

Called to Testify?



Martha Vockley

In the course of a career, the odds that a medical technology professional will face a deposition as a fact witness over a medical device or equipment incident are slim: Only 10 percent of cases ever require the deposition of an expert. The chances for a court appearance are even slimmer—95 percent of lawsuits are settled out of court.

But that once- or twice-in-a-lifetime chance can be enough to rattle even the most seasoned professionals.

With proper preparation, though, medical technology professionals can face the long odds of a deposition—or even a court appearance—with confidence. In fact, the formula should be “90 percent preparation, 10 percent deposition,” according to Frank Painter, a certified clinical engineer who is president of Technology Management Solutions, LLC, in Trumbull, CT, and the director

of the clinical engineering internship program at the University of Connecticut.

Follow the Boy Scout Motto: Be Prepared

No one can predict which diagnostic, therapeutic, or rehabilitative medical device or piece of equipment may fail or be involved in an incident that causes injury, property damage, or death to a patient.

Even with the requirements of the FDA Medical Device Reporting regulations and the FDA database of serious incident reports known as the Manufacturer and User Facility Device Experience (MAUDE), available at www.fda.gov/cdrh/maude.html, it's wise to assume that any device or piece of equipment could become the focus of litigation over a product defect, misuse, or negligence.

Therefore, preparation for a deposition begins with work habits that should characterize everyday job performance for medical technology professionals. Not coincidentally, the same work habits that make patient

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safety a priority protect medical technology professionals and their employers from potential legal liability. Here are a few guidelines:

- **Adhere to Standards, Policies, and Procedures.** In your work setting, make sure you have a written job description that spells out your roles and responsibilities, Painter advises. Know your employer's standards, policies, and procedures for selecting and purchasing medical devices and equipment and for internal incident reporting and investigation. If your facility doesn't have guidelines in place for these activities, make the case for developing them.

These policies and procedures are important, first and foremost, so that your facility purchases the best equipment for the intended purpose and so that device-related incidents can be thoroughly investigated—and thus avoided—in the future.

You also should adhere to procedures and schedules for routine inspections, maintenance, and repairs, which can come from manufacturers; from independent, expert organizations, such as ECRI; or from experienced, trained, in-house medical technology professionals. Pay attention to product recalls and follow the appropriate recommendations for correcting problems.

Fact Witness vs. Expert Witness

If you are called to testify in a deposition involving an incident at your hospital or healthcare facility, chances are it will be as a fact witness, not an expert witness. What's the difference?

Fact witnesses are generally employed by the facility at which the incident occurred. A fact witness's role is just that: To state the facts about what happened. An opinion should never be part of the testimony.

An expert witness is typically an independent consultant hired to render an opinion about the incident, device, or equipment. While you could be asked to serve as an expert witness for a lawsuit involving another facility, it is very unlikely you would do so for a case against your own employer.

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Stick to industry standards in performing your job as well. Keep track of medical device and equipment problems reported to the FDA or through ECRI. Follow your facility's policies and procedures for reporting incidents.

All of these practices will serve you well if you are ever called to testify at a deposition or in court, experts say. These are the same practices your employer should expect from you on the job every day.

“By performing the duties in your job description, and doing the routine tasks you are expected to do as a normal course of business, you will protect yourself from any personal liability in the event of a lawsuit,” Painter says. “You will be covered under the hospital's liability insurance umbrella and you won't be identified individually in a lawsuit.”

Only in the case of “gross negligence” is it likely you will be named personally in a lawsuit over an incident at your facility, adds Jerome Anderson, principal of Biomedical Consulting Services in San Clemente, CA.

In addition, “clinical engineers or biomedical equipment technicians should be able to defend the equipment acquisition process—that it is suitable for use and that there was an evaluation process based on a comprehensive evaluation program,” says Mark Bruley, vice president for accident and forensic investigation at ECRI, based in Plymouth Meeting, PA. “If there is a recall, they need to be able to say, ‘Here's what we did to handle that recall.’ They need to show that they tracked it and responded to it.”

Further, attorneys will look for evidence of “improper inspection, calibration, or repair” of medical equipment or devices as part of any legal investigation of an incident, even if it appears irrelevant to the case, Bruley says, so proper inspections and preventive maintenance are essential.

In short, medical technology professionals need to be able to defend their work—and the best way to do that is by following standard procedures as a matter of course.

