you're just dealing with a much greater variety than as in ISO particularly in one specific area looking at a couple different manufacturers. The volume is going to be very different.

MS. ROSS: Back mic?

MR. FORSELL: Okay. Thank you. Ray Forsell, University of Vermont Technical Services

Partnership. I'm a clinical engineer.

So I have one comment and one quick question. The comment has to do with the fact that healthcare providers routinely have to use equipment well beyond the end of support dates of the actual manufacturer. So having parts available on the, you know, the third-party market is essential to continuing to provide quality care in the tough times that we're in. So that's just a comment.

The other question I had is really directed at OEMs and related to information flow and the QSR. And that's the sales reps are very often involved in problem solving. Whether or not they're qualified is another issue.

But does your system or your systems adequately intake those interactions, which very often might be sticky situations of application and maybe use error and things like that? Are those being taken in as complaints into your QSR systems so that they're actually showing up in your analysis? So thank you very much.

MS. SHRADER: The quick answer to your

question is yes. We are obligated under the quality system regulation to look at all of our -- all the information that comes into us including from service. And we do record every -- we actually record every call. We identify those that are complaints, whether about the product or the servicing of the product, and they are -- they're handled in accordance with our system.

This means we make a decision to investigate, we try to identify the root cause of the problem, and identify a corrective and preventive action.

MS. ROSS: First mic?

MR. SPEARMAN: Hello. My name's Jim Spearman. I'm with Consensys Imaging Service. I'm the President and CEO. I've just got two quick comments and then I've got a question focused for the OEMs.

As I mentioned in my earlier comment, we, as Consensys, we really straddle both sides of this. In certain instances we represent the OEM. We are an approved service provider to those OEMs, but

officially we are an independent service organization.

So two quick comments here regarding notification of the OEMs there's what's called field modification instructions from one of the major OEMs. Any time Consensys takes over a medical device we notify that OEM immediately because we know that the challenges that were cited earlier regarding the removal of those units, transportation, et cetera, the OEMs need to have visibility. So we formally do that, we notify them, and we let them know we are the service provider on record.

With regards to parts, we use almost exclusively non-OEM parts. And it was very interesting because one of our big three OEM service partners came in to audit us and we showed them who we were using -- well, should I say we didn't show them who we were using, we showed them our 104 qualified suppliers. We showed them their chosen supplier that was disqualified in our quality management system.

And the next question was is please tell us who the other 103 were. So there's a lot of good evidence out there that there are good, high-quality

parts in the aftermarket.

My question to the OEMs is specific, it's three-fold. One of the things that we hear a lot in the aftermarket space is a lot of barriers to service, tools, whether they be service manuals, some OEMs will not sell parts unless you own that medical device and other OEMs will create encrypted barriers to servicing those units.

Now that's very interesting because, again, Consensys is an approved service provider to the big three, but they will block us from servicing their equipment. They will hire us to service the other two, whoever the other two are, but they will block us from servicing their equipment.

So I'd like to hear from the OEMs in the regard.

MR. NESTEL: I guess it's difficult for me to comment on that because I can't speak to the other OEMs and how they operate their business. You know, everybody has their own priority and program for how they choose to sell and distribute parts or service. There are a variety of barriers and there's also a

variety of partnerships that are out there today.

But, you know, I can't -- I don't know if you can speak for how everybody else runs their organization. And I'm here today kind of speaking on behalf of the group or organizations. I can't speak individually.

MS. ROSS: Okay.

MR. MACKEIL: Yes. I'd also like to, you know, speak to the question of the gentleman from Consensys. And if I may speak to that in the form of a question to the FDA panel here in the room and Sean Boyd.

And on one side of this room we have Olympus, Hitachi, Pentax from Japan, Siemens, Karl Storz, and Bayer from Germany. The Dutch company Philips, AGFA from Belgium, Medtronic Convidien from Ireland. Ethicon J&J of New Brunswick, Cana -- Canada and along with the MITA and the MDMA.

On the other side of the room we have professional associations representing America's clinical engineers, a number of our top tier third-party servicers and marketers, have the VA hospitals

and Americas Healthcare System.

As I see it out of all this the FDA is the stakeholder facing the greatest challenge here today because in this room we have some of the world's wealthiest offshore global, multinational corporations asking America's FDA to shift its regulatory framework to protect and enhance a portion of these global corporation's service revenue streams at the expense of the American healthcare system at a time when the American government, American businesses, and lastly, you and me, can't afford to tolerate it.

MS. ROSS: Okay. Scot --

MR. MACKEIL: I'm a simple biomed guy.

MS. ROSS: -- Scot, we appreciate your comment, but I know you said you had a question. In the interest of time --

MR. MACKEIL: Yes. Here's the question. That was the setting. Could the FDA see itself doing a 180-degree turnaround on the request by MITA to regulate our third-party servicers and business and instead turn that around and regulate the -- these large multinational corporations to provide parts and

training they need to do their jobs as a -- as a condition for having the privilege of doing business in the United States?

Am I wrong to ask where the FDA's efforts should be directed? Biomeds need the issues repair parts and service manuals, procedures to find and the America healthcare system, including our VA and the working Americans that need affordable care, need the FDA to take a -- to turn this problem around and look at this challenge in a different way.

You know, this is a controversial question, I'm sure. But, you know, I really felt the need to answer it -- ask it. Pardon me. Thank you.

CAPT. BOYD: Right. So you're hitting on a lot of different issues and to some of the points that I made in conclusion yesterday to the workshop, we're here to hear the perspective of all stakeholders involved.

We've even heard today that we -- we need to engage some additional staker -- stakeholders in terms of users of the equip- -- of equipment and patients to understand their perspective and their preference in

this space, as well.

So I can't give you a definitive answer today on what our decision is ultimately going to be. I can say that you're -- this venue and everybody participating is giving us a lot to think about. It's giving us a lot to go back and deliberate.

And, as I've said before, this is not something that FDA is going to go alone. This is not something that FDA's going to solve alone. And I think in terms of what's going to happen after this workshop you'll see additional opportunities for engagement convened by FDA or other stakeholders that have participated in the workshop over the last two days. You'll see additional opportunity for providing comment and input into the solutions and what we think this future state ought to be.

So it may not directly answer the question in terms of a 180 turnaround as you requested, but that's where we're -- we're going somewhere. We need this community's help in order to get there.

MR. MACKEIL: Thank you, Sean, that was great. I hope that wasn't too much of a hardball

question.

MS. ROSS: Okay. And now we'll have our last question that's at the front mic there.

MR. OHLAND: Thank you. My name's David Ohland. I represent an independent service organization that repairs medical lasers across the United States.

I'd like to address a challenge that ISOs face in an effort to provide safe and effective service on a medical device.

My concern is the access to proper documentation and removal of lockout software and my desire that the FDA will be able to effect changes to this evolving policy.

If I could for a moment explain some of the history that I've gone through. 10, 15 years ago I used to work with the OEMs on a very, very good basis. Communication was open, I spoke with them, I was able to purchase parts from them, I had access to service documentation. And in the end I was able to perform safe and effective service on a medical laser.

Something's changed. Today I don't have

that communication going on with OEMs. I don't have manuals made available to me anymore. They're being restrictive and there's this new method of locking out software to prevent people such as myself, independent service organizations, from being able to service a piece of equipment safely and effectively.

And so my question simply is how do you reconcile this dichotomy between talking about having safe and effective service provided when we're restricted from the tools we need to do just that?

MR. LEAHEY: And anybody can take a shot. We represent mostly small to mid-sized companies. And I know from MDMA's perspective no one's out there talking about restricting access.

I think, again, from our member's perspectives if there are issues where we can do a better job of providing the service manuals, I think we're absolutely willing to do that and take a look at that. I think the VA standard out there is one that we'll certainly address.

But, again, from -- most of our members don't have the ability to service all their products

across the country so we rely upon these third parties.

MR. OHLAND: And then if I could just follow up. If this idea that you've just presented -- oh, sorry. Sorry.

If, in fact, this idea that you've just responded with is shared by the whole OEM community, I know -- I know that we'll be able to achieve this goal of providing safe and effective service on equipment.

And if that's truly the goal, then let's work together and get to that goal. And that's all I have to say.

MR. GOLDNER: Jim Goldner, First Source. I've always thought a solution to that problem because it's becoming more and more widespread restriction -- restrictions to service software.

I've always thought that the software, all the rights to it, all the manuals, everything pertinent to any piece of equipment should be given to the end user, to the owner. And then they should have complete say through their quality systems to determine how best to service that equipment in their

environment.

Because in many situations what I see it's very discriminatory. A big health system gets whatever they want whenever they want it. Smaller community hospitals, they have no choice. And there are very few choices as to where you buy some major capital equipment, you know.

MS. ROSS: Okay. Well, that actually was, like I said, the last question from this panel. We're going to break now from 12 to 1.

DR. BITTLEMAN: Hi. This is Katelyn Bittleman. I just wanted to say one more thing about from the FDA's point of view.

We are basing all of our decisions on evidence. So for those -- for -- like Sean had said, we have not made any decisions and we won't make any decisions until we have all of the facts and all of the information necessary.

But we need -- we do need evidence to showcase your opinions and your thoughts on these things.

MS. ROSS: And so like I was saying, you'll

have a break from 12 to 1. Next panel will convene at 1 o'clock so we will see you in about an hour.

(Whereupon, at 12:01 p.m., a recess was taken and reconvened at 1:02 p.m.)

CAPT. BOYD: Welcome back. So this afternoon the first portion of the program will begin with some additional presentations from workshop participants. And, again, due to the overwhelming interest in speaking during these slots, we have several pre-scheduled speakers for this first section. And if time permits, we will open the floor to attendees to kind of add some remarks of their own.

Each speaker is going to be limited to five minutes and I'll thank you in advance for adhering to that limit out of respect for other colleagues who also have comments to make.

And I believe we do have a timekeeper that will give you kind of a yellow card when you've got a minute left and a red card when your time is up so.

Following that session, we'll have our fourth panel on current best practices and future recommendations. That panel will have presentations

from each of the stakeholder groups to include OEMs, service providers, hospital end users, and other organizations involved with standards.

And then each group is going to present their viewpoint regarding current best practices sounding -- surrounding refurbishing, et cetera, and servicing of medical devices as well as addressing any gaps with future recommendations.

And I'm certain we're going to hear opinions on both sides regarding the value of regulation or not regulation. And I would ask each of the participants to also provide more broad recommendations on other pieces of this puzzle in terms of other -- what are the other things that we should be considering in terms of next steps and future recommendations.

So with that, I'm going to turn it over to Tori Wagman and Astin Ross to moderate the participant presentations.

MS. WAGMAN: Hi. Could we ask that the people who have been told to come up so that we can split you off into two groups?

CAPT. BOYD: So I think we're asking

presenters to kind of organize themselves around one of the two mics so that we can alternate between the two and work through all the presenters.

(Brief pause.)

MR. GRIMES: Good afternoon. My name's Steve Grimes. I'm the -- currently the principal consultant in -- for Strategic Healthcare Technology Associates.

I'll give you a little background about, you know, where I'm coming from. I've been in the industry 40 years as a clinical engineer. I've worked for academic medical centers, independent service organizations, and also worked a fair amount as a -- in the consulting arena, as well.

A little more information, I'm a fellow of the American Institute of Medical and Biological Engineering. Also a fellow of the Health Information Management -- Health Information Management System Society and also a fellow of the American College of Clinical Engineering and a past president of that organization.

In recent years and over the last ten years

or so I've been heavily involved in what we've seen as a convergence in terms of the technology that we're dealing with between the IT and the medical technologies.

I'm also a board member of the commission that certifies clinical engineers and also a board member of the institute that certifies -- professionally certifies biomedical equipment technicians and healthcare technology managers.

Also a member of various standards development committees, including those that do medical equipment management standards as well as maintenance standards.

What I'd like to speak to today is, first of all, you know, speak to or talk about how I think what many of us realize is that the industry is going through some significant challenges and will be over the -- in the coming years in the near future largely because of the evolution and adoption of increasingly sophisticated clinical technologies, including things like software and network-based systems, robotics, 3D imaging, 3D printing, micro and Nano technologies and

such.

The nature and speed of this evolution represents significant challenge to regulators like the FDA, to manufacturers, and support services including in-house clinical engineering programs and independent service organizations.

The whole nature of what constitutes support service and maintenance is going to change radically I would suggest given the way the technology is evolving.

Some of the points I'd like to make is, first, I want to suggest that I and my hospital-based and ISO-based colleagues are willing to listen to and work with anyone who has suggestions on how we can provide a safer and more effective support.

We need to take advantage of existing forums and establish new forums as appropriate with all stakeholders. AAMI has -- which is the Association for the Advancement of Medical Instrumentation -- has been an objective convener of a number of these forums in the past and I would suggest they be considered as a convener going forward for some -- you know, if

additional efforts and opportunities are things of interest.

There's no question that better collaboration between the stakeholders is critical now and is going to be critical in the future. Evidence and data's been provided by various stakeholders represented here both anecdotal and statistical data.

A credible case I would suggest could be made by those who've provided the statistics on medical device service and that this service has not historically posed a significant safety issue for patients.

Others have provided anecdotal data evidence of safety problems related to the maintenance they claim that significant data -- and they claim that significant data would exist if the data were collected more reliably and consistently.

The -- I would suggest perhaps that citing anecdotal data would that -- we're making a case where requiring better data -- makes a case for requiring better data collection, but not necessarily jumping into more burdensome -- or what might be more

burdensome regulations.

I'm concerned about adding burdensome regulations when there is no data other than anecdotal that would justify those Regs. I've seen regulations, not fortunately from the FDA, but others that affect hospitals, in-house clinical engineering programs, and ISOs who are acting as the hospital's clinical engineering agents that were issued without there having been any demonstrated benefit.

Those Regs have been a solution in search of a problem. Unfortunately, compliance with these types of regulations often requires valuable resources be diverted from what in hospitals we know to be the real safety issues.

So summing up, I would suggest that we ought to collect and share better data between the stakeholders if we think there are growing safety issues and make our decisions based on real data.

I would suggest that we collaborate between stakeholders to ensure healthcare providers have good choices in their access to technology support services, including maintenance repair. And I would

also suggest we collaborate on best practices and developing standards before considering regulations. Thank you.

