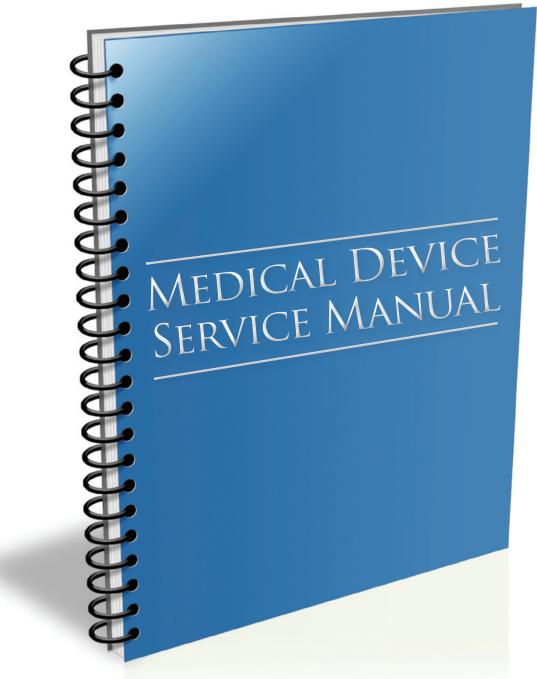
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Have You Seen Me?



The availability (or lack thereof) of service manuals points to bigger questions about the support and service of medical technology in a changing healthcare world.

Jane Sherwin

Pat Lynch has been fixing or managing medical devices for 37 years, either as a hospital employee or with device companies such as GMI, an ultrasound vendor based in Charlotte, NC.

"Engineers can fix anything with a proper service manual," said Lynch. He believes that "people who purchase equipment should have the right to determine who should repair their devices and the right to demand complete repair manuals and information. Maybe the big hospitals like Mayo and Cleveland can afford to have the manufacturer do their service, but others need to save their money for the hospital's bottom line."

On the other hand, Pat Baird, a systems engineer with Baxter Healthcare Corporation, believes manufacturers have, at times, good reason to insist that they conduct repairs, rather than provide parts for hospitals to do this work. Baird described, as an example, a malfunctioning pump mechanism he encountered at a customer site.

"I was visiting the customer to investigate complaints of device failures," he recalled. "We took apart several devices on their lab bench, and I was able to see that the repairs weren't performed properly. There were devices reassembled with only some of the screws, there were missing gaskets, and in one instance, rather than replace a harness, the hospital spliced the wireless in the harness and the splice came apart. This was not a question of the bottom line, but of safety."

Lynch and Baird are just two of the voices in a long-running debate about the support and maintenance of medical devices and technology. It's a debate that's heated up anew as healthcare facilities feel intense pressure to contain costs and face new scrutiny from federal regulators; healthcare technology management (HTM) professionals see their roles and responsibilities evolving; and the delivery of healthcare undergoes fundamental, sometimes dramatic, changes.

The question of who services what and when (and how) is more than a matter of money, although that is a critical component. The service and support conundrum—with the availability of service manuals being a lightning rod for the broader issue—also touches on matters of liability, risk, patient safety, job security, business propriety, regulations, education, training, hospital hierarchy and relationships, the fast-changing nature of technology, and an appreciation for how devices and systems are increasingly interconnected.

In that context, AAMI has launched an initiative "to facilitate greater understanding by both manufacturers and users, to find common ground and meet the needs of both groups," said AAMI President Mary Logan. There have been some initial meetings, and this cover story is part of that effort.

The HTM Perspective

While the lack of useful repair information has been a complaint for years, many biomeds say they are also frustrated by the lack of flexibility in repair arrangements, the rising costs of training, and manufacturer insistence on returning devices for repair rather than allowing repairs on site.

"It's been a constant battle for the last 40 years to get manufacturers to provide repair information," said Glenn Scales, CBET emeritus and recently retired from his job as a patient safety specialist for the Department of Clinical Engineering at the Duke University Health System. At the same time, he believes "manufacturers have their good reasons for limiting the release of information. It's always a balancing act, between their financial and legal obligations, and the needs of clients."

Jim Piepenbrink oversees the management of some 13,000 devices of increasing electronic complexity at Boston Medical Center. While he said that "some big companies go out of their way to help us with service options, and small, nimble companies can also help, with many large companies there is no flexibility in terms of service options.