- **Train Clinical Staff—and Yourself—Appropriately.** As a medical technology professional, you may be responsible for making sure that clinical staff are properly trained to operate medical devices or equipment.

You should have protocols for training—whether you conduct the training yourself, arrange for the manufacturer to provide training, or use a train-the-trainer model in which department heads or supervisors provide training to their staffs.

Training should include specific procedures about what to do in the event of an incident. First and foremost, of course, is the safety and care of the patient. Other immediate responses may include securing the device or equipment, saving all disposables, and retrieving all packaging.

Industry requirements, such as those of the Joint Commission (JCAHO), should be used to develop appropriate training protocols for your facility.

Anderson advises medical technology professionals to update their own skills as well by taking courses, attending conferences, reading journals, and so on. At large facilities, this is fairly routine. As smaller facilities, you may have to advocate for regular training, Anderson says.

In the event of a medical device or equipment incident in which clinical misuse or negligence of a product is alleged, you may be asked to defend your training protocols and your own training and qualifications.

- **Keep Meticulous Records.** “Clinical engineers and biomedical equipment technicians can be held accountable for almost every part of their careers or jobs,” Painter says. “If you didn’t document it, you might as well not have done it.”

Every job function should be meticulously documented—every purchase, inspection, and repair;

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every response to a recall; every training session (with attendance records, as required by JCAHO); and every incident. The most effective record-keepers keep a copy of the procedures used for the activity as well.

Leslie A. Geddes, Showalter Distinguished Professor Emeritus of Biomedical Engineering at Purdue University, recommends keeping records electronically so they are readily accessible, but a well-organized paper system of file folders works just as well. The key is to keep these records updated and retrievable at a moment’s notice—organized by date, medical device, or area of the facility in which the equipment is located, for example.

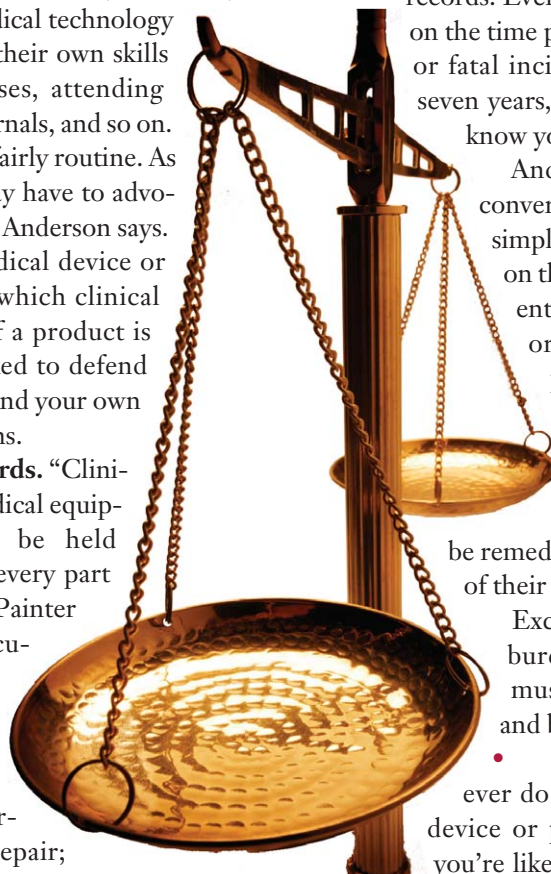
Further, it’s important to know how long to keep records. Every state has its own statute of limitations on the time period for filing a lawsuit after a harmful or fatal incident, typically ranging from three to seven years, Painter says. It’s your responsibility to know your state’s laws in this regard.

Anderson notes that many organizations converting from manual to electronic records simply toss the old records. If you have input on this decision, advise your facility either to enter the old records into the new system or to store them for the requisite time period.

Service records are critically important resources in the event of an incident or lawsuit, but many medical technology professionals “may need to be remediated” about keeping up with this aspect of their jobs, Painter says.

Excessive record keeping may seem like a burden in the midst of a busy day, but it must be done. “I have seen records make and break cases,” Anderson says.

- **Create an Incident “Toolbox.”** If you ever do face a serious incident with a medical device or piece of equipment in your hospital, you’re likely to be called to the spot immediately.



You'll want to have your investigative equipment ready so you can grab it and go.

Painter recommends a good digital camera; a tape measure or other measuring device with clear, large print that will show up in a photograph; pre-printed "Do Not Use" and "Impounded" labels; and a standard list of questions to ask clinical staff about the occurrence.