MR. OHLAND: Hello. My name is David Ohland. I'm a principal owner of Precision Laser Specialist, an independent laser service company servicing over 2,200 lasers per year.

We began servicing lasers in 1993 making us one of the oldest laser service organizations in the United States. With this background, I'm thankful for the opportunity to share my insight and perspective on this important issue as it pertains to medical laser service.

It's with great concern when I listen to groups trying to restrict alternative methods of laser service. If the true intent is service that ensures medical devices are safe and effective for use by the healthcare providers and patients, then work with us by providing service manuals and removing lockout software.

At the same time I'm encouraged to hear healthcare providers stand up to these restrictive

trade practices. I've spent the last 30 years of my career speaking with medical laser owners who are happy to find out that they will no longer be held captive to these restrictive practices.

Principal owners of PLS each have over 30 years' experience working lasers from research and development to manufacturing within industrial, scientific, medical applications. Further, we've produced our own laser commercially with great success. We feel this qualifies us to provide safe and reliable parts for lasers that we service.

The proof of this is in our spotless safety record, our high customer satisfaction, and resulting customer base. Today's -- today PLS employees qualify technicians across the United States.

OSHA defines a qualified technician as one who, quote, "by possession of a recognized degree, certificate, or professional standing or who by extensive knowledge, training, and experience has successfully demonstrated the ability to solve or resolve problems."

All PLS technicians meet this definition

with biomedical engineering, electro-optics engineering, or electrical engineering degrees. They must go through a classroom setting to learn the theory of a Gibbon laser along with a working understanding of the laser and its subsystems, calibrations, safety circuits, and applications.

They are then put in front of an in-house laser to perform actual hands-on work until they're comfortable with that device. Only then do they go into the field to perform service.

It is this level of training that ensures we deliver safe and effective laser service. We continue to be a qualified laser service provider for a number of the leading laser OEMs and we're also a vendor for other OEMs who have entered into a third-party laser service industry.

Our technicians document and store every service event performed during a full -- performed building a full traceable history for customers to view online at any time.

We also adhere to the CMS SNC 1407 memorandum in accordance with guidelines provided by

the OEMs when made available or by writing our own procedures when an OEM is no longer in business or refuses to abide by the FDA codes. These codes require the OEMs to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures.

Our test equipment is identical to that used by the OEMs and is calibrated regularly to NIST standards. Once a laser is repaired into its proper operation we fully test the system to ensure safe and effective use.

Finally, the service reports are provided to the relevant healthcare professionals that are also subject to FDA standards, state department rules, CMS guidelines, and accrediting surveyors.

With over 30,000 service reports backed up on our server we do not have a single reported service incident involving patient injury or death. Should an incident occur, we would abide by the MDR process to identify and correct unsafe laser devices.

Today -- today's lasers are supported by the OEMs for seven years. After this brief period of time

OEM support is dropped and OEM parts are no longer available. Additionally, laser OEMs tend to go out of business prematurely leaving customers with no alternatives for parts or service.

This presents a problem for smaller healthcare providers who cannot afford this turnover rate. The ISO, however, is still positioned to provide continued support for these obsolete laser systems. This can extend the life of a laser for another seven years.

The FDA asks us what information do ISOs need to perform service that results in safe and effective operation of a medical laser. And the answer is simple. We need access to complete service manuals from the OEM. Our customers need access to software and hardware updates. Our customers need access to restricted parts. Okay. Thanks.

MS. GLAVIN: Good afternoon. My name is Ann Glavin. I'm CEO of Total Scope, Incorporated. We're a small woman-owned business that has been repairing medical devices for the last 24 years. We specialize in the repair of rigid and flexible endoscopes,

surgical hammers and couplers, as well as surgical instrumentation.

First, I want to say thank you for the opportunity to be part of FDA's process to seek more information and on the servicing of medical devices by third parties and the OEMs.

Total Scope is unique in that we chose over 16 years ago to become an ISO 13485 certified company. Although our industry was, it is not currently regulated. We made the decision to hold ourselves to the highest standard in the public domain.

For those of you who don't know, and I'm sure many of you do, ISO 13485 is specific to the medical device sector whereas ISO 9001 is a general and generic standard for all quality management systems.

Under ISO 13485, Total Scope is audited annually and recertified every three years by an independent third party. We pay someone to assess our systems.

We have systems for product identification and traceability of all parts used in the repair

process for consistent training and competency evaluation of our technicians and for planning documentation and implementing collective and preventative actions.

We review non-conformances, address customer complaints, annual evaluate our suppliers and vendors, assess risk, and are able to conduct recalls, if necessary. We conform to the FDA's quality system Reg.

These are our everyday best practices. As I said, we have been doing this for over 16 years and we are a better company because of it. It is our belief that the third-party repair is an important part of the medical device industry allowing the market better pricing, better service, and customer experience in most, if not all, device platforms.

We are grateful for the time we have been given here today to address best practices and that's what we feel are the best practices.

We recognize that the devices we repair can be used on any of our loved ones. That is why we have chosen to exceed the highest standard in the

marketplace and will continue to do so. Thank you.

MR. SPEARMAN: I want to thank the FDA for giving me the opportunity to speak to the group. My name is Jim Spearman. I'm President and CEO of Consensys Imaging Service, a private equity backed portfolio company with a national footprint.

We service MR, CT, mammography, and ultrasound medical devices. I'm also a Consensys board member and vice chairman of the board of another healthcare company.

Like many, I'm an OEM alum, as well, having spent almost 11 years with one of the big three. I also spent 12 years as a uniform police officer, so needless to say, I know a little something about enforcement, risk mitigation, and voluntary reporting, cough, cough.

Consensys is unique in that we are officially a third party, but we're also an approved service partner for several OEMs. And in two other instances we represent the OEM providing initial installation and service during the warranty period of

new medical devices. We affectionately call what we do coopetition.

Let's talk about why we're here. Yesterday we heard concerns about unqualified personnel, no documentation, service manuals and/or service repair records, underreporting, and improperly repaired and service medical devices.

We also heard best practices including a well-documented QMS, training certification of personnel, and robust documentation.

Recommendations were ISO 9001 and 13485, the medical device specific quality cert, better training, high-quality parts, and device-specific tools and test equipment properly maintained including routine calibration checks, of course.

Saying all of that without stumbling hints at the fact that we have core competence here. Having just recertified this week to both the new ISO 9001 2015 and ISO 13485 2016 quality standards.

This was our fifth straight year of external audits with zero findings. We've only missed one preventive maintenance in the last four and a half

years nationwide on approximately 500 devices. All of which is proof positive of a company-wide culture of high quality and regulatory compliance. It's also a perfect case study of how an ISO has consistently delivered high quality third-party service.

Looking a little deeper, it's not hard to appreciate this fact considering one of our business units held 15 patents on ultrasound probe repair which we sold to GE Healthcare back in 2013.

Consensys has since been awarded two year U.S. patents and we have a vast library of intellectual property which we continue to build upon daily.

Enough about problems and credentials, let's talk about solutions. Let's agree on a baseline for everything else I'm about to say. Number one, this is America, not some third-world country. We have the FDA so think best medical care on the planet.

Number two, these are medical devices we're talking about. Think 21 CRF Part 820. Now, think back on several of the comments from both yesterday and today. You didn't come here to say look how bad I

am and please let me continue doing bad things.

Trust, but verify. Lack of reporting doesn't equate to lack of problems. I can attest to that first-hand based on what we've seen during new contractual initial inspections including taking over from an OEM.

Patient safety is what we all care about. As a veteran police officer, a CEO of a healthcare company, a board member times two, my personal commitment to patient safety is obvious.

Ask yourself this one question. If that police officer who risked his or her life dodging traffic to get to that rollover crash with injuries calls out for a life flight for a five-year-old girl unconscious and breathing with obvious head trauma and she actually makes it to the ER alive, don't we all expect that CT to function properly per the original FDA requirements regardless of who's servicing it?

I propose that we agree on either ISO 13485 2016, which mandates regulatory reporting, or the application portions of FDA's QSR. Let's also work with our OEM partners to get better access to

training, service documentation, parts, and tools. After all, the buyer owns the device after purchase.

Let's also agree to communicate effectively to ensure the highest quality device history files. We also need HIPAA, blood born pathogen, lockout/tag out, electrostatic discharge, and other regulatory and safety training because not all medical devices are in hospitals.

Consensys empowered a major idea over a three-year period to service 330 ultrasound devices completely on their own. If Consensys can do that, we all can do this. So let's be part of the solution as I'm sure we can all agree there is a problem. Thank you and I'm happy to engage. Just let me know however I can help.

MS. KLACIK: Hi. I'm Sue Klacik and I'm representing IAHCSMM. IAHCSMM is the International Association of Healthcare Central Service Materials Management. Basically we process surgical instrumentation and I'm going to address that.

Medical devices do require repair and preventative maintenance. It is the position of

IAHCSMM that if medical devices do require repair or preventative maintenance servicing by either the OEM or a third-party repair company, they should be functionally equivalent to their original condition as validated and cleared by the FDA 510(k) process or better.

Instrumentation and equipment should be repaired using the same type of replacement parts that are functionally equivalent to or better than the original parts that were included in the FDA 510(k) clearance process demonstrating compatibility to the cleaning processes and sterilization modality validated in a medical device IFU.

Replacing of original parts with materials that were not submitted for 510(k) clearance could affect the cleaning and sterilization processes. The material may not be compatible with the cleaning processes or cleaning chemistries and disinfection or sterilization modalities, adhesive may not be adhering in a part rendering it to become dislodged during use, the device not achieving sterilization or it may leave a residue being left on the device or damaging the

device.

These issues may not be detected and can cause patient harm. Not using the correct repair part could result in the medical device malfunctioning doing so, a chemical injury, or a non-sterile device.

The original 510(k) clearance provides instructions for cleaning and disinfection or sterilization for the medical device. Parts should not be used that are not cleared. It may affect these processes as they have not undergone the rigorous validation process.

Personnel performing the repairs should be qualified and documented with verified competency for the equipment or instrumentation to prevent the device from malfunctioning.

Healthcare facilities are under pressure to reduce costs. Repair costs can have a major impact on operating expense. Should original equipment manufacturers, OEM, be the only source for repair it would provide them with a monopoly on repair cost, service levels, and quality.

In addition, requiring only the OEM medical

device repair would eliminate the ability of a device to be repaired should the original manufacturer no longer exist.

As users of medical devices, IAHSCMM recommends continuing the use of OEMs and third-party repair facilities provided they are able to restore the medical device to 510(k) clearance condition.

And I wish you'd know exactly who is able to do such a thing. When commissioning a third party repair company or OEM, IAHSCMM recommends that the FDA guidelines be followed including the GMPs.

Having the OEMs and third party repair companies under the regulatory oversight of the FDA will assure the healthcare community that repair devices will function as originally designed and can be safely processed for reuse in the healthcare facility as stated in the 510(k) clearance.

It is also recommended that devices undergoing repair by a third party repair company have a permanent identification mark on the device indicating that it underwent repair by a third party repair company identifying the repair company. This

alerts the user that the medical device was repaired by a third party repair company and who the company is. This will leave a trail should the device be sold or should the healthcare facility merge or be sold.

I'd also like to clear up a few things that were talked about earlier today. There was a lot of talk about the Joint Commission having oversight, you know, on repair companies. And in CS (Central Supply) that's not necessarily true.

When the Joint Commission comes in they have -- they look at it at a high level. For the repairs that are performed in a CS department I don't see them coming in and looking at those records of the medical device manufacturer.

Also another issue that was talked about is that all items coming back from repair go through the clinical engineering department. That isn't necessarily so with some of the medical devices also. So just I just wanted to clear that up.

MR. ZEGARELLI: My name is Benjamin Zagarelli and I'm an attorney with the law firm Mintz Levin. I'm here today on behalf of our client, Karl

Storz, Endoscopy America.

As we've all said repeatedly, patient safety is the goal of this workshop. Accomplishing this goal requires accountability on the part of every entity that will handle a medical device throughout its lifecycle. However, no matter how they are formulated or the degree of consensus they achieve, best practices alone will not ensure consistent accountability among all medical device entities.

Best practices are essentially industry self-regulation and may be appropriate in certain circumstances; however, in the case of third-party servicing of medical devices, best practices have not been a realistic alternative to formal regulation as technology has developed.

While regulation of service and repair entities may not have been necessary in the past, the advancement of medical device technology since FDA last considered this issue has dramatically increased the requirement for specific expertise to repair sophisticated device systems.

Furthermore, many of these advance systems

by nature must be used on multiple patients and healthcare professionals depend on them when performing sensitive procedures.

For all of these reasons, these systems entail greater risks than past medical devices. And the FDA has acknowledged this by increasing regulations and publishing guidance related to medical device reprocessing.

For these same reasons best practices related to servicing these complex systems will not reduce the associated risks. There are four necessary elements to create the appropriate level of accountability.

One, an adequate, fully-implemented, and well-maintained quality management system; two, ensuring that personnel have the proper expertise and certifications to perform their job functions and that they receive regular training; three, adherence to device performance specifications that have been cleared or approved by FDA; and, four, the obligation to report device problems or malfunctions.

These essential elements have two things in

common. Each is a requirement under regulations that apply to OEMs and not one of them is required of ISOs. Only formal regulations can ensure that ISOs are held to the same high standards expected of OEMs.

Karl Storz and a number of stakeholders highlighted in their comments to the docket how critical quality systems are to the safety and quality of reusable, critical, and semi-critical and other high-risk medical devices.

And for the ISOs with QMSs in place, excellent. You're part of the solution. But our concern is consistency across the industry. Many stakeholders also rightly pointed out that while ISO personnel may be able to perform routine repairs, complex medical device systems like endoscopes require specific expertise to repair.

Two of the many examples of third-party repairs of Karl Storz devices provide further evidence that greater regulatory oversight is necessary and you heard both of these yesterday.

In one example, material from the outer sheath of an endoscope flaked off inside of a patient

because an ISO replaced the insulation cover with an unvalidated material.

And then there's also the now infamous example of a chewing gum like substance used to repair and endoscope. This is simply unacceptable.