"Some HTM professionals feel taken advantage of because we're not authorized to work without factory-level training but when the hospital budget gets tight, training tends to get cut first. It seems counterintuitive to have to send out devices or have the manufacturer come in to do the work. It's as though they thought we weren't capable."

Michael Fraai, director of Biomedical Engineering at Brigham and Women's Hospital in Boston, listed a number of the problems he

About the Author

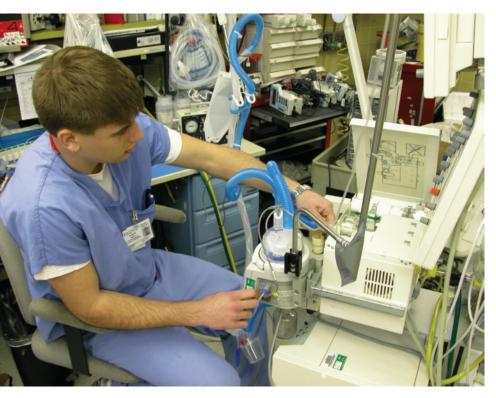


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Healthcare technology management (HTM) professionals says comprehensive service manuals and reliable information from manufacturers are a huge help when working on medical devices.

sees with serviceability. "Manuals are not current," he said. "The manual, whether hard copy or online, seems like it's becoming a legal document to protect the manufacturer rather than provide the content needed for in-house service. And when we do go online for information, the navigation seems to be different each



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— Jim Piepenbrink, Boston Medical Center

day. Also, domain expertise by manufacturer's technicians can be unpredictable, and there is not enough flexibility in available choices for service agreements."

Kenneth Maddock, vice president of facility support services at Baylor Health Care System in Dallas, said it's unrealistic to think that

manufacturers could provide all of the information biomeds might need, but some manufacturers aren't even coming close.

"With device circuitry being so complex and so dense, schematic diagrams are an unrealistic expectation and are of limited value," he said. "But some manufacturers have gone too far in limiting content or providing no manual at all."

The Manufacturer's Perspective

Manufacturers, too, have a variety of concerns about the repair and support of devices. They need to ensure that repairs are done right, and even though many express their confidence in the ability of HTM professionals-whether they are clinical engineers or biomedical equipment technicians (BMETs)—the number of hospitals is large enough that quality of work can vary. They also face the challenge of ensuring that repair information, whether in the form of a hard copy service manual or not, is kept up to date. And at least one manufacturer described a program to support hospitals who wish to do repairs in-house.

Michael Angel, director of customer quality at GE Healthcare, works with both original equipment manufacturers (OEMs) and purchasers. "I think HTM professionals have a valid complaint about getting the information they need," he said, but "just handing out a service manual is not always the best solutionand manuals are not always updated adequately." He also thinks OEMs are right to insist on proper training for critical equipment.

Jack McNerny, CBET with Ethicon Endo-Surgery Inc., a Johnson & Johnson company, said, "First and foremost industry needs to support our customer base." But, added McNerny, "we have to look at the broader picture, both manufacturers and HTMs. HTMs have to ask where their specialist's time and value are best applied. For a hospital, it may be more cost effective to send a device back for service depending on the type of device, and the level of service required. In the case of highacuity devices, on the other hand, the provider will need to have expertise on site, along with adequate training."

McNerny also pointed out that "actual ownership of capital-manufacturer vs. facility—can raise regulatory and legal issues limiting manufacturers' opportunity to freely share some service information. That's frustrating for both sides, but a result of our litigious society. The lack of regulated education and training requirements for HTM professionals poses additional concerns around proper service level competencies."

Having said that, McNerny said his company provides service information, both by PDF and on the company website. He said some biomeds have been surprised to find that information so readily available.

Baxter's Baird said he doesn't doubt the commitment of HTM professionals to their facilities and the cause of patient safety in general. But he said the question of who services and supports a device or system ought to come down to who is most qualified, and that can sometimes be the manufacturer.

"A lot of HTMs give 110 percent to their work," said Baird. "They are engaged in their careers and caring about patients, but are not always equipped to handle certain repairs."

Like a number of other manufacturers, John Brown, director of service engineering at STERIS Corporation, expressed concern about quality, regulatory, or safety problems resulting from the level of service provided. "The manufacturer has no control over the level of expertise of the technician providing service. The technician could be a fully trained biomed, a third-party contractor without any medical equipment training, or could be at a level somewhere in between. Liability and equip-



"We have to look at the broader picture, both manufacturers and HTMs. HTMs have to ask where their specialist's time and value are best applied. For a hospital, it may be more cost effective to send a device back for service depending on the type of device, and the level of service required."