This toolbox can be invaluable in helping you to investigate any incidents that occur on your watch.

- **Develop a Collaborative Working Relationship with the Risk Manager.** The time for you to forge a collaborative working relationship with your facility's risk manager is now, not after a medical device or equipment incident, Painter says.

The biggest part of the risk manager's job is avoiding larger incidents by investigating incidents that do occur, finding out what went wrong, and implementing practices and procedures to prevent problems. When incidents involve medical devices, a medical technology professional should be cooperating in these efforts.

Typically, the risk manager is responsible for developing incident protocols; coordinating the facility's immediate and ongoing response; and working directly with you, the involved clinical staff, and the facility's legal counsel.

"The risk manager is the team leader during an incident investigation," Painter says. You may need to work closely with this person if there is an incident, and especially if there is a lawsuit, so you should lay the groundwork for such a possibility in advance.

Serious incidents require more intensive action. As soon as possible after a serious incident, your facility's risk manager should be on the scene. Clinical engineers are most likely to be called as first responders as well; biomedical equipment technicians may hear about incidents only hours or days later, Anderson says. If you have a good working relationship with the risk manager, you are more likely to be part of the investigative team that gathers initial information and evidence about what happened.

Your incident toolbox will help with this process, which Painter likens to a crime scene investigation. Use the camera to document the scene. Note the settings and the model and serial numbers of the equipment. Ask clinical staff what they did and what happened. All of this information should be kept confidential, a point that is typically stipulated in risk management guidelines.

Depending on the incident and the equipment, it may be necessary to try to re-create the event, test or impound the equipment, or cordon off the clinical area. Or it may be appropriate to get the equipment back up and running after this investigation. To preserve evidence and possible exhibits in a legal case, it may be necessary to consult a third party, such as ECRI, the hospital insurer, an outside expert, or the vendor, before taking any actions.

It's important to keep in mind, Anderson points out, that sometimes there is no "fault" in a medical device or equipment incident. It may be that the equipment has been well maintained, the staff has been well trained, and everyone did their jobs correctly. Spontaneous failure that could not be prevented, such as a circuit or part failure that inspection or preventive maintenance would not have discovered, should not be ruled out.



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Incident Response: A Prompt and Thorough Investigation

Any incident involving medical devices or equipment will make your preparations seem highly relevant and prudent. Sometimes, your involvement will be limited to pulling the records that document purchases, standard maintenance and repairs, and training on the equipment in question. Or you may need to follow up with an equipment inspection or arrange for a service call from an independent expert or the manufacturer to evaluate the equipment.

Deposition Demeanor: "Just the Facts, M'am"

If an incident leads to a lawsuit and then a deposition, there is one overarching theme to keep in mind: You are a fact witness, not an expert witness (see sidebar, p. 430). Your role in a deposition is to provide the facts, based on your technical expertise, the documented history of the equipment, and the evidence from the incident investigation.

Fact witnesses typically are employed by the facility in which the incident occurred or by a shared services group responsible for the equipment. Expert witnesses, by contrast, typically are independent consultants from businesses or universities whose role is to render an opinion about the incident, device, or equipment. Most hospitals and other clinical facilities bar employees from serving as

expert witnesses; this is seen as a conflict of interest, Geddes says. Still, there are medical technology professionals who do testify in cases not related to their own facilities.

Before a deposition, your facility's attorney should prepare you by letting you know what to expect: What are the plaintiff's charges? What is the specific complaint about the fault of the device or equipment? What questions are likely to be asked? What kinds of answers are appropriate? What documents should you bring? If the attorney doesn't brief you on these topics, ask questions yourself.

You also should prepare yourself for the deposition by reviewing all the documents available to you, on the advice of your attorney—the documents your department generated, the work you did, and the standards you applied. Typically, you'll be asked to state the materials you've reviewed in the deposition. However, Geddes advises, don't write anything down. Even notes can be subpoenaed.

Once you are in the deposition room, here is some useful guidance from the experts for getting through that once- or twice-in-a-lifetime ordeal:

- **Tell the Truth.** This is the fundamental, unbreakable rule of testifying at a deposition or in court. Answer every question truthfully. If you don't know the answer, say so. If you don't remember what happened—and memories do fail in the years between incidents and depositions—say so.

Attorneys are trained to pick up on false testimony. They are trained to ask the same questions in multiple ways to uncover discrepancies in your answers. If the case goes to court, any discrepancies in your testimony will be used to discredit you, Anderson says. Fooling attorneys is difficult, so don't try.