After hearing these two examples of shoddy, irresponsible third-party repairs, I don't think anyone can blame an OEM for saying that no one other than the OEM and its staff should be servicing its devices.

Not only are there no quality system or training requirements for ISOs, they do not have to indicate by a labeling or other documentation that a device was repaired.

Doesn't it seem reasonable for FDA to require ISOs to document repairs and issues found during repair and to report this information to the OEM or FDA particularly when such reporting would help ensure that malfunctions are adequately investigated and tracked to the root cause?

This question is especially relevant in light of FDA's recent efforts to obtain more evidence

about device failures from hospitals because deficiencies at any point in the chain of responsibility for medical devices can result in devastating patient injury.

Let me be clear, Karl Storz does not believe that a monopoly on servicing and repairs is practical or serves the interest of patients or the industry; however, we do believe that anyone who repairs a critical or semi-critical medical device should adhere to the four elements that I mentioned previously.

Karl Storz believes these practices are essential for patient safety and require FDA regulation since best practices cannot ensure that all third parties will implement and maintain them.

This is not regulation by anecdote. It is regulation to ensure consistent accountability. And I want to remind everyone here that regulations are meant to prevent harm rather than cure past instances of harm.

Accumulated data of past patient harm only is essentially irrelevant. It is consistent, appropriately tailored regulation that ensures patient

safety. Thank you.

MR. ROBINSON: My name is Alex Robinson. I have over 20 years of experience in biomedical engineering, 16 years in-house working in the hospital, 11 of which I spent as a department head. I have four years also of third-party work.

I've worked in at least three of the categories here so I have also had experience dealing with them. I think everybody tries to do the best that they can.

The reason I'm here is a little different from the rest of you because I actually work for a not-for-profit philanthropic organization. We gather equipment and I process it, I fix it if it can be fixed, I certify it to meet all of the specifications included in the owner's -- or in the manufacturer's service manual if it's available to me.

I work for Afya. That's the Afya Foundation of America. It's a -- located in Yonkers, New York, and we have done work all over the world. We send equipment to various clinics around the world that need this equipment. I mean, absolutely need it.

They don't have access to it. We provide them access to it.

And we've shipped millions of dollars' worth of equipment. In Nepal we immediately shipped 33 pallets. Within the first week we shipped 33 pallets to Nepal. That was in cooperation with the federal government.

Since I don't actually work in a hospital, I don't work for a third-party service provider, and I don't work for an OEM my reason for being here is because I do have a stake in all of this. Because when I get the donated equipment from hospitals I like to know that it's been well-maintained and that it's going to be safe for me to send overseas.

Now, the best practices that you can have require open mind and open communications. Some manufacturers I can call and I can get the assistance I need, others are not so forthcoming or they put me through to an automated line that asks me for my credit card before I can even ask a question.

And working for a not-for-profit I can't really afford to do that so I'm usually restricted

from being able to do that. We don't even know how much it's going to cost us to get the actual answer.

So my reason for being here is to plead with everyone here to cooperate in the process. And I would expect that any changes, any new regulations that come out of this would be designed not to restrict, but to facilitate the job that we all have here. And not to protect anyone's individual interest in this, but to provide guidance to the entire community. And that's it. Thank you

MR. FORSELL: Thank you. My name is Raymond Forsell and I'm a clinical engineer with the University of Vermont Technical Services Partnership. We are a non-profit department of the University. We've been around for 43 years serving northern New York State, New Hampshire, and Vermont.

So I'd be classified or our group would be classified as an ISO, but it's a complex relationship with mergers and networking. We work with ISOs and OEMs, hospitals directly so I think I look at myself and my role more as being an owner agent or an owner advocate in many ways.

So I want to kind of look at best practices for a few minutes just, you know, trying to look from the owner's perspective which would generally include in-house biomeds or ISOs that are part of a healthcare organization.

So and we really need strong relationships with OEMs for support, for pricing, for, you know, lifecycle, happy customers, and well cared for patients.

So I want to hit on maybe seven best practice points if I can in the five minutes before I run out of time. Number one is that the biomed community has tons -- tons of data. And I think one of the things that's come out in the last two days has been a need for maybe more data in certain aspects as to, you know, is the -- are the quality management aspects of ISOs and in-house owner advocates, you know, is it adequate.

And I think it is, but we've been building our data for a certain set of regulators. And I think with very little time and effort we could, you know, produce some very good representative data that the

FDA could look at and see very clearly what's happening. And that would be helpful.

Certainly I respect the ECRI data and we certainly feed into that as much as we can. So that is good data, but if they're looking for more than we're certainly willing to participate with that.

Point two, I think as owners we need to use the market. The presentation by the VA in terms of their -- you know, and they represent a significant buying block. They have some leverage over vendors to say we need training, we need support, we need parts, you know, service manuals, et cetera, in order for you to have a successful purchase.

So I think we need to use the market as buying groups, as individual networks or hospitals to try to steer our vendors towards being more like they used to be. And many of them were very agreeable 10, 15 years ago and are much less so today. So I think there's a way the market can drive that, you know, with or without regulation.

Number three, plan service over the life of the device. A vast number of the devices that would

be in hospitals can very easily be maintained in-house without service contracts and often times without even interaction with the OEM over the life of the device.

I've got some old Medtronic pacemakers that are still in service that are, you know, well out of support are still chugging away so it is possible to support things in that fashion.

But there are other things that require either full service, maybe it's a very complex one-only system, very -- you know, very critical that would be an ideal option for, you know, OEM contract or other contract options. But it needs to be a scalable thing and we need to look at that, you know, throughout the organization.

There are insurance coverage plans, there are first-look plans that are very good where you have a partnership between biomed and the OEM or the other company.

So four would be invest in staff. So we've talked a little bit, we've heard a little about qualifications and training. Our organization is very strong about certification. We support clinical

engineering certification. A lot of our techs are CBETs and we push that and encourage them to the highest degree. And for specialties they are also certified and we go after as many service schools as we're able to, as well. So we want to be as qualified as we can and we have Joint Commission looking over our shoulder and our hospitals for that, as well.

Manage all vendors including yourself. So things like validation if you have a service person come in, you know, we always do a post-repair inspection, performance inspection after that's done. Validate that the work is done.

Look at -- oh, okay. Thank you. If you want to hear the other three, come see me.

MR. BRAUN: Thank you for the opportunity to speak here. My name is Markus Braun. I'm representing Siemens Healthcare. And I'm the quality manager of the business line refurbished systems so I will talk about refurbishing today, maybe the first person.

So I would like to refer to the definition we saw here on the screens. And we think there's a

clear borderline between refurbishment and remanufacturing. And I'm sorry to say, but I disagree to this definition because it contains three words "not significantly change."

And this is up to the room for -- for -- for interpretation. We think a refurbished system has to meet at the end of refurbishment specifications defined in a valid 510(k). That's it. In a valid 510(k). It could be the original one or a newer one of a newer version of the system.

But it's very important with a newer version because we like to update our systems to newer versions to give the customers and the patients newer technology. So I would like to rephrase the definition in this way and it would help, I think anybody, not only the manufacturers, but also third parties and, at the end, the patients and the customers. Thank you.

MR. WEEMS: Hi. I'm Peter Weems with MITA. I spoke for a couple minutes yesterday. I'd like to again thank everybody for this opportunity to discuss this very important topic. I know that over the last

day and a half I've learned a lot about the industry, about what you all do and what you all value.

I do have to admit that my background is a little bit different than many people in this room. I'm not a J.D., I'm not an engineer, I don't have an MBA, and I'm not a clinician. I studied philosophy back when I was in school. Somehow ended up finding a job, unlike many of my peers.

But anyway, you know, because of this I sometimes find it instructive to, you know, think about hypotheticals. You know, I can be very boring because I do hypothet- -- you know, talk about device hypotheticals all the time with my friends and family.

And so I think, you know, one hypo- -- you know, hypothetical that we need to consider and that the agency should consider is what were to happen if all of the OEMs were to divest themselves of their service businesses? Essentially say we're no longer going to service medical devices.

In an instant there is no regulation. The entire industry has no controls. And I really think we have to wonder is that a situation that we would be

comfortable with?

I know that I wouldn't be comfortable with it. I know that many of the people I know wouldn't be comfortable with it. And I really have to wonder if the agency would be comfortable with that. I'm not going to try and put words in their mouth, but I think we can assume that they wouldn't be otherwise they wouldn't have tried in the past to extend regulatory oversight to everybody, they wouldn't have regulatory oversight over OEMs, and we wouldn't be sitting here today.

And so if zero percent is undesirable, what percent is? 10 percent, 50 percent, 80 percent? How is it that any amount other than 100 percent oversight is unacceptable?

And now I know that many of us have talked about, you know, evidence and data. In my presentation I showed off several examples. In our comments to the agency I included many more. I know that my group are customers. Many of the other device companies have submitted through MDRs, through comment, through meetings, all sorts of examples.

And I know that many of you who are here today and who were here yesterday took the opportunity to dismiss all of that as anecdote. And I'm not going to say necessarily that you're wrong, but I do want to remind everybody that every single one of these anecdotes does have an impact on a patient's life. And we're talking about an MDR, we're talking about a patient who is injured, a patient who died, or a patient who is not able to get the care that he or she needed. I don't think that we should so easily dismiss this as just pure anecdote.

Further, I think that, as we've discussed and established over the last day and a half and as many of us have agreed to, reporting is currently insufficient. And this is the case because reporting is not required. And until reporting is required we don't fully understand the scope of this issue.

I sort of have to go back to the hypothetical that I was discussing just a moment ago. How many instances, how many events does it take for this to trigger action? Is it 1, is it 2, is it in 50 percent? How is it that we can accept any amount of

adverse events? Thank you.

MS. WAGMAN: Is there anyone who wants to get up for five minutes before we go for break?

MS. FOX: I'm shorter than Peter. Hi. I'm Tracey Fox with GE Healthcare. And as I listened over the last two days and heard all of the issues that were discussed, many of which were summarized by FDA before we started the meeting, and we built upon those.

And now we have the details which should help us break down the walls that Dave Francoeur told us about yesterday so that we can work together to start to solve some of those issues.

But I had a growing concern as I sat here. Not over regulating all of us that are here because so many of us have said we have a quality system in place, we agree with what the QSR has in place, and not about the cost or what that will do, but about those that did not show up today.

Over time, FDA has helped protect the American -- the American population from quackery, right? And I say that quackery can be found in the

mom and pop shops operating in a garage without a quality system in place, the two reloaders that are in small warehouses all over that really scare me, the places that are harvesting parts and calling them OEM equivalents and there's no testing involved, the third parties that are refurbishing to whatever level they can piece together with the parts that they have. I'm not sure where that line is that Markus talked about that becomes remanufacturing and, therefore, not registered. And those who are willing to repair anything for the customer even without the right parts or training.

Those are cared enough to show up today and had the passion to discuss these issues, we're the ones that are here to be part of the solution. Those that aren't here are still part of the problem.

And what I ask is that this is where we need help from the FDA. Please help us with the quackery that's out there.

MR. SZEREMETA: My name is Brian Szeremeta. I'm the Global Director of Quality and Compliance for PerkinElmer.

Our company screens -- we primarily focus on maternal screening, newborn screening, and prenatal screening. So we screen about 40 -- 50 million babies annually saving about 65 lives every day by searching for 60 -- over 60 disorders that impact babies and mothers.

So the perspective that I have is I want to make sure that we weed out the bad people out there. There's bad OEMs, there's bad ISOs, there's bad hospitals. Everybody knows that. They aren't here. The ISO groups that are here I applaud you for going through getting your ISO certifications.

But keep in mind that FDA doesn't recognize those ISO standards. They're not part of the recognized consensus standards that FDA indicates on the website.

So what I recommend to the FDA is that we require the ISO organizations to register with the FDA. We have contract manufacturers that are required to register, we have manufacturers that are required to register, so why not the ISO organizations who are performing that critical service on those instruments

out in the field?

We have a quality management system in place so let's do it. Let's get that registration in place. I ask the FDA add those -- add those ISO registrations or those ISO quality management systems to the recognized consensus standards with the scope that it applies to ISOs so they have -- so that ISOs organizations out there have a mechanism to prove that they meet the intent of those regulations, they meet the intent of the FDA, and they're registered with the FDA.

I think what we might find is once that happens the OEMs might be more encouraged to share information with those organizations knowing that they're being held accountable to the same standards that the OEM.

So the OEM -- FDA has mechanisms to weed out bad OEMs, right? We all know 483s, warning letters, consent decrees, injunctions so there's mechanisms to effect those OEMs who are -- who are poor performers or putting adulterated product out there on the market.

But there's no mechanism to control that middle ground between current FDA regulations and CMS regulations at the hospital level. So what I'm looking for is that to happen. And I think that's all I have.

Oh, one other comment. I think there was a comment on one of the panels about part tracking that could help -- you know, I think it was one of the ISO groups that mentioned that about -- about part tracking and when we, as an OEM, are selling parts.

If the ISOs aren't using our OEM parts, we have no way to track that. We have no way to know whether -- I think as Scot said, you know, he goes into the ER and replaces that one component on the instrument. If it's not being replaced with an OEM and sourced through the mechanism that we have, we lose visibility to that.

If we lost visibility across multiple hospital systems, then we don't know parts are failing early or earlier than what we anticipated so we lose visibility to that.

I think we all need to come together and

share information and communicate with each other. So thanks.

MR. MACKEIL: Just real quick. When I spoke earlier today I said that J&J was from New Brunswick, Canada. I misspoke. They're from New Brunswick, New Jersey.

I have a lot of family roots in New Brunswick and I think -- thought that was the only New Brunswick in the world. Sorry, J&J.

MS. WAGMAN: All right. Do we have one more?

MR. CANNON: One more, please.

MS. WAGMAN: Okay. This will be the last one and then we're going to take a 15-minute break. Thank you.

MR. CANNON: Good afternoon. My name is Steve Cannon. I'm Senior Vice President for Sodexo CTM.

And I've been quiet listening the last two days. Just to give you a little idea about my background, I was a medic in the military, came out and became an x-ray technologist. So I've worked on

the clinical side of the business. I've worked for two global service companies, I've worked for a private equity group, and I've worked for an OEM.