— Jack McNerny, Ethicon Endo-Surgery Inc.

ment performance will reflect back on the facility, and often the manufacturer.

"At the same time," added Brown, "STERIS offers an in-house partnership program, including a brand new training facility. If customers choose to maintain their STERIS equipment in-house, we support them in that endeavor."



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Other Perspectives

It's not just HTM professionals and manufacturers who are concerned about support and service. George Mills is director of the Department of Engineering at The Joint Commission, the nation's largest accrediting organization for hospitals and other healthcare facilities. "Clinical engineers are doing a great job with the resources available to them," he said. "At the same time, manufacturers need to make sure they provide the right repair information for their customers." He said he has not found evidence of clinical engineers modifying instruments in the process of repair—a concern of some manufacturers.

"Clinical engineers are doing a great job with the resources available to them. At the same time, manufacturers need to make sure they provide the right repair information for their customers." — George Mills, The Joint Commission

> Mills also pointed to the commission's adoption of the National Fire Protection Association's codes concerning the provision of manuals for medical equipment, as a way to making sure there is adequate repair informa-

tion. "NFPA 99-1999's 9-2.1.8.1 section on

manuals contains 13 bullet points specifying the information that should be made available for repair."

During its evaluations of medical devices, ECRI Institute—an independent, nonprofit organization that studies the best approaches to cost-effective and safe patient care—considers service manuals, ease of repair, and other issues associated with maintaining equipment over its expected life. "Infusion pumps, for example, should not require preventive maintenance beyond cleaning and battery replacement, and tech support and repair parts should be readily available," said Tim Ritter, CBET, CCE, senior project engineer at the institute. "Software upgrades are a lot less burdensome when pumps can be upgraded via wireless communication."

Ryan Lloyd, director of medical device strategy at PTC—a company that supports aftermarket services for manufacturing—said that manufacturers in general, including those in healthcare, are behind the curve on communicating service information, although "maturity is coming." Lloyd said manufacturers are very cautious about releasing data, and rightly so. "They are concerned about who has input internally, the level of quality of information, and how the information is distributed. They are working toward techniques for

Questions to Consider

Both HTM professionals and manufacturers have questions about how to best service and support equipment—and support their respective employers. Some of their considerations include:

HTM Professionals

- How can I manage the increasing costs of repair and maintenance, and avoid getting hit with unexpected repair costs?
- Why can't I more often get good service information for the devices I purchase?
- Why, increasingly, do I have to send devices back to the manufacturer for repair?
- Can I afford repair training, which often includes travel, room, and board?
- Can I trust the technicians who are sent by the manufacturer to fix my equipment?
- How do we enhance patient safety?

Manufacturers

- If I release the service information, what means do I have to make sure it stays up to date?
- Who will actually repair the device if my company doesn't? While I trust my clients, I can't always know the level of their expertise.
- My revenues come increasingly from training and service. At the same time, my clients are under terrific pressure to contain costs. How can I shape serviceability to protect my bottom line and to meet their needs so they will buy from me?
- How do we enhance patient safety?

updating and communicating service information to ensure accuracy, promptness, and ease of access for clients."

Feeling Cost Pressures

GMI's Lynch believes that in 1985 hospitals began to obtain deeply discounted prices through group purchasing organizations (GPOs). In response, he said, manufacturers turned to service and training as another source of revenue. Piepenbrink said that since the launch of GPO arrangements, service personnel have been "a lot more aggressive in pushing service and repair purchases."

At STERIS, Brown said that the company has seen GPOs pushing for extended warranties as part of the initial purchase and service contract bundling to reduce service costs.

Scales also thinks that manufacturers have turned to service and training to recover revenue reduced by GPO arrangements. "Hospitals are cut to the bone," he said, "and at the same time manufacturers need to make a fair profit. They need to cover the costs of R&D, and their margins are in some places pretty skimpy. Service information isn't cheap, and it has to be 100 percent right."

Baird, however, sees the issue from a different vantage point, saying that at Baxter, "We don't have a significant income stream from repair." The concern, he said, is "quality and safety."

Scales said that serviceability costs can be about the same, whether the hospital or the manufacturer does the work. "At Duke Medical Center, when the economy tanked, our training and travel funds were reduced, and we had to turn to the manufacturers for repair and ended up spending similar amounts. These folks are judged on Wall Street, and it's difficult for them to keep the bottom line in balance for stockholders."