Make sure you understand the questions before you answer. If you don't understand, ask the attorney

to repeat or rephrase the question. If you are asked for your opinion, you can say, "I'm a fact witness, not an expert witness."

- **Be Brief.** Many questions can be answered with a simple "yes" or "no." Don't launch into a 20-minute dissertation on the incident. Just respond with a direct answer focused on the specific question.

"You get nailed for bad things that you say, not for what you don't say," Geddes says.

- **Be Prepared to Defend Yourself.** Attorneys likely will question your credentials and every aspect of your work related to the medical device that is the subject of the lawsuit. Stay calm and defend yourself. Make reference to any employer, professional or industry standards, policies, or procedures that support you.
- **Speak Plain Language.** Your role in a deposition is to educate attorneys—and, in a trial, judges and juries—about medical technology. Like any specialist, you may use technical terms or acronyms to talk about equipment in everyday interactions. In a deposition, though, even highly educated attorneys won't understand you. Instead, Geddes says, "explain that an electrical current is like water running through a hose." Use common analogies and plain language to explain how things work.
- **Slow Down and Take a Breath.** Walking into a deposition room can be a daunting experience. There may be a whole handful of attorneys representing various parties to the lawsuit, all ready to question you.

"The best advice I've ever been given by an attorney is, 'Take a breath before you say anything,'" Anderson says. "Talk slowly. This also gives your attorney a chance to object to questions.

"When you are in a deposition, you are in control," Anderson adds. "You're the star of the show. You can ask to take a break or stop to have a drink of water." ■



Case Study: A Cautionary Tale for Moonlighters

Frank Painter offers this case study of a medical device lawsuit:

After a medical staff meeting, a physician on the hospital staff asked an administrator if the hospital's biomedical equipment technician could perform a routine inspection on a defibrillator at the physician's office. The administrator was happy to oblige and asked the biomedical equipment technician to do this.

Believing that this was part of his job and eager to help, he stopped at the physician's office before work one day and inspected the defibrillator according to standard procedures. Also following standard procedures, he documented his work; put an inspection sticker on the defibrillator; and noted the due date for the next inspection, which—again according to standard practice—should occur in six months.

Eighteen months later, a patient undergoing a cardiac stress test in the physician's office suffered a massive heart attack. When the physician and his staff tried to use the defibrillator to revive the patient, the device didn't work. The patient died.

In the ensuing legal investigation, the patient's attorney discovered that the biomedical equipment technician had inspected the device 18 months before. The attorney also discovered that the device had not been inspected since then. The patient's family sued the physician, the medical practice, the manufacturer, the hospital—and the biomedical equipment technician.

"To me that was a real eye-opener," Painter says. "I was surprised that that happened."

In hindsight, Painter says, there were a number of red flags in this case. The biomedical equipment technician performed work that went beyond his regular duties, at an off-site location, and without a written order—all actions that left him vulnerable and without legal protection under the hospital's liability insurance policy.

"This biomed person just wanted to help," Painter says. "He thought he was being asked to do this as part of his job. He went off and did something a little out of the ordinary. He had no written authorization to do it."

Ultimately, the biomedical equipment technician was exonerated and dropped from the lawsuit—but the legal investigation took two years and caused him plenty of angst. By deposition time, for example, the hospital administrator had moved on to another job—and couldn't remember either the informal chat with the physician or the oral request to the biomedical equipment technician. "When people are being sued, they forget what they heard and they may say things that don't put you in the best light," Painter says.

The biomedical equipment technician also had to testify at a deposition. Fortunately, his documentation supported his statements that he had performed his inspection by the book. He was not held responsible for making sure that the defibrillator was inspected on a routine basis or that it had failed during the cardiac arrest.

For Painter, this case serves as a cautionary tale for medical technology professionals. "A lot of biomed staff moonlight," he says. "They should be careful about what they do. I'm not proposing that they get liability insurance, although that might not be a bad idea. But they do need to follow strict practice standards and have good, established reasons for what they're doing. They should never modify medical equipment or do things they'd never do in a hospital. If you get creative, you may get into trouble."

And by all means, get a written authorization—an e-mail confirmation, for example—for outside work and even for on-the-job work that sounds unusual. Document everything and keep copies of your records. Even a handwritten note on an invoice for services—with the next inspection due date noted—could prove invaluable if disaster strikes. ■