You know, it's interesting the conversation over the last couple days. And I've heard terms as unqualified staff, okay. How many colleges and universities and technical schools do we have across the country graduating individuals trained in this industry? Specifically, biomed techs and imaging engineers, okay.

And I will tell you that we, as an organization, dedicate a large amount of money every year to continue training our engineers and our biomed techs, okay.

Heard terms such as unqualified parts or incorrect parts. I was the president of All Parts Medical. If any of you know that organization, it was owned by a private equity group and purchased by an OEM. Why? Because that OEM is in third-party service.

Now that's a third-party parts company providing technical support, training, and parts to

the imaging service industry. So the OEMs are in this business, too, along with the rest of us ISOs and in-house groups, right. So they're doing the same things, they're pulling parts, they have quality processes in place.

We were ISO 13485 certified as part of Philips Healthcare. So they're in this business, too. If the OEM is not delivering service on the third-party equipment -- equipment other than their own -- then they're subcontracting that out to someone else, right.

You know, when you look at documentation anyone that is in this business in a formal way is required to document and track service on medical equipment. Everything from the time the device is purchased to its installation to its service and maintenance to the trends of that equipment to the clients that we serve including mean time to failure and overall reli- -- overall lifecycle cost, that's a requirement. Joint Commission requires that and other regulatory agencies.

I guess my point is is that what's the real

purpose of this meeting? The purpose of this meeting is not to speculate about are we reporting correctly because I heard that just a moment ago, are we using the correct parts. I thought the purpose of the meeting was about patient safety, okay.

And if that's truly the purpose of the meeting and the workshop, then let's let clear, objective data drive any regulatory change. And I'm not opposed to regulatory change, by the way.

But it can't be driven by anecdotal evidence because I will tell you we have anecdotal evidence on both sides of the fence, right. Because what are we talking about? We're talking about individuals that are delivering service. It doesn't matter whether you work for the OEM or you work for a third party or you work in-house, there's a certain amount of human error, right.

And I can tell you in my 30 years of working in this business I can count on one hand how many times we've been involved in an incident that was claimed to be driven by equipment failure.

Now, guess what? What do you think really

drove that patient incident? Somebody said it earlier today. Operator error, right? Operator error.

So, again, not opposed to regulation, but let's focus on the issue at hand. Thank you.

MS. WAGMAN: Okay. Thank you all. We're going to have a 15-minute break which will take us to 2:15 and we'll start the next -- the last panel.

(Whereupon, at 2:00 p.m., a recess was taken and reconvened at 2:17 p.m.)

MS. WAGMAN: All right. Welcome back. We're going to start our fourth and final panel of this workshop and we'd like to thank everyone who has been participating.

After we have the panel, there will be discussion questions and answers afterwards. Just remember, it's questions. So we would really appreciate if you stuck to that and ask a question of the panel.

If you have a statement, you can submit it into the docket, but we really want to have -- we have wonderful expertise up here and for us to move forward we need to hear your questions. Thank you.

So I'm just going to announce all the speakers. We have Malcolm Ridgway, Acting Director, Maintenance Practice Task Force, American College of Clinical Engineering; Robert Steldt, Program Manager, Biomedical Engineer, U.S. Department of Veteran's Affairs; Heidi Horn, Vice President, Clinical Engineering Service, SSM Healthcare Integrated Health Technology; Diana Wurzburger, Executive Quality and Regulatory Affairs, Canada, GE Healthcare; Jeff Semone, Senior Director of Regulatory Affairs Post Marketing and Safety Surveillance, Varian Medical Systems; Alex Robinson, Biomedical Engineer Consults, Afya Foundation of America; Julie Mardikian, Senior Compliance Auditor, Oxford Instrument Healthcare; and Mary Logan, we're crying, she's the President of AAMI and we wish her well; and Stephen Spiegelberg, President of Cambridge Polymer Group. And thank you all for being here.

We're going to start with the hospital groups. I believe that's Malcolm.

MR. RIDGWAY: Thank you. Good afternoon. It's Friday, it's after lunch, it's getting towards

the end so let's do it.

My name is Malcolm Ridgway. I'm recently retired from active duty in the healthcare management business. I'm still putting in a little bit of time on odd projects where it seems worthwhile.

And today it's my privilege to present the viewpoint from the end users and engineers -- hospital end users and engineers sub group as it has been formulated by me and my co-panelists here, Heidi and Bob.

We also reached out to some other in-house programs and each of them sort of endorsed what we had to say so I think it's fair to say that we're speaking generally on behalf of the entire end user and engineering community as we go forward.

I won't waste much time on the background. This has been ground out at length. Third-party services are already well regulated, da-da-da-da-da. There's very credible real world evidence that the frequency with which adverse safety events are encountered is not statistically significant.

My way of characterizing that would be that

we're really down to the irreducible minimum, .005 percent is as Mark Burley indicated earlier, is way down there. It's off the radar.

Just two other points on this slide. I would like to point out that equipment today is getting more and more complicated. And what complicates the servicing end of this is they're becoming more and more integrated into multi -- multi-types. Different devices, different manufacturers integrated into one network. And that makes diagnosing just like your TV system at home, is it the Internet that's gone down, is it the service provider, or is it the original originator. It's very hard to diagnose where the problem is when you get everything networked together.

Huh, before we present to the FDA our candidates for what we feel are best practices and our recommendations, we think it's very important that they get a very clear view of what the full scope of onsite equipment support is the term I use, what the scope of that support is in hospitals as they need it today.

So we reached out to several individuals and I asked them to help us describe a day in the life of a member of the onsite equipment support group. And here's what I assembled. I have three -- three pieces that I concocted here.

The first individual was a manager of a small group working onsite at a fairly large medical center. He said, "Last week we had a very brief power outage, but it was enough to cause two patient central stations to lock up. The team immediately scattered to all the affected areas and began verifying that everything was still working properly and we got everything back online within five minutes."

And he said, "A few months back we had a sterilizer containing a unique instrument that was needed for a particular upcoming case that failed in mid-cycle. His team managed to get the sterilizer open and relocated the device to another sterilizer and got everything done in time for the case."

And then he said, "One morning during EOC environment of care rounds I was walking around. I noticed that one of the defibrillators in one of the

units had failed its morning self-check. I'm not sure why the nursing staff hadn't noticed it, but we were able to get it fixed, replaced and fixed so it was ready if it was needed."

"Then one time," he said, "not too long ago we found the system -- an imaging system in the cath lab had failed because it had overheated." He said, "We quickly found out it's an air handler. Got the case back on track, notified plant operations to come and fix the air handler."

Second individual was someone who covers several areas including several ORs. He said, "There'd been many times that I took a call when there was an anesthetized patient on the OR table. For example, I had open heart cases where a surgical light failed in mid case and also times when something such as an anesthesia gas machines stop working in mid case. It's then a bit of a scramble to find a spare backup unit and swap it out."

He said, "Most of the failures are not very complicated or difficult to fix, but it can still mess up the continuity of care if we were not there to take

care of it promptly. For example, I've had situations during endoscopy procedures where it was just the bulb in the light source that failed and even simpler issues like no video on a monitor screen which usually just requires the cable be reconnected or a switch changed to the proper input.

We recently had a genuine emergency situation where we had -- where they had to bag a patient who was connected to a room full of equipment where the room circuit breaker tripped. Required a little bit of a scramble to bring power in from other nearby sources."

And then last thing he said, "One other situation comes to mind. We had a software upgrade installed that included the OR monitors; however, the monitors had been left in an operating mode that was unfamiliar to the OR staff. Fortunately they spotted this on time before the next case started. We were able to get the monitors reconfigured and up in time to continue without delaying the case."

The last individual gave me some input. This is someone who's in charge of a large number of

ORs in a large teaching hospital. He said, “Here’s -- here’s my short list of typical calls.”

He said, “Everything in the ORs a challenge from patient on the table under anesthesia with his or her chest open. Case one, the argon laser stopped working. A recent case.” He said, “This was because the operator had not seeded the probe into the front panel properly.

Two, the staff is not -- is not getting a reading on either their blood pressure or vital signs monitor. This is almost invariably a cable problem.

Three, the ESUs (Electro Surgical Unit) not delivering enough energy either because the cable’s failed or because the foot pedal’s plugged into the wrong socket.” But he said, “In one case it was part of the resectoscope that had broken off.”

Case four he cited, “The OR table frozen in position. Most recent case,” he said, “was because the hand control on the microprocessor had lost sync and fortunately all it required was to have the system rebooted.”

And then the last thing he said, “The

anesthesia machine is no longer reporting gas values or flows. In most cases this is because one of the sensors failed."

So I think this gives you just a view from the trenches of what every day is like for these onsite support people. He concluded by saying, "This is a very challenging, but very satisfying job. Let me just share with you two things that really aggravate me. One, I have a one device to inspect and the OEM tells me the factory service manual, which NFPA 99 says they must provide to me, is proprietary. And so for liability reasons they will not share it. They also tell me NFPA is just a voluntary standard. It doesn't apply to them."

And the second gripe he had was he said, "I need a minor part for a relatively simple device, the OEM tells me I'm not qualified to replace a part in what is basically a power supply in a metal box. So their position is they won't sell me any parts."

So my point in reading all that to you is to really say these individuals are what in another circumstance will be called first responders. Excuse

me. And just like firemen and EMTs, they, too, can be a critical part of a life and death situation.

So the other point about the slide is I just wanted to say that the maintenance part of the many levels of support consists of preventive maintenance and the, well, let's call them the simple repairs requires a staff of competent generalists to diagnose and triage the majority of the failures and then maybe 15 percent of the maintenance is what we would call special skills where you will require someone with a little more training. And they can be drawn from either a trained in-house person, an ISO, or from the OEM depending on the situation.

Now, today is more than just maintenance. There's a second part to the onsite support and let's call this the administrative or management tasks. The 10 or 11 small items in small print here.

Managing ever increasing number of hazardous recalls, not a trivial task. Could be many hundreds of recalls to deal with per month in a medium-sized hospital. Ensuring regulatory compliance and so on. You can read down there. And that completes the kind

of job description, if you will, for the onsite support function.

One last comment I would make is that this is very different from the kind of support you need for equipment in hospitals than the day 50 years ago when I first got in the business. At that time the support was a few contracts with a few of the large manufacturers, the hospital I worked in it was Hewlett Packard that had most of the equipment.

And there's a huge difference between support for equipment in those days and where we're at now and going -- it's going to go on getting more and more complicated. And this vital function of having people onsite to do hand holding for the clinical staff is absolutely the model of support going forward.

I know we talked about challenges in earlier session, but just to recap. This is a more concise list. You heard a few gripes from one of the technicians in the field. This is a more organized list that would come from the manager of an onsite group.

Three bullets. The first bullet: The early relegation of devices to end of service life, EOSL. Now that can be really bad news if that's one of your workhorse devices like a mobile x-ray machine, lab device, a sterilizer. I mean, you're not going to be able to get parts from where you got them if you go them from the OEM and probably little in the way of other support.

And that's a fairly major pain in the neck for most people because these things come through with regularity. There's a working unit, but they said, I'm sorry, it's obsolete. We've got a new model. We're no longer going to support this. So great.

Second one is in this age of more and more devices becoming cyber sensitive, if you will, less than prompt delivery of patches and other safety related upgrades is high on the list of gripes from managers.

And then there's this third category which I labeled certain manufacturers reluctance. Many people characterize these things as impediments to getting their job done. And it's the usual list -- the list

of usual suspects that we've talked about at some length.

One pet peeve that I have in particular, the first bullet there or sub bullet, is the critical QA procedures. And I mentioned this yesterday. Unless we can get from the OEMs a simple procedure for checking to confirm the device is working -- performing accurately and safely, there's very little that you can do to assure patient safety.

And those procedures, although they should be forthcoming and in some cases are, I would like -- I would like to find a way of making that a much more consistent and solid process.

We talked about service manuals, we talked about technical support on the phone, we talked about factory training at a reasonable price, diagnostic software reasonable price, repair parts at a competitive price.

And the last two bullets have to do with the efficiency of managing your program. Some manufacturers will not do business with you through what we call a shared risk agreement, which is a

discounted way if you have people onsite you will take first call. You can buy support from the manufacturer on a shared risk basis.

And the last one, support on an economical time and materials basis. Many manufacturers feel they don't want to work with you that way. They would rather sell you a contract.

So moving onto the current best practice. We have three. The first one is what we call the blended resources model and onsite staffing. How you construct the blended resources depends on a number of things -- where your hospital is, how big it is, whether you belong to a system, and so on.

But the onsite model can be -- and forgive the use of acronyms. The onsite staffing can be in-house people, they can be contracted with from ISOs or from the OEM in the form of their multi-vendor programs.

And the onsite people, as I said, do PMs and the simpler repairs and connectivity issues. Then you have the specialists which again can be in-house, ISO, multi-vendor, or OEM. You can contract or do business

with the OEM for those more complicated repairs. Repair parts from third-party vendors, ISOs, or OASMs and so on.

But for efficiency -- for cost efficiency using a mix of managed time and materials or shared risk contracts is much more flexible and much more efficient than full service agreements.

We had two other best practices which we would like to sort of plug. One is what we call HTM community partnerships with local colleges. And this is where the training establishment, the school, works with the hospital to give their students part-time internships which gives them a very important practical base.

MS. WAGMAN: Your time's up.

MR. RIDGWAY: My time's up?

UNKNOWN SPEAKER: We're getting the hook.

MR. RIDGWAY: Excuse me. Two seconds? The one I should mention -- sorry about the time thing -- is the community initiatives where we're collaborating between individuals in the HTM community with the manufacturers.

And, I'm sorry, I overran -- mismanaged my time because this was really one of the things we wanted to have in the recommendations. Let me just move to the recommendations.

Encourage manufacturers. Just let's try and find a way of providing better after sale support for the users.

The other two recommendations we have is to find a way if we can of encouraging collaborative activities which I didn't -- failed to describe but which I hope will get into the record.

And the third one was to encourage the collaborative activities which we thought was a best practice in terms of the combination of the school.

And last, but certainly not least, we do not think there's anything good that can come out of imposing any additional Regs on third-party servicers. Thank you.