Sometimes, HTM departments can make the case that they can help contain costs by keeping service and repairs in-house. But, experts advised, they'd better have firm numbers to back up their claims, and not rely on generalities in making their case with C-Suite executives.

"Too many clinical engineering departments don't know what it costs to maintain their equipment," said Robert Stiefel, president of RHS Biomedical Engineering Consulting in Baltimore, MD, and a retired clinical engineer



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— Glenn Scales, CBET emeritus

with experience at large hospitals, including Johns Hopkins. "If they are part of a larger department, they may not be familiar with managing a budget, or if they do manage their own budget, the director may not share it with the staff. But if you know what your costs are, you may be able to argue for internal repair versus payment for an outside service."

Building an Alliance With Purchasing

In looking for long-term and substantive improvements in how medical devices and technology are supported, veteran biomeds and other experts emphasize the value of fostering relationships with other departments, particularly purchasing.

"We've been telling hospitals forever that they need to get in writing the kind of support they expect," said Ritter, "whether this is diagnostic software or training. Unfortunately, equipment support is frequently overlooked during purchase negotiations. However, more experienced HTM professionals are proactive with their purchasing group, and are on the watch for the full range of support requirements, from parts and service manuals to installation and training."

In short, questions of maintenance and support should be addressed even before a device or system is purchased. "From my experience, the only way to get service manuals from the manufacturers, is to make it part of the purchase order line item. During the demo phase, ask the sales rep to allow you to review the service manual. If it is poor or points to future costs to maintain the equipment, those facts should be documented and presented to the purchasing committee," said Chris Alexander, BMET III, ICC Certified (CBET), with ARAMARK Healthcare Technology.

Articles about the financial challenges faced by hospitals are in the headlines virtually every day. Fraai, at Brigham and Women's Hospital,

THE BOX-AND-SHIP DEBATE

Many HTM professionals are frustrated by the time they spend shipping devices back to the manufacturer instead of repairing them in-house. On the other hand, some manufacturers and hospital executives say that a return-for-repair arrangement may in fact mean a better choice for the hospital, in the form of cost savings. Here are some perspectives:

J. Scot MacKeil, a member of Massachusetts General Hospital's Anesthesia Clinical Engineering Department, describes his frustration at what's called "the tape-gun service model" for equipment repair—in other words boxing and shipping. "It's an absolutely painful process that sucks the life right out of you. If I wanted to pack and ship things for a living, I would work at the UPS store."

Michael Capuano, manager of biomedical technology with Hamilton Health Sciences, believes that in general it's less expensive to service a device on site. "If it can't be serviced on site," he believes, "then the vendor did not design it to be serviceable in the field or simply decided not to support field service. The cost of shipping, time wasted, and a higher servicing fee usually applies."

Michael Fraai, director of Biomedical Engineering at Brigham and Women's Hospital in Boston, said "often, 'box and ship' is not the only—or the right—method to reduce your service cost. 'Box and ship' is frequently useful for devices calling for specialized service, including highly specialized and expensive tools best done by the manufacturer. It's not a question of the engineer's or technician's capability."

On the other hand, "the industry is changing," said Michael Angel, director of customer quality at GE Healthcare. "We just don't see as many component repairs as in the past. More and more devices are designed for manufacturer repair."

HTM professionals have to ask where their specialist's time and value are best applied. For a hospital, it may be more cost effective to send a device back for service depending on the type of device, and the level of service required, said Jack McNerny, a CBET with Johnson & Johnson's Ethicon Endo-Surgery unit.

Steve Kent, CBET, project manager in purchasing for Johns Hopkins Health System, believes that "a well-covered warranty is a positive thing. It could include lots of shipping and no maintenance for ten years. This is a huge advantage to a hospital, but a disfavor to clinical engineers, taking them out of the business of repair."

said that he sees increased pressure on HTM departments to save money, often by cutting training and service budgets. That underscores the need for HTM professionals to find partners and advocates outside their own department walls. "We should be collaborating with nursing, other clinical departments, and IT to determine the total cost of ownership prior to acquisition. We should be working with the contract departments to develop agreements with 'teeth' for the lifecycle of the technology to reduce cost."