MS. WAGMAN: Thank you, Malcolm. And next we'll have Diane.

MS. WURZBURGER: Good afternoon, everybody. So one down, almost two down, and you're almost ready

to go into your Friday afternoon and weekend.

I appreciate the opportunity to be here. And on behalf of MITA and the OEM organizations and to be part of these discussions that I think are very useful for our way forward in helping the agency define -- consider that pathway as they -- as they move forward with their deliberations.

We've heard over the last two days that in addition to -- whoops! Do I have the clicker? I'm sorry. I should move on. Sorry. Thank you.

All right. Sorry. Let me start that again. In addition to the regulated OEMs who have quality systems implemented in accordance with the FDA quality system regulation as well as ISO 9001 or 13485 certifications, there are some non-OEM providers, many of which are in this room today and we've heard from, who also have embraced a quality of culture and who have chosen to become certified to quality system standards and ensure that the servicing that they're providing to medical devices is a quality -- of a quality way.

However, there are many who are not in this

room right now. And it's those OEM providers who do not necessarily manage their activities in this way that we do need help I think across the board on behalf of all who are represented here to ensure that there's consistency in how those practices are being moved forward.

If we look at the current best practices for OEMs, this, of course, you've seen yesterday, which is our quality system regulation under the FDA. OEMs are regulated by the agency throughout the medical device lifecycle.

So that means from the design of that device through production and manufacturing as well as post-market maintenance and then through the end of life all of those activities, and particularly the servicing activities, touch upon the different elements in this regulation in one way or the other.

A critical element of this quality system is the maintenance of product complaint files. This is where we're getting feedback not only from our field organizations, but from other sources in the real world documenting when the device did not meet its

intended use specifications, the investigation into the cause of those issues, as well as the corrective actions that were taken in response.

These files are reviewed for reportability to the agency under the medical device reporting requirements. Not only those death and serious injury events that we -- that user facilities are asked to provide as well, but also when we become aware of a malfunction that could cause or contribute to such a death and serious injury when we look into the root cause of that issue.

We're required also to report that data into the agency and ensure that we include that in our trending systems in the complaint data so that we can, then, base any of our corrective actions or improvements to those devices based on that information.

In addition, most OEMs also have their quality systems certified to, again, either ISO 9001 or 13485 as some of you have expressed you do, as well. Requirements -- where those requirements between the quality system regulation here and the ISO

overlap, OEMs don't implement redundant systems and processes to cover both of those.

What we do is ensure that we leveraged the processes we have in place so they're covering both of those requirements where needed and scaling them appropriately.

These procedures and processes are the same that are applied to our servicing activities when we go into healthcare setting across the industry. So whether that be the hospital setting or the ambulatory surgical center or the outpatient centers we're applying those same procedures there. There's no distinction in what we're managing as our quality system.

As we discussed yesterday, the regulations are scalable and risk based. FDA has given flexibility to the OEMs to adapt these requirements as appropriate depending upon the size of the operation, the risk level of the device, as well as the nature of the activities that are performed.

So if we're doing activities that are more to the level of a remanufacturing activity, the

requirements there have more of a complex burden than do ones where we are merely doing servicing or repair on something. There is -- there is a scalability there that's part of the quality system regulation.

The higher the risk of a device, the more rigor is expected throughout the system. And the greater the complex -- the complexity of the work performed on the device is the more detailed the processes and the procedures are expected.

In addition, we do have that oversight. FDA regularly inspects us. We're also inspected by those ISO 9000 -- excuse me, those ISO certified bodies who come in to inspect our quality system and then we also have the regulation our own internal audit programs for that oversight.

If we look at some of the current best practices for a subset of non-OEMs, as we said, who have blended these processes and controls under quality systems, some of the -- some of you guys, you high-performing guys, have implemented these quality processes based on the ISO standards.

Other frameworks, specifically hospitals as

we've discussed here several times, have -- are regulated by the centers for Medicare and Medicaid services or CMS and, therefore, are required to be accredited by some of the organizations you see on this list in order to be eligible for reimbursement for the healthcare services that are provided to patients.

This is really important framework. There's no doubt of that. And while the requirements between the Joint Commission requirements and the Quality System Regulation (QSR), some of those do overlap, as Barbara had pointed out this morning. There are still some gaps there in the requirements that are -- that are side by side, but also in the fragmentation of the oversight by these organizations.

The elements of compliance are not standard across these organizations you see listed here nor are they necessarily aligned directly with what the FDA has in place for medical devices. And these fragments are not consistently applied.

It's also important to remember that there is a critical distinction between CMS and the FDA

missions. CMS is focused on whether the healthcare services provided are reasonable and necessary for the patients; whereas, the FDA is focused on the effective and safe use of devices for the patient in public health.

The oversight exercise is based on that as well. CMS is -- and the implementation of the Joint Commission requirements are there for different purposes than the FDA oversight. Therefore, we feel the accreditation framework of these organizations is not alone sufficient to meet the safety and effectiveness requirements defined by FDA for the activities impacting medical devices. And they're also hard to enforce given that they are voluntary standards.

Some other best practices, again, as we've discussed where the I- -- the third parties are implementing quality systems to the ISO certification. We're seeing many elements here that are similar.

Training of personnel, calibrated tool and test equipment, qualified parts for service providers, documentation of those procedures, cooperation with

the OEMs to implement appropriately any device corrections or recalls, and then, of course, documented service history that's available upon request if needed for investigation.

Given this, the application of FDA regulation and oversight to ensure the continued safety and effectiveness of medical devices should not be a huge leap. Again, there is overlap between both the QSR and the ISO and processes and procedures can be leveraged to meet those requirements while ensuring those gaps are filled.

Looking to the future, OEMs are not advocating new, broader regulations. Rather, we are advocating the FDA to extend the existing medical device regulations to all medical device service providers.

And, as we've seen, there is overlap of those requirements among the quality system schemes. Even some of the requirements of the accreditation schemes are found in both the systems that will work towards ensuring the safe and effective device performance.

We support minimum requirements for all service providers. That includes the OEMs. The same risks exist to patients regardless of who is performing those activities on the device. These minimum requirements should include those that you see here as well as an appropriate level of oversight to ensure the safe and effective performance of medical devices is intended.

It is within FDA's authority to determine how best to implement that oversight from many of its tools that it has at its option. We believe voluntary standards alone are not sufficient to ensure patient safety.

It's also important to remember that all service providers are linked to the device lifecycle. Feedback of service events and malfunctions to the OEM, including those events not recorded -- excuse me, associated with a death or serious injury is essential to the continuous improvement of medical devices and ultimately our patient care.

In summary, we've heard that we are all aligned on the same shared goals. The first priority

is patient safety. OEMs are not about limiting choices or increasing cost. Rather, it's about safe and effective performance of our devices for patients.

Patients and clinicians should be able to presume the same level of safety and device quality regardless of a service provider. And devices should be available for use when needed by the healthcare provider.

We believe that knowledge of and compliance to requirements -- FDA requirements is essential regardless of who the service provider is. These devices are designed, manufactured, and maintained under FDA regulation and oversight to ensure safe and effective performance over the defined lifecycle.

It does not make sense that a section of the industry that is servicing the same regulated medical devices do not have the same accountability to those regulations that govern them.

Again, we're not advocating that only an OEM can do this work neither are we advocating that FDA has to create a whole new regulatory framework. Rather, applying existing device regulations and

scaled implementation based on size, risk, and the activities that are performed.

We support minimum requirements for all medical device providers. That includes documented procedures and records, training qualifications, and parts sourced, among other -- other specifications.

A lack of data does not mean that there aren't problems. We heard from both the clinical engineering and independent service organization providers that there is a lack of data and service history on devices in some places.

That information on service events, particularly malfunctions, is not necessarily uploaded to the hospital's reporting system. If the hospital is not reporting those events and the OEMs do not have visibility to that information from those clinical engineering departments or independent service organizations, of course there won't be data reported as malfunctions in the MDR systems that the FDA maintains and the reports and analysis that are done by organizations like ECRI will be incomplete.

I'd like to reference the FDA report

recently on their inspections of the user facility reporting based on the Safe Medical Devices Act of 1990 released earlier this week.

Of the 17 hospital facilities inspected, 15 received a 483 citation. Of those 15, 12 had not reported a death or serious injury as required by the regulations.

OEMs are -- are trying to get that data on deaths and serious injury and malfunctions so that we can analyze that and include that not only in our reporting, but also in what we incorporate in our trending and our continuous improvement.

As an industry we do need to collaborate on a solution to the lack of -- so that the lack of this visibility of devices and malfunctions is resolved. All people at the workbench need to better understand and give appropriate time to documenting how devices malfunction and what repair was done, especially in those cases where those malfunctions may cause or contribute to patient injury if it happened again and to report those malfunctions into the hospital system for visibility.

Additionally, this data, especially for events of death, serious injury, and malfunctions that could cause or contribute to a death or serious injury, must be shared with OEMs for analysis in the interest of continuous improvement of our medical devices.

OEMs have systemic approaches -- systematic, excuse me, approaches to monitoring and analyzing data of device performance, but given these missing segments of data it's challenging if not impossible to effectively do so.

While many clinical engineering and independent service providers are already operating under a set of requirements for CMS, and for some ISO certifications, voluntary standards alone are not sufficient when we are considering patient safety.

Regulation and oversight is needed to drive behaviors of all medical device service providers. It is the FDA's review to determine what that oversight it and what is appropriate.

As FDA looks to the next steps and potentially considers how to collaborate with other

agencies, we ask that it not lose sight of the agency's public health mission to ensure the safe and effective performance of medical devices across the device lifecycle in the interest of patient safety. We hope that FDA will not wait for a safety event to try this policy issue.

All medical device service providers -- OEMs, clinical engineering departments, independent service organization -- should conduct their activities under the same framework of minimum requirements that preserve the approved intended use of the medical device. Everyone working towards the same safe and effective product for patient care. Thank you.

MS. WAGMAN: Thank you. Alex or Julie, does anyone from the ISO want to make any statements? You have your 15 minutes.

MS. MARDIKIAN: Hi. I'm Julie Mardikian, Senior Compliance Auditor for Oxford Instruments Healthcare, a division of Oxford Instruments, who is listed on the London Stock Exchange.

I would like to thank the FDA for the

opportunity to participate in this workshop. Oxford Instruments invented the superconducting magnet and, with Siemens, pioneered the use of the superconducting technology to create the superconducting MRI system.

Our division, Oxford Instruments (OI) Healthcare, provides refurbished CT and MRI, CT and MRI maintenance services, CT and MRI replacement parts, CT and MRI component repair and mobile imaging systems.

OI Healthcare is committed to providing our customers with quality products and services that meet or exceed their expectations. We ensure the quality of our products and services through adherence to our quality system which include certification to the International Organization for Standardization, ISO 9001 and 13485.

Our quality system is aligned with 21 CFR 820 ensuring that we comply with the current FDA standards. As an organization, we strongly believe in the value of our quality system and work closely with our trade association, the International Association of Medical Equipment Servicers and Remarketers, to

develop and promote best practices across the third party industry.

As a part of our quality system, we measure and document our performance using key processing indicators (KPI) some of which include our net promoter score, a measurement of customer satisfaction, which is consistently in the high 80th to low 90th percentiles.

We document that our repaired component failure rate is less than 1 percent. We document that our refurbished equipment goes through strict checklists to ensure compliance to OEM specifications. We document that requests for maintenance are responded to by a service engineer -- are responded to by a service engineer within 30 minutes.

In addition to our KPIs, our quality system includes risk analysis and mitigation as well as ensuring traceability of the products that we sell and service.

To compete as a third party we understand that our offerings need to be delivered at a lower price than the OEM and with a higher level of service.

For an example, when you call OI Healthcare for service, 24 hours a day, 7 days a week -- I'm sorry, 24 hours a day, 7 days per week the phone is answered and services dispatched by one of our team members. Not by a computer and not be an external service.

To understand the value and the need for the products and services we provide, it is perhaps most useful to know some of our customers that come to us for solutions are as follows: John Hopkins, Memorial Sloan Kettering, Langley Air Force Base, VA Medical Center Leavenworth, Overton Brooks VA, Cherry Point Naval Hospital, Kansas City VA, VA of Illiana, Alexandria VA, Jonathan M. Wainwright Memorial VA.

We sell replacement parts worldwide. We have 400-plus service customers in the U.S. And it's important to know that we value GE, Siemens, and Philips as customers.

Finally, our sister company, OI Service, provides MRI maintenance service to over 1,100 customers in Japan. We understand through our trade association that third parties have not been responsible for any adverse patient outcomes;

therefore, we question the need for additional regulation.

We would, at the same time, encourage the FDA to compel the OEMs to make sure documentation required to service and maintain equipment to OEM specifications is available to all users, both original and second-hand.

We believe that the user has the right to choose their service provider and that the third parties provide a vital check to OEM compliance, to their own standards, as well as competitive buffer to potential runaway OEM pricing schemes. Thank you.

MR. ROBINSON: Hi. My name is Alex Robinson. I work for the Afya Foundation of America, philanthropic, not-for-profit. We take in used equipment and remanufacture it -- or not remanufacture it, but repair it and make it useful and safe for the end users of it.

I'm not really going to take up a lot of time here with this. There's been a lot said here and I've found all of it very informative. What everybody's had to say here has a point.

I understand the kind of, you know, tug of war that goes on between the OEMs and others who do maintenance work. I have a couple of little observations on that from my previous experience working in the hospitals that the -- first of all, there's no guarantee of quality service no matter who it is. You know, you could get somebody who was an OEM tech who may not be as good as you would hope, but you can get a tech from an ISO who will be. So anybody can deliver quality care or quality, you know, service to your equipment.

My hope is that there will be a cooperative effort out of all of this and that any changes or new regulations that are required will take into account the needs of the community as well as the safety of the community to keeping service within reason and price as well as ensuring that the quality of it is every bit as good as what they would get from the OEMs.

I know that in my experience in the hospital there's always documentation no matter who does the service for you because if it's not generated by the

-- by the OEM or by the ISO that comes in, the in-house people in charge of it have to keep records.

My plea would be that hospitals not parse out their biomedical engineering departments. I know that in some instances when they have merged with other hospitals they have simply used shared services between the hospitals. So that, to me, is not a good way for them to go.

But, again, this is all from my own experience which was awhile back so I don't know how applicable it is today. The only other thing that I wanted to add vis-a-vie, you know, safety is the issue of cybersecurity.

There's more than one method of cyber attacks. And I'm speaking specifically of a case where a gentleman who was in the hospital was on pain medication. He went online with his smartphone, found the service manual for his IV pump, and found out how to modify it, which he did.

And, I mean, it comes to the issue of making, you know, the documentation readily available to those who need it, but also protecting things like

that. I think that there has to be some sort of, you know, check procedure that's put in there so that you can verify who it is that's getting into that because that was one -- the one big thing that I wanted to bring up because, you know, everybody has spoken about cybersecurity. And that's a kind of not well-known issue with cybersecurity is actually the patient tampering with it because they can go online. And, of course, we don't want to restrict it to the point where, you know, the techs who need it can't get to it.

The other thing I wanted to know is those -- do the OEMs define what is an OEM part? Is it anything that's used in the equipment even, you know, like common -- common semiconductor devices? Is all of that considered OEM?

That's what I would like to know because it was common practice for me to go to a vendor for any semiconductor device. And if you look in the manufacturer's manual it has a part number there for that device. It's their own part number, but it's something that if you're very careful about selecting

you can come up with the identical part.

That, to me, is not modifying it because you are using the very same device that you took out. Now, some people may not have the expertise to be able to do that, they may not know how to read the markings on to make sure that they pick up something that is at least as good if not better.

So that's pretty much all I really wanted to say. I would like to say something about the organization I work for. We have delivered healthcare devices and supplies to over 70 countries around the world. And we always respond to natural disasters.

Haiti when they had the earthquake we were one of the first down there and we actually maintain a healthcare facility down there right now. We employ 33 Haitians in there who do -- who have been trained in how to do, you know, basic triage on a patient as well as more advanced stuff like, you know, they can build a prosthetic device for them if they need to, you know, to help them get around.

And -- and Nepal as soon as they had their earthquake we shipped 33 pallets. Within two weeks we

had 33 pallets in Nepal already. And one of the things that we pride ourselves on is that we have channels of -- we have channels of delivery that manage to get through. 90 percent of everything we ship actually ends up in the hands of the person it was intended for and that is difficult to do in the kinds of places in which we operate.

So I would besiege all of you not just to us, but if you have equipment that is at the end of life to you, donate it to someone who collects used equipment and sends it to people who need it overseas.

In our operation we actually -- I am a biomedical engineer. As I said in my five-minute presentation, you know, I have over 20 years total in biomedical engineering. So I -- and was retired and then I found this organization and I was thrilled.

You know, I go there. I started there volunteering. I wasn't even being paid. They pay me all of $1,000 a month now, but, you know, you do it because you want to be providing this service. And if I didn't do it, nobody else would.

So we like to know that the equipment we

send over there is going to work when it gets there. And 80 percent of our equipment gets there with no damage whatsoever. And most of it gets there without any, you know, functional damage to it. It may have a ding or, you know, a scratch or something, but it's still quite useable. And we pride ourselves in that.

So, again, donate to Afya or donate to somebody who does take this equipment and send it overseas. Hopefully they also make sure that it is safe to use and effective to use.

MS. WAGMAN: All right. Thank you, Alex and Julie. We're going to move to Stephen.

MS. LOGAN: I'm going first.

MS. WAGMAN: Oh, I was going to save --

MS. LOGAN: Yeah. Stephen --

MS. WAGMAN: Oh, I wanted to save you for last, Mary.

MS. LOGAN: Oh, that's okay. Stephen and I are sharing.

MS. WAGMAN: Okay.

MS. LOGAN: And he was kind enough to put my slides first so I'll go first.

MS. WAGMAN: Okay. Thank you.

MS. LOGAN: So I have three slides. I shared them yesterday. I'm going to talk about them in a slightly different way today.

Standards come in three forms. There are voluntary standards, there are quasi-regulatory standards, and there are codified standards. And 13485 is a really good example of a standard that started as a standard and it's codified. The other -- there are other parts of the quality system regulation that are very similar.

A lot of AAMI standards we call quasi-regulatory because they help the medical device companies primarily get their products through the 510(k) process more easily.

And electrical safety is a really good example. If you can certify the electrical safety to 6061, which is the seminal electrical safety standard, than it's easier to get your products through the process or it should be. Arguably it's easy to get it through the process.

There are other AAMI stand- -- there are

some AAMI standards that do impact healthcare delivery organizations that I would call -- you could argue about whether they're regulatory, codified, or quasi-regulatory or voluntary.

But they -- the healthcare delivery organizations definitely consider them, themselves, to be regulatory because CMS and the Joint Commission or the other certifying accrediting organizations ask about compliance.

One of those is the dialysis -- AAMI dialysis standards so which is on the next -- on the next slide. So dialysis equipment AAMI has standards for dialysis equipment. And the water quality standards are for the healthcare delivery organizations that deliver dialysis treatment. So those standards are used by technicians and by the dialysis techs, but also in the service and calibration preventive maintenance and repair process.

So HTM professionals who do work with dialysis equipment are very familiar with and know that they could be asked and are asked by CMS or by the Joint Commission about compliance with those.

The same with AAMI sterilization standards. If you ask Sue Klacik who spoke from International Association of Healthcare Control Cervice Material Management (IAHCSMM) what is the sterilization bible for healthcare delivery organizations, she would say ST -- AAMI ST79 and there are others.

The Joint Commission will ask for proof of compliance with ST79. And when I say the Joint Commission I'm using that very loosely. It could be one or the other accrediting bodies. When they go in they all do it a little bit differently.

So there are examples of where regulators participate in the standards development process because they have an interest in seeing the higher level of compliance and they regulate to standards.

I talked a little bit yesterday about the two new standards development activities that are starting up in December by AAMI in the equipment maintenance and repair and servicing area.

One is the definitions committee and that is a direct result of the FDA's docket item here. So thank you, FDA, for -- for us one of the most

important early learnings from this docket was how much of a need there is for common definitions.

If you look at all of the submissions that people made, there's a lot of variation and need for conformity and harmonization around definitions so AAMI's tackling that. And if you didn't get the e-mail address from yesterday, come and see me at the end and I'll be happy to tell you who to contact if you're interested in participating.

And then acquisitions is another one. We actually have as a part of our strategic plan the board has made a priority the development of -- at least the start and development of at least two new service-oriented standards a year because it's an area that is in need of standardization across -- across.

It's very hard -- especially with the consolidation of healthcare delivery organizations, it's hard when service procedures are different across all of the different organizations that have been acquired by a system.

So it would -- standardization of all kinds of things is happening in healthcare delivery.

Service is one of the areas where it's low hanging fruit to develop more standards.

Other areas that I've heard from this event that would benefit from additional standards development are -- and we've heard this from other events, as well -- recalls, the needs for some standardization of recall management, a standardized recall form.

Healthcare delivery organizations have begged AAMI to work on a standardized recall form. If you're managing 200 or more recalls a month, which is very common for a large system, having 200 different recall forms is very difficult for them to track so they say.

And then more standardization of sharing information and from near misses, from adverse events, what does that mean just from equipment malfunctions so that service organizations and manufacturers, regardless of whether the manufacturer is the service organization, but all service organizations need to be part of that feedback loop. And the information should be consistent so that it's useful and can be a

part of that lifecycle.

And then standardizing what process validation means and what it is, how it's done in standardizing the documentation part of service in healthcare delivery would be -- would also be really helpful I think from hearing all of the discussions yesterday and today. That's it.

DR. SPIEGELBERG: My name is Steve Spiegelberg. I'm here to talk about ASTM activities, the other four letter standards organization. ASTM stands for American Society for Testing and Materials. It's a volunteer organization, consensus organization.

All the standards that come out of ASTM are drafted by its members and the members tend to be OEMs, testing labs, regulatory and other government agencies, raw material suppliers, consultants, and really anyone who wants to participate in the process of drafting these standards.

My particular task at ASTM involved cleanliness of medical devices. ASTM got into that activity back in 2000 following a problem that one of the orthopedic manufactures, Sols Orthopedics, had in

2000 with an acetabular cup called the InterOp which had a manufacturing residue that was left on due to an improper cleaning process.

About 2000 patients had to be revised and the resulting $1 billion settlement kind of got the attention of the orthopedic industry and we realized that we needed standards to assess how clean devices are and how do you verify those processes.

So starting in 2003 we started to develop workshops, we've had symposiums and we actually have a workshop next month in Orlando on reprocessing of reusable medical devices. And I encourage anyone interested in that area to attend.

The -- we've been working in a couple different areas and standards over the past 16 years. The first one is designing of medical devices for cleaning. It's often an after effect that people think about, oh, yeah, I need to clean this before it get sterilized, packaged, and off to the clinical setting.

But you want to be considering what materials are used in the device and can they handle

the cleaning process for reusable devices or reprocessable devices, can they handle multiple cleaning cycles including sterilization cycles for reusable devices, are there biological materials that are left on there that need to be processed and removed in addition to the manufacturing materials used to refurbish the devices, and then what cleaning devices are available for use. And what the standards are working on is how you design medical devices with all of these factors in mind.

We're also very active in standards for verifying that you've done a good job of cleaning your medical device. And there are multiple standards that we've developed over the years for determining what residues were present on them, what levels identifying what they are, and moving towards established acceptable limits of residues on the medical device to ensure that it'll still be safe and effective.

And along the way we also have a standard guide for selecting test soils to challenge your medical device cleaning process and for validating your cleaning process.

And there are additional standards from ASTM that you may be interested in involving specific types of medical devices as well as cleaning processes, themselves.

MS. WAGMAN: Okay. If people have questions, if they want to come up to the microphones. Just, again, if you say your name and affiliation and keep it to a question.

I'd like to start with a question, if I may. It's from Penny Butler, the American College of Radiology.

How do we take the system and practices described by the successful service area and propagate those practices throughout the service industry?

MR. STELDT: I think through standards like we suggested -- I think through standards as we suggested I think AAMI offered some workshops and they have great standards for dialysis. And producing those standards would allow us to share those best practices throughout the industry and other organizations.

MR. SEMONE: Hi. My name is Jeff Semone.

I'm with Varian Medical and I'm also here representing manufacturers.

I'd like to point out that standards are wonderful. Honest to God, every time we get one it's helpful because it makes it easier for all of us, I mean, literally all of us, to figure out exactly what's supposed to be done.

But one of the differences between standards as they're enacted in the United States versus other countries is that there are ramifications if they're not followed in those other countries that are very different from what they are here.

For example, with 13845, while I'd agree it is codified. It's codified with respect to the current MDR and with respect to the forthcoming MDR. And what that leads to is the opportunity to have regul- -- regulatory, excuse me, actions taken against companies that are found to not be following those standards.

And I think you'd agree with that, right?

MS. LOGAN: Me?

MR. SEMONE: Yeah.

MS. LOGAN: Yes. Like the example I gave with sterilization and healthcare delivery would be another example of that.

MR. SEMONE: Perfect. Thank you. So the reason I mention that is because in the scheme of the United States -- and I'm, again, glad to hear that everybody here is, in fact, agreeing that we should be following quality systems that are laid out.

The fundamental difference is that the companies that are selling their services and/or products into the European market lose the opportunity to sell so there's a very real implication if there's a failure on their part to do those.

Whereas here it's a voluntary thing in the U.S. if you're only following 13485. There's no meaningful regulatory action that can be taken place against a company that fails to follow the standard.

It may be that their customers say, well, if you can't tell me that you're following it I'm going to choose to go with somebody else who is, but there's no regulatory action that comes against it.

Whereas under the quality system regulations

that exist, the FDA shows up, it's a police force. They walk in, they have badges, they can do all those unpleasant things that I think we heard mentioned earlier today. And there's a very real impact in terms of the meaningfulness of that little visit every two to whatever number of years that choose to show up.

That's very different from if an ISO organization shows up and says, hey, you're not doing this very well and we'd like to see you fix it in the next year. And I think that that's a real impact, again, back to the throughput of the whole lifecycle of a device that we need to be cognizant of as we talk about where the future of this, you know, current situation should go.

MS. HORN: Okay. If I could respond to that, please. So I think we have, you know, obviously some differing opinions in the group as to whether there truly is a real issue or not. You know, we've provided some statistics that says this is not an issue. Please don't fix what's not broken.

But I also wanted to address why there is

some concern from in-house organizations such as myself and the ISOs. You know, one of the questions I hear is, well, why wouldn't you accept these standards, why wouldn't you adopt these standards. And so I was jotting down some of the recommendations and I just wanted to kind of tell you about maybe what we're thinking a little bit.

So, first of all, make no mistake, this is a -- the service industry is a multibillion dollar industry. There's a lot of money at stake here. And so and patient safety I truly do believe is at everybody's top of mind and the reason we're here, but there's also a lot of money involved. And we have to keep that in mind.

So the fear is one of -- some of the things that were outlined by some of the OEMs is a process to ensure personnel are trained and competency is verified.

So what's going through my head is who decides that? Where are they trained? Do the OEMs -- does it -- do they have to go to an OEM school? And, if so, again, an example of this is that we spend

about a million dollars a year to train about 110 technicians at my organization alone. $40,000 to send them to CT school, you know, cath lab schools are -- it's getting more expensive and more expensive.

So if we, as an in-hour organization -- and I'm sure the third parties are thinking -- or the ISOs are thinking the same thing -- if the vendors or the OEMs, rather, are saying you have to send them to our school and you have to pay $60,000, you know, $40,000, whatever the case is, for every technician, for every model, that is cost prohibitive.

Most organizations don't have that kind of money do send them to that school. So, in fact, what happens is it becomes an issue with providing safe and reliable service because we cannot train our people.

The same -- the other part was use of calibrated tools and test equipment. So for us to get these calibrated tools and test equipment, again, we must go to the OEMs. So we're talking, you know, $24,000 for diagnostic software from some of our OEM vendors.

And this is not uncommon. This is for every

single device and these are devices that we have many of them throughout our system so we're talking again, you know, hundreds of thousands of dollars for these calibrated tools and test equipment. So these are just some examples.