Numerous managers with purchasing experience argue that no matter the size of a hospital, it's possible to build an alliance with purchasing, one in which HTM professionals educate purchasing staff and get them to think beyond the goals of lowest price for a device purchase. Maddock, of Baylor, said first choice is always to work with purchasing and the manufacturer on a mutually agreeable deal for service. "It's rare when a manufacturer can't help," said Maddock. "Of course, we have a lot of clout, because we're so large, and can make the case that by working with us the sales rep can achieve a good financial return."

Steve Kent, CBET, project manager in purchasing for Johns Hopkins Health System, sees value in department collaboration. "To strengthen negotiations for serviceability, I would recommend bringing together the variety of individuals and departments involved in device purchasing and maintenance, from the directors of purchasing and maintenance to the chief information officer and the vice president of finance, and to seek out the presence of

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clinical engineering at all meetings discussing serviceability down the line," he said.

One particular point to consider, according to Kent, is "access codes." Some devices require passwords to access the service mode, which can limit the ability to work on them. "Access codes should come into play as early as the request for information or proposal, to avoid unexpected manufacturer charges," Kent advised.

For Stiefel, it comes down to having friends in the right places. "Your hospital purchasing department can be a strong ally," Stiefel said. "Especially if you are in a smaller hospital, where engineering and purchasing offices are on the same campus, and it's easy to get together for a cup of coffee, you can learn to work together. But this takes patience. Hospitals in general are not well run as businesses. They are a conglomeration of dozens of little functional areas very, very different from each other, and extremely difficult to coordinate."

Alliances with purchasing can help to address more specific challenges. For example, Stiefel told of how one clinical engineering department was able to work with the purchasing department to cut down on repair time.

"Clinical engineers want repair to happen as soon as possible," said Stiefel, "and this is understandable, in the medical environment. When parts have to come directly from the manufacturer, though, this can take weeks." An agreement between clinical engineering and purchasing allowed the CE team to place purchase orders directly with the manufacturer and expedite parts shipping. They also learned to be aware of changes in the purchasing team and the need to renew this arrangement over time.

Michael Capuano, manager of biomedical technology with Hamilton Health Sciences in Ontario, Canada, made the point that clinical engineers have the technical knowledge needed at the negotiating table and should be involved. "Clinical leaders and purchasing agents are usually focused on the device itself, and not about the significant costs of maintenance, repair, and training."

He also observed that, when buying equipment, they also prefer to focus more on features and specifications and spend less time haggling over support issues. If vendors were more compliant regarding these issues from the start, then hospitals can indeed spend less time on this. On the other hand, said Capuano, while an alliance with purchasing can be helpful, there are significant challenges to making it effective. "For every new device, we have to start over again with each vendor." And even when the purchasing agreement covers service issues, they are not always enforced.

Finding Common Ground

It might be tempting to conclude that manufacturers and HTM professionals are hopelessly at odds over the question of service and support. But that would ignore signs that the two can build on a more productive relationship—even if disagreements remain on some points.

For example, Patrick Bernat, AAMI's director of Healthcare Technology Management, pointed to the comment of one manufacturer during a meeting about this issue. The manufacturer, he recalled, "made the clear point that in order to provide service manuals, he needs to be able to demonstrate to upper management that there is some return on the investment, that increasing access to these materials actually improves customer loyalty."

Both manufacturers and HTM professionals have suggestions to improve support and service—and ensure quality at the same time from the creation of advisory boards and new training arrangements to "design for repair" and "standards for serviceability" considerations. Here are details on some of those ideas:

A customer advisory board for repair and maintenance teams. "Generally," said Boston Medical Center's Piepenbrink, "manufacturers have advisory boards for clinicians to help develop their products, but we don't see this for HTM professionals, with the exception of GE, which is ahead of the curve. Why not work with the people who actually do the repair, who have a lot of experience and knowledge and can lend a different perspective on customer needs?" Piepenbrink said such service boards "would permit the client to work with the vendor to help guide service process and enhancement, and be a sounding board for the manufacturer."

That idea may be catching on. STERIS' Brown said that his company has initiated a customer service advisory board and it was set to have its first meeting this fall. Additionally, Brown said that STERIS conducts in-depth serviceability reviews during each stage of new product development.



Using Online Technology To Reduce Training Costs

"Online technology like webinars and webcams," said **James Piepenbrink**, director of Clinical Engineering at Boston Medical Center, "offer a low cost and potentially high yield for training. "Manufacturers are stuck in an old mold. We can't operate in that environment, why can they?"