And I want to make sure so, you know, I kind of think of -- I was going back to my little high school literature days and the Edgar Allen Poe story about the monkey's paw. You recall that one where they have a -- you know, you wish for something and it's going to be a great thing and you're going to get it, but every time he -- the fellow wished for something, something horrible happened, was not the intended consequence. And I keep going back thinking about that story when we talk about this.

Everybody here agrees that quality service, patient care is extremely important, but how we get there and what we wish for we have to be very careful that we don't wish for something that has those unintended consequences.

And, again, you know, I want to applaud the FDA for getting the other side of the story here. But

when we talk about cost -- and somebody else suggested that cost was not an issue or we shouldn't be talking about it -- we truly do believe it's one in the -- they're together. You can't have quality service without getting the training and the parts and things that we need and we can no longer afford to do that because of the skyrocketing costs.

I probably didn't answer your question, but.

MS. WAGMAN: Anything from the audience? You guys have gotten very shy all of a sudden. You're just ready to go home.

We knew Scot would be here. Remember it's got to be a question, Scot, so.

MR. MACKEIL: I have a small question.

MS. WAGMAN: Okay. Go to the mic. Thank you.

MR. MACKEIL: So I -- during the break I had a lovely chat with Ms. Federici from AdvaMed and in a lot of ways we're at the opposite ends of the spectrum. And she told me the story about how valuable intellectual property, also known as service manuals, are to her clients.

And I told her my side of the story is that when a piece of equipment comes into my hospital and the salesman asks me to inspect it I want to read the service manual to understand what that device is so that when I put my initials on that inspection sticker and fill out that work order that the value of my work is validated by the service manual.

But there's that dichotomy of they don't want to share their intellectual property and I want to serve my caregivers.

Who on the panel can tell us about a middle ground where the needs of both parties could best be served?

DR. SPIEGELBERG: Do you think it would work if they were to provide an IQOQPQ (Installation Qualification, Operational Qualification, and Performance Qualification) guidelines? That would be a subset of the overall service manual.

MR. MACKEIL: (Off mic.)

MS. WAGMAN: Scot, can you come to the mic? Thanks.

MR. MACKEIL: So, in other words, a

performance verification procedure?

DR. SPEIEGELBERG: Yes.

MR. MACKEIL: That's a great middle ground as long as that -- that might come along with if they were special tools or test fixtures that would accompany that device. That's something I always tell the service representatives if it needs cables or disposables, bring them because I'm going to use them. So, excellent.

MS. LOGAN: I don't have an answer for you, Scot, because this -- that question and some of the others, the question of why wouldn't you be okay with regulation, why regulate, that's a tough question, too. Where's the middle ground there?

I -- there's so much mistrust and a history of mistrust between -- and I'm speaking from the middle of hearing it from all angles. There's so much mistrust that's built up over the years that I think people have to start with easier common ground and build the trust. And once the trust is built, then finding middle ground is a little bit easier.

Right now those -- the hardest questions no

one really wants to find middle ground because of views all the way -- or everybody's views are so far apart on some of the toughest issues. I think everybody would agree training is important. Everybody would agree that credentialing -- I haven't heard people talk about certification. Why not mandate certification? That'd be really good for AAMI.

I don't think there'd be middle ground on that -- on that either. There's a -- it's the how to achieve the different ways that people look at this that middle ground is going to take some work.

MR. ROBINSON: I'd just like to add one little point on that. If the issue is intellectual property, once that product is no longer being promoted, sold by them, then where's the proprietary concern for it?

It's no longer of use to anybody to compete with you so once it's no -- once they consider it to be no longer on the market, why not release the manuals, then?

MS. WAGMAN: Do we have any other questions

for this group?

MR. SHRADER: Pat Shrader with Medtronic. Mary, I appreciated your comment and I actually had the word certification written down here.

My question, which is probably a multipart question, is, you know, Medtronic is a company that does work with ISOs and works with biomeds and hospitals and we don't insist by and large on doing all the servicing ourselves.

My ques- -- first question is listening to people today I can hear a clear distinction between good third parties and not-so-good-third parties. And my question was going to be so we only want to work with the good third parties. How do we determine which ones those are?

And I've got to believe here that there's some common ground between us that we want good third parties, you know. As far as hospital personnel, I'm going to assume that the hospital in order to meet other standards and in order to maintain its reputation has to assure themselves that they have properly qualified and properly trained people.

But how do we assure the same thing about third parties? Any response other than should we be thinking about a certification program from anyone?

MS. MARDIKIAN: Well, what I would say is you do your due diligence. I mean, if you were going to go to a doctor you would verify or check to see through the reputation of that doctor if you're going to have them do a surgery on you.

Wouldn't you do the same thing if you were going to employ a company to service your medical equipment whether it be a hospital or a third party?

MS. SHRADER: I agree with what you're saying if this was someone that I was approaching to, you know, provide service for the company's products I would do that. I guess I'm just -- I'm not certain how if someone comes to me what is it that I would look for.

MS. MARDIKIAN: You would look to see if they had standards in place, do they check their vendors, do they have a vendor list in place, do -- ask them to show you documentation.

MS. SHRADER: Okay.

MS. MARDIKIAN: I mean, if they can't --

MS. SHRADER: So --

MS. MARDIKIAN: -- provide the documentation, then I would question their reliability. If they can show you documentation that they're doing and providing the bridge between CFR and their standard and they can legitimately show you that documentation, then I would classify them as somebody to work for you.

MS. SHRADER: So if we were selecting a new vendor sometimes we look at documentation, sometimes we actually audit the vendor in their physical facility. And I would think that might be particularly important if you were talking about providing service for a higher risk product, auditing.

DR. SPIEGELBERG: I think auditing should be done all the time on your service providers. Your quality management system extends to all your service providers so you have to make sure that they're compliant with it.

MS. SHRADER: Well, historically our quality management system applies to people who are selling

services to us and it would also apply to someone that we -- with whom we have a contractual relationship, you know.

That is not necessarily the case with all of the third parties who come to us and ask for a service manual, but may not -- may not ask for or may not choose to get training.

MS. HORN: Okay. So, you know, I'll change the question a little bit. If I were looking at hiring an ISO or a third party and what would I look for. And some of the things you mentioned, you know, obviously we'd look for.

It's worth noting, though, it does not take very long to find out who is not doing a good job. Word travels very, very quickly in a hospital setting about cases where there might be, you know, I think somebody used shoddy workmanship or something like that.

And so at that point in time we will cease and desist doing business with that person or that vendor. And so -- and this is -- you know, and they are not going to stay in business very long, quite

frankly.

So it's, you know, there's a competitive thing going on there that if they are not providing quality service that the doctors and clinicians are seeing equipment that they see that, you know, that they feel is not being maintained properly, they will let us know very, very quickly about that.

And we will validate, you know, whether it was an issue and, again, cease and desist doing any kind of business with those people. So it's, you know, we -- in this particular case we have not had any issues with any patient injuries due to service thankfully. But, again, we'd very quickly find these things out so.

And I'm sure that most hospitals are the same way. The physicians and clinicians are very, very obviously and rightly so particular about their devices. So if they're not working properly, they will let us know.

MS. SHRADER: I appreciate that. And it would be really helpful if that kind of information were also available to the OEMs.

MS. HORN: And, you know, I would say that all you have to do is ask. We do have that information. You know, again, we do collect it in the database. We have risk systems where we track patient incidents where any -- any relatable patient incident whether it's a drug adverse event or whether it's a, you know, clinical device.

And so, you know, I agree that that's something that we should be sharing if asked. And, you know, again, it's just more a matter -- when vendors and OEMs come to me and say can we have that information, we hand it over to them because it's not anything that we're trying to keep to ourselves.

MS. SHRADER: Okay. Thanks.

MR. RIDGWAY: If I could just add to what Heidi said. I think we need to step back a little bit and take a look at the forest. Economics is really at the heart of this issue.

Healthcare is under a lot of economic pressure. And the industry has found a solution, which is the onsite model that we talked about, and there's an allegation that onsite model is adverse to

patient safety because servicing as performed through this model doesn't meet the standards of some of the people.

And I'd like to just go back and quote again from the FDA's regulatory science priorities for 2017 where they had a statement that talked about leveraging real world evidence to supplement traditional data to inform regulatory decision making.

There is real world data out there and the data is that there is a patient safety problem, but it's not from servicing. It's from use errors and other things. I mean, there is adequate statistics that say these are the real targets that we should be addressing if we're really concerned about patient safety.

And I would just suggest that, you know, the allegation that servicing problems onsite are creating a problem with respect to injuring patients that it isn't -- there is no evidence to that effect.

And I feel the consequence of passing some unnecessary regulation will be a further reduction of economics which will ultimately damage patient safety

by taking funds away from the hospital to spend where they -- on where the problem really is.

And I think we've sort of lost sight of that longer vision. I mean, to me the whole challenge is where is the real world evidence that there is a service-related problem with respect to patient safety. And that case is not proven.

And, as I say, the adverse thing which I think we need to keep in mind is there is a downside to passing unnecessary regulation or solving a non-existent problem- it's going to take away from our ability to solve real world problems where there is evidence that there -- and, you know, I think if the manufacturers are upset, they should think about designing equipment that would minimize the use of -- the prevalence of use errors.

You know, I think we could start a whole different campaign saying, you know, take the evidence we've got from the hospital that says there are certain device designs which are contributing to the problem of patient safety by being hard to use.

So I could talk for a lot longer, but I

don't want to get the hook again.

MS. WAGMAN: Yeah. Thank you, Alex. We're going to go to the question at the back.

MR. SZEREMETA: Hi. Brian Szeremeta, Global Regulatory -- sorry, Global Quality and Compliance Director.

My question is to the team up there representing the ISO group. So if you're not aware, the FDA spent many, many years through Kim Trautman working with notified bodies to develop a medical device single-audit program.

That program is for notified bodies and registrars to come into FDA regulated sites, perform an audit or inspection of that site, provide that information to the FDA, and the FDA will use that either to react or just keep track of what's going on at the registered sites.

Would you consider participating in a program like that since you're ISO registered, you have a quality management system. You would have to engage you registrar. Your registrar would have to be approved to perform those types of audits.

But would you participate in that type of activity to further show that you have a quality management system in place?

MS. MARDIKIAN: I hesitate to answer that question because my boss is in the room. But I'm pretty confident that all three of our sites would definitely have some issues, but I would say absolutely. Definitely.

MR. SZEREMETA: Because there was a comment I think yesterday about not wanting to place additional inspection burden on the FDA. Well, that program places no additional inspection on the FDA. It's actually taking inspection burden away from the FDA to focus on PMA audits, to focus on for-cause audits, and not the routine inspections that take up so much of their time.

So I think that's an important perspective for us all to think about if registration by the ISOs is required.

MS. WAGMAN: Uh-huh. Thank you.

MR. GRIMES: Thanks. Hi. Steve Grimes with Strategic Healthcare Technology Associates.

The question I have is for those of you who are familiar with AAMI's EQ56 and EQ89 standards -- you know, and this is along the lines of a question that was asked previously -- would -- and then those standards both are referenced both by CMS and the accrediting agencies.

Would those be appropriate guidelines for the organizations, you know, manu- -- the OEMs and others who are perhaps looking to determine whether someone is the appropriate systems, quality systems and such in place?

You know, would that be an appropriate reference both for the OEMs as well as organizations perhaps who are looking to contract with ISOs to see whether they have those kinds of capabilities? Would those standards be useful in that sense?

MR. RIDGWAY: Yes.

MR. GRIMES: And for those that aren't familiar with the EQ56 or the EQ89, those -- well, the EQ56 is a medical equipment maintenance standard and EQ89 is -- or EQ56 is medical equipment management standard and EQ89 is a maintenance standard so.

Again, so it's useful to know again those have been referenced by CMS.

MS. LOGAN: And they do get -- and they do get referenced in the audits and inspections.

MR. GRIMES: In the Joint Commission and DNV (Det Norske Veritas Healthcare, Inc) and other accrediting organizations, right, they use those as a --

MS. LOGAN: Yeah.

MR. GRIMES: -- reference. Thank you.

MS. WAGMAN: Okay. We're going to take a question from online. Would the top three OEMs be willing to submit in writing what requirements from ISOs is needed in order to access the different level service keys?

MR. SEMONE: Can you repeat that?

MS. WAGMAN: Would the top three OEMs be willing to submit in writing what requirements from ISOs is needed in order to access the different level service keys?

MS. HORN: I think what they're saying is that in some cases -- they're talking about the

service diagnostic software. And in some cases there are what the OEMs have, their technicians have, and then there's a less functional level that is provided to third parties.

And so I guess the question if I could translate for them is what would they need to do to get that higher level of software.

MR. SEMONE: So I'm not from one of the top three so I've got to be honest, I'm not sure exactly who that refers to. I think I know, but I'm not positive.

I think part of it is, again, we have to operate under the regulations. If we were going to provide that level of access, I believe that we want to have that person be qualified as a supplier to us. And so they'd have to go through the appropriate supplier controls, pass whatever those criteria are based on the activities that are being done, and then you also have to have a business contract to say you're going to go into. And you'd be responsible for protecting the IP, just to come back to that issue, to be doing that type of work.

So I don't think it's all that difficult. I think the hard part becomes where, again, I think as was stated earlier, somebody just wants the manual, but they don't want all the burden that goes with it I think is where the problem comes in.

And also to separate, I mean, that's why we're talking about third-party servicers as opposed to the second party, the customers. The customers have paid to have those devices, paid to have the service materials. It seems a little unjust and is truly in the spirit of real competition to be asked to give away our IP to somebody else who is not involved in the purchase of the devices.

If somebody's appointed as a surrogate for the hospital and is doing their service, I don't think people would have any problem -- I don't think, excuse me, the companies would have any problem saying, okay, as long as they meet the criteria I just laid out and had an agreement not to disclose the information and not to use it inappropriately why that would inherently be a problem.

But I think there's a lot of reticence

towards doing those types of things, as well.

MR. RIDGWAY: Can I ask you a question? If the FDA relaxed their oversight of service from OEMs, would that change anything in terms of their willingness to train other people as it would be a revenue source?

I mean, you seem to be quoting some obstacles that come out of the regulations. I'm not a big fan of requiring that service, even by OEMs, be regulated. I'm not sure if that's on the agenda, but I was just curious as to whether or not it would change the attitude of the industry. What do you think?

MR. SEMONE: Well, I don't know. Are you saying that the FDA should stop regulating all of us for that because we might be willing to be fine with that, right?

MR. RIDGWAY: Well, I think a good argument could be made if there really is no evidence that service causes patient injuries, then relaxing the requirements -- I mean, I'm fine with the FDA regulating the manufacturer's devices. It's very

appropriate.

But I think service got slipped in there kind of by accident because I don't think service or service-related issues have anything to do with patient safety as we found out. Maybe we didn't know that at the time, but that's the way it's turned out.

MR. SEMONE: So I've got to be honest, I think I'd challenge that concept. So yesterday we heard Dr. Hemphill specifically state that the VA, until they have had a number of problems at some lower level, they don't typically go back to the OEMs because, quite frankly, they didn't have time.

In addition to that we had -- and I believe it was Scot and, forgive me, I don't recall your last name -- yesterday also say that in his experience there were not a whole lot of biomeds (biomedical engineers) that were either well trained or well experienced in understanding how to deal with the MDR system which I will agree can be challenging if you're not used to dealing with it. I totally agree with that.

I think the result of those two things is

results in a couple of black holes of data. I think it's unreasonable to conclude at this point that the data is tied together to effectively say that service does not play a role in injuries.

I suspect it's not great. I'd be the first one to agree with that; however, you simply don't know right now. There is more data that needs to be collected and it may be out there, but I suspect it's squirreled away hundreds of hundreds of different places particularly with the ISOs, with the hospitals. I mean, I think everybody has their own little piece of the piece of the pie. Certainly OEMs have their piece of the pie.

I don't think there's any coherent view of that at this point so I think it's a real stretch to say that that doesn't impact it. So I wouldn't be willing to ascribe to that at this point.

MR. RIDGWAY: Well, I think you have to take science into account. I've got photographs of airplanes that have crashed. That doesn't mean the statistics for flying makes it unsafe.

I mean, I don't think anecdotal evidence --

MR. SEMONE: As a former helicopter pilot for the Navy --

MR. RIDGWAY: -- like photographs of incidents really builds the case statistically or scientifically.

MR. SEMONE: As a former helicopter pilot for the U.S. Navy I would tell you at times flying is very unsafe.

MS. WAGMAN: All right. Scot?

MR. MACKEIL: Earlier we had gone down the road talking about how we can assure manufacturers that the people other than their staff who would service their devices in the hospital are qualified and trained correctly.

We had mentioned the word certification. We had mentioned, you know, certification as a means to ensure the quality of the service providers.

One of the privileges that I have is to work with a lot of young biomeds and interns and clinical engineers who are coming into my facility. And back in 1994 when I passed the CBET exam I was running a one-man biomed shop and I had to know everything about

being a biomed that, you know, from bed pans to CAT scans and then the next place I am I'm in a --

MS. WAGMAN: Scot, can we make sure we get a question in here? Sorry.

MR. MACKIEL: Yes. Here's the question. Certification, licensing. Here in my hand is a general class radio operator's license issued by the FCC. But there's a level below this called the technician class and a level above this called the extra class.

What I would like to see for my -- the youngsters coming up is a BMET (phonetic) class of certification where they get all the basic information about how they -- what they need to do to service equipment safely in compliance with regulatory standards.

And it would be an entry level certification. I would like to have that certification include things like reporting. This is what you need to know about reporting, this is what you need to know about the manufacturer's quality standards.

And not only would I like to see services like BMETs in hospitals have to take that exam, but the services employed by manufacturers to take that exam that come to our hospitals because as part of that entry level licensing exam they would learn about blood borne pathogens, they would learn about safety in the clinical environment, they would -- a license -- an entry level license that was applicable to all services at all levels would build common ground and understanding so that when we took the next level of exam, which might be a BMET II exam where you get into specific specialties and modalities, where the CBET and CLETs and CRES-type exams and HT management are the highest level, you know, equivalent to the extra exam or the airline transport pilot's license.

Can we think about this type of a thing to ensure the quality? What would some of the panel members think about changing the way we look at licensing and certification to meet some of the needs of all the stakeholders? What do we think?

MS. LOGAN: Okay. I'm going to separate certification and licensure because I think they're

two separate things. There -- if you want to talk about diverse opinions, I think there would be -- there would be diversity within OEMs, there would be diversity within the service industry, and there's just a lot of really strong opinions about whether or not service technicians should be licensed.

And people who want it say you can't cut hair in a state without being licensed, but you can work on a critical medical device. So AAMI has had in its strategic plan for almost since I've been there for the last five years we keep pushing the date out to figure out, to assess whether or not licensure would be a good thing for the entire field.

And it's a hard one for AAMI because we're not an advocacy organization so all we could really do would be to develop tool kits that people could use when the issue comes up because it does come up. There have been states that have wanted to license these professionals.

And there isn't really an organized answer to the question so it's just; that's a really hard one. It's worth continuing the conversation, it's

worth a group finding common ground on it and having good answers when the state legislature pops the question.

Certification, great -- some great suggestions there, Scot. I took some notes. AAMI has a BMET exam. It doesn't have the basic -- it's working on a BMET 101 course for people to come into the field whether it's working for an OEM or elsewhere.

That if someone's coming to work for an OEM and their experience is in the car industry, which is not an unusual path, the BMET 101 course could be something that people could take. But we're not sure there's a market for it yet so it's been kind of slow in development.

But I think you have some really good suggestions about the current CBET exam adding more robust questions about adverse event reporting obligations and I would add to that infection prevention because we worry a lot about hospital acquired infections and the knowledge of service professionals across all sectors really understanding

that.

MS. WAGMAN: Okay. We're going to take one last question and then Scot's going to wrap us up for the day. So thank you.

MR. SPEARMAN: Jim Spearman, Consensys Imaging Service again.

First of all, I just want to say thanks for everyone pulling this together. And I think there's been a lot of positive comments here about the folks in this room are leading the path. We are not the problem all of us collectively, including all the OEMs. And it sounds like there's been a lot of tug of war on both sides of this issue.

Let me state something very clearly from my perspective. As we mentioned previously, Consensys plays on both sides of the table. We represent OEMs, we represent independent service organizations.

To say that there is not empirical data that there's no patient safety or risk issue is a problem. We know that there is a reporting issue, okay. We've heard multiple times today hospitals, hospitals, hospitals.

You're completely blind to the large vast numbers of imaging centers that are not affiliated with large health organizations, okay. Those organizations are not mandated to report we know for a fact unless this gentleman who provided all these wonderful photographs of damaged systems and injuries and patient risks and safety issues, unless he doctored those through Photoshop they're real.

I don't know about you, but this is America. We have the FDA. There's medical devices. They were regulated when they went into service. There should be some level of compliance to those regulations regardless of age, who's servicing those.

We've heard a lot of argument back and forth about, well, I don't like this, I want this from the other person. I would encourage us all to think this is a workshop environment, let's think of the words from JFK, "Don't ask what your country can do for you, ask what you can do for your country."

What would you, as individual stakeholders, be willing to put forward? This is supposed to be a best practice and future path forward. What would you

recommend as individual stakeholders?

And then put on the FDA's hat for a moment and say I'm sure they don't want to have to go out and comply and do all these checks and everything else. What would you as individual stakeholders with your peers -- not all OEMs are maybe appropriately represented here as we heard one comment, well, my boss is in the room so I'm not sure I may be able to speak.

What would you recommend as what we should do going forward?

MR. RIDGWAY: I would certainly -- I didn't get the full story out, but a best practice is collaboration between both sides, between the OEMs and the users, to make sure we've got good information about where the problems are.

And I'm here to say the door is open if we can get some collaboration for the sake of the country, for the sake of patient safety to get some real information and based on that move forward.

And I think that should be the flag under which I'm willing to walk forward.

MS. HORN: I completely agree. And, you know, to take it one step further, you know, we would certainly commit to send our people to as much training as possible, again, assuming that it's -- we can afford it.

And we certainly would be willing to use OEM parts all the time, again, if we can afford it. And so that's -- you know, that's where the give and take comes. When we cannot afford to do those things and it becomes cost prohibitive to do that that's when we start looking, you know, okay, now we have to go to the ISOs, now we have to find alternatives.

And so, you know, again, I still think that having that competition with the ISOs is a good thing. But that's where, you know, we are certainly -- and I know I speak for all hospitals and in-house clinical engineering service organizations -- willing to do that so, but it has to be something that is feasible.

MR. RIDGWAY: Let me just add to that. We can afford to do the things that Heidi was talking about if it's going to buy us something in terms of patient safety. But if putting those dollars into

buying those parts and buying that training at extended prices is going to take away funds from training users so that we get -- so it hurts patient safety, we don't want to do that.

We want to put our money where it's going to do the most good for us. And I think we should all drink to that.

MS. HORN: Good point. Here, here!

MS. LOGAN: I think the gentleman from Consensys just did a beautiful summation of the whole event. At the end of the day that was beautifully stated.

And I want to turn that into an expression of gratitude to the FDA. I'm not answering your question, sorry, but an expression of gratitude to the FDA for putting the issues out on the table and spending all of this time. I mean, 177 comments that they've had to go through and will have to go through, holding this workshop, finding great people to speak, getting industry and this other non-OEM service people in the room together, that's the beginning I think.

I hope in five years when I'm sipping a

beverage on some deserted island in my retirement that someone will tell me how much success has been made in bringing everyone together to find that common ground. But I think this is the start of it, so thank you, FDA.

MS. WAGMAN: Well, on that thank you, Panel. Thank you. And good luck, Mary, with your retirement.

And I'll turn it over to Sean.

CAPT. BOYD: Yes. Scot, you've had so much to contribute over the last two days we almost thought you were going to do our wrap up. So you fooled our moderator, but I'll do a brief wrap and let you go.

So first I want to acknowledge the FDA planning team that worked over the past few months to pull this together. So it's all the people that have been sitting at this table, it's your facilitators, it's your timekeepers, and others who have really made this event a success. So if you'd just join me quickly and acknowledge them, I'd appreciate that.

(Applause.)

CAPT. BOYD: And I also wanted to thank each of you for participating in it whether you're a member

of the audience, whether you had remarks to make during our open public comment sessions, or whether you're a speaker or panelist. You've given us a lot to think about over the last two days.

And I think we've heard here's what you can do for me, we've heard here's what we think we can do together, and you did steal some of my thunder with some remarks that I wanted to make now.

I think we're getting to a place where we're asking the question how can I help you be successful or how can we help one another be successful going forward. And that's what we've started over the course of the last two days and that is the attitude and the momentum that we want to carry forward as we continue to work through many of the issues that we've heard.

So just to kind of give a brief recap over what we've built on between day one and day two, we heard stakeholder perspectives and a lot on benefit and risk yesterday. And a lot of common themes in the same -- in the sessions today regarding characteristics of good servicers, challenges that

stakeholders face in performing these various activities, and most recently the best practices and future recommendations at this panel and you were able to engage on.

So I think some of the clear themes that were -- we continue to hear that we need to better understand the problem, what data exists out there, where are there gaps, and what sources of data might be untapped that we can really utilize to kind of best understand what options we should consider going forward.

We heard echoes of visibility and transparency of the activities that are being performed of information that's out there regarding errors or adverse event reports, for example, so that we have a good handle on what the true experience of the device is in the hands of the user when we're performing these activities.

We've heard echoes of the importance of quality management systems over the course of the last two days. Whether that is related to adherence of the product or to -- or ensuring that servicing activities

ensure adherence to performance specifications whether that is servicer competency, whether it is related to recordkeeping, supply chain integrity, or reporting of event and errors.

We've heard questions about what are roles of standards, what are the roles of licensure and certification most recently as we seek to identify solutions going forward. And that's really the place that we're at right now is working to determine the appropriate balance of oversight and reliance on really market forces to drive this ecosystem toward high-performing servicers and ensuring high-quality service is provided to customers for devices over their useful life.

CDRH's vision is to ensure that patients have access to high quality, safe, and effective devices. A public health importance first in the world. What we're trying to accomplish here or what we're trying to accomplish going forward is really to ensure that that is sustained over the useful life of the product.

So in terms of next steps you've really

given FDA a lot to deliberate on. We've said before that we didn't come into this with any preconceived notions. We're certainly not aligned with any one of the organizations or entities that have been represented over the course of the last two days.

Our interest is in patient safety. We heard the importance of recognizing FDA's mission in that and we do take that seriously. And then that is going to guide our thinking and guide the actions that we take as we look to collaborate with you more in follow up to this workshop.

We're going to have a lot of material to digest. I don't know how many dozens or hundreds of pages the transcript will produce, but that will be -- that will take us some time.

But based on analysis of that, I would expect to have additional opportunities to weigh in and work with one another, work with us on what the possible solutions are going forward.

So with that, one upcoming workshop that I wanted to mention and encourage some from this venue to consider participating in, as well. Another aspect

of our vision is to ensure that U.S. post-market surveillance really quickly identifies poorly performing devices and accurately characterizes the real world performance in order to facilitate and to facilitate device approval and clearance decisions.

It was mentioned that we had some information go out recently regarding hospitals and reporting. And there's an FDA public workshop that is -- that has a longer title than this one if you can believe that -- titled The Role of Hospitals in Modernizing Evidence Generation for Device Evaluation, Harnessing the Digital Revolution for Surveillance.

That is on Monday, December 5th. And I understand the registration is currently open. That workshop will explore the critical role that hospitals play in evolution of basic device surveillance and how we work to create more robust capabilities.

It's related to our strategic priority to stand up to national system for health technology and it's really looking to ask how we can best access and utilize patient data on medical devices to better understand other device experience in the real world

environment.

So with that, I sincerely thank each of you for your participation again and wish you well.

(Whereupon, the proceedings concluded at 4:08 p.m.)

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CERTIFICATE OF NOTARY PUBLIC

I, NATE RIVENESS, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

NATE RIVENESS
Notary Public in and for the
State of Maryland

CERTIFICATE OF TRANSCRIBER

I, LISA BEAUCHAMP, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

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NOVEMBER 9, 2016 LISA BEAUCHAMP