Purna Prasad, director of the Department of Clinical Technology and Biomedical Engineering at Stanford University Medical Center in California, would also like to see multimedia channels. "With today's video technology and multimedia technology," he said, "a service manual basically should be a virtual expert who can instruct and guide the engineer."

But **Ryan Lloyd**, director of medical device strategy at PTC, said manufacturers can be somewhat limited in the types of training they offer.

"One answer to this question concerns the regulatory constraints on manufacturers," Lloyd said. "You won't find much of an online training presence because, like pharmaceuticals, device manufacturers are subject to regulatory control. They must be very cautious about ensuring that their messaging is consistent with the intended use documented in their submissions to the FDA." Innovations in training. Piepenbrink, like so many of his colleagues, faces severe restrictions on spending for training. He would like to see manufacturers explore regionalized training and greater use of online instruction. "It feels as though they want the purchase order and the money but they don't make it easy for us to support the equipment they make," he said of manufacturers. "At the same time, manufacturers hold over our head that parts will be higher priced if we don't have the training. We spend all sorts of money on this stuff; they need to help." Many manufacturers do provide onsite training, but HTM professionals said they'd like to see more training options.

Working toward a shared perspective. Several veteran HTM professionals believe that finding ways to work together with manufacturers is an essential part of improving serviceability. Scales emphasized the value of working with manufacturers to understand how a device is designed and how it can be improved. "When your device arrives from shipping, that is the beginning of our relationship, for the long term. We become partners in use and in integrating that use into the care environment. That includes selecting the right accessories and supplies. We need to be aware, together, of the quality of those supplies and how they integrate with device and patient. Together, we need to look at how the device is integrated into clinical operations, and what the human factors are."



"We want companies to know that removing barriers to serviceability reduces cost and creates efficiencies."

Michael Capuano,
Hamilton Health Sciences

Standards for medical equipment serviceability. Capuano is one of many HTM professionals who would like to see a standard for medical equipment serviceability. He defines serviceability as "the level of ease with which a specific medical device or system is serviced by individuals and entities other than representatives or direct agents of the original equipment manufacturer."

Capuano thinks that such a standard would benefit both hospitals and manufacturers,

clarifying what each can expect or require in the process of purchasing. "We want companies to know that removing barriers to serviceability reduces cost and creates efficiencies. We're finding that companies are coming up with devices that aren't designed for us to service or the vendor doesn't offer support for in house repair, so we've got to send the device in, even though we have the know how and the capacity to support it." That process, Capuano says, adds costs to an already expensive healthcare system.

Devices designed with repair in mind. Baird thinks that manufacturers need to design devices with repair in mind. "So often, repairs involve something as simple as plugs, jacks and other connection points. We know these have the potential to need more frequent replacement, so let's make them easier to replace. Manufacturers need to look at existing designs, see what breaks the most, and feed that information into new designs." Baird would like to see AAMI standards that address this question.

A license in addition to CBET certification. "CBETs conduct themselves as professionals in every sense of the word, and we know many have passed a certification exam and have a certain degree of understanding," said McNerny. However, he would like to see a license for professional qualifications, as is true in other countries such as Japan. "A license would confirm a skillset, and a consistent level of education and understanding, and would convey that message to our clinical partners. Even though the CBET is a pretty tough exam and worthy credential, it is only optional to date, and does not achieve the same level of public acceptance as a licensed professional." Licensing, he argued, would give manufacturers greater confidence to support HTM professionals as well.

AAMI efforts to address the serviceability challenge. Logan thinks AAMI can develop guidance documents to bring both perspectives to the table and to explore what is reasonable for a manufacturer to provide. AAMI began its initiative to address the challenges of serviceability with a meeting at the 2012 Annual Conference & Expo. There manufacturers and HCTMP's met to explore the issue. AAMI will continue with activities and articles aimed at exploring potential solutions and finding common ground. © Copyright AAMI 2012. Single user license only. Copying, networking, and distribution prohibited. Cover Story

"From AAMI's beginning, we've had a multidisciplinary approach to technology and its lifecycle," said Logan. "It's part of our DNA to create a safe space for industry and healthcare technology management professionals to work together. Our standards are stronger, healthcare technology is safer, and people's needs are easier to meet when we work together. That includes serviceability.

"My hope and my goal for AAMI is to facilitate greater understanding by both groups and to meet the needs of both. We've started the conversation, which has been needed for a long time. I'm grateful to folks on both sides willing to have a conversation, to find some common ground, to ease up the tension and meet one another half way. Stay tuned—we are at the beginning of a journey."



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