

Safety is Job No.1

Don't outsource your laser safety to a rental company. Make sure safety is your priority.

John E. Hoopman, CMLSO

At the University of Texas Southwestern Medical Center at Dallas, we are fortunate to have access to more than 240 lasers. When looking at a new procedure for a service that has no established patient base, I have the luxury of borrowing technology from another facility until I can justify the purchase.

Most likely, you're not in the same situation. Cost constraints often limit your laser choices and options. Therefore, you might establish a relationship with a laser rental company and lease your laser.

No matter which avenue you pursue, you must accept responsibility for your laser safety program. Many laser rental companies may try to push their own laser safety technicians to do your dirty work, but you're the only one who can ensure your lasers are safe for staff and patients. For larger facilities, this means having a designated, trained laser safety officer (LSO) to provide oversight. For smaller private practices, this means having the physician take on this responsibility, deftly delegating some tasks to others.

Limiting Risk

The laser rental company provides an ideal solution for managing the expense of lasers. In this way, the fledgling aesthetic practice can establish "laser days" one to two days a month to see how the laser works and whether the procedures can be profitable.

In surgical applications, physicians can rent the laser on a case-by-case basis. The rental company will supply all the accessories, delivery and setup of the device for one flat fee per case. This works well for a small facility trying to establish a urological laser program, for instance. A rental company supplies the Holmium YAG laser, appropriate laser fibers, safety accessories, such as warning signs at each entrance of the procedure room, safety glasses and/or goggles for each person in the nominal hazard zone.

Many rental companies offer to provide an LSO, even packaging the administrative services as a bonus at no additional costs. They will tell you that relying on their technician for the safety aspects can relieve you of the "burden" of training and staffing.

This may sound like a great way to save time, money and headaches. In reality, the company is ensuring you stay a customer. By relinquishing control of this aspect of your practice, you're giving yourself another excuse not to purchase a laser of your own. You're also relinquishing control of measures that safeguard your patients and staff.

I have many questions for those who are considering outsourcing this position. First, are you willing to turn over the safety of your patients to a rental technician? In the case of bigger facilities, does your safety committee know you've outsourced your laser safety? Most importantly, do you know if the training of the rental-provided technician as a "qualified medical laser safety officer" has been documented as current? Moreover, who trained and provided that certification?

When used incorrectly, lasers can be dangerous to your patients and to your staff. A rental technician might not have the gumption to stop a procedure in progress and remove the laser from the operating/procedure room if patient safety is compromised. Furthermore, a rental technician may have a difficult time putting safety above profits.

In addition, if an incident occurs, you need to feel confident in the company's ability to defend the actions of the facility in a litigious situation. This means knowing the rental company is carrying the proper amount of medical liability insurance, if at all.

LSO Responsibilities

The LSO isn't concerned with profits or hurting feelings, but with protecting the patient, staff and organization. By definition, the LSO is the person responsible for laser safety in your health care facility in supervisory and administrative roles. A successful program requires continual oversight and training.

In a larger facility, this is a full-time position. The LSO establishes laser safety policy alongside the laser safety committee. Smaller facilities may look at the option of cross-training existing perioperative personnel to assume these duties. In a private practice, the onus falls squarely on the physician's shoulders, since staff turnover often can be variable. The important thing is having an assigned person or people who take responsibility for this role.

The LSO has several responsibilities, including the following:

Ensure facility-wide initiatives. Large facilities likely will have a risk management or safety committee for specific site policy and procedures. These procedures establish standards for the clinical operation of medical lasers in the operating rooms, clinics and laboratories. The LSO ensures that these initiatives are followed whenever a laser is fired. The LSO guides the risk management and safety committee on the proper safe use of medical lasers. Again, in smaller private practices, this role would fall on the physician.

Develop and provide annual review of policy and procedures. Laser policies frequently change. Equipment updates, new lasers and upgraded standards may require additional training. For these reasons, we recommend staff training once a year and quarterly training for updates on equipment if necessary.

Ensure physician and staff meet training requirements. Those working with lasers should undergo consistent review annually. Many classes provide laser essentials. This education should be documented, since this can reduce liability if someone doesn't operate within the safe parameters. Manufacturers often offer education on their specific lasers. Other organizations, such as the American Society of Laser Medicine and Surgery, Laser Institute of America and the Rockwell Laser Institute, also provide good training programs. These classes should offer a basis in general physics, safety and tissue interactions.

Coordinate with all laser vendors. Laser rental companies may not always deliver on their promises. For example, they may deliver equipment late or not provide safety goggles. Having someone in charge of this oversight ensures the company provides safety equipment.

We've had a laser rental technician tell our operating room (OR) staff that they didn't need to wear safety glasses simply because the tech neglected to bring any. Of course, our OR staff turned him in, and he is no longer welcome on our campus.

We have policies and procedures that delineate the laser rental technician's responsibilities, and the laser rental company must sign this as a contractual agreement. This ensures there is no miscommunication, with a he-said/she-said situation.

Act as liaison among all medical specialties. Certain lasers, such as the CO₂ and Holmium, have multiple applications. In our facility, the LSO coordinates laser use among departments. In addition, the LSO ensures that those who use the laser fill out a log that details how they used the equipment, at what times and whether any incidents occurred. The log

provides a paper trail, if anything happens to the equipment or the people in the nominal hazard zone.

Review and approve laser privileges. An LSO also ensures that the people using the laser have received clearance from the hospital. This means their training is up to date and that their laser privileges are signed and current. In addition, the LSO can also revoke laser privileges if he notices abuses.

Report and resolve all laser-related incidents and accidents. Whether you're a large facility or a small practice, you need to ensure an open and publicized conduit for recording every accident or incident. Each person on the staff must know the procedures for reporting an adverse effect or a product malfunction. This will ensure that the LSO can take measures to minimize further incidents.

A complete list of the LSO's duties and responsibilities are in the American National Standards Institute (ANSI) Z136.3. The Laser Institute of America provides these guidelines and offers LSO credentials. If you don't have a copy of the ANSI Z136.3 "Safe Use of Lasers in Healthcare Facilities," you should obtain one. Keep it on site for reference as part of your facility's policies and procedures. No matter how small the facility, someone must accept the role of overseeing safety for lasers. In smaller cosmetic practices, physicians must ensure their staff is properly trained and that each staff person is meeting safety requirements.

To date, I have yet to meet the medical professional who would let a rental company control the operating or procedure room. A safety committee would take definite heart-stopping pause if you relinquished this control to someone who most likely is not as qualified or as educated as you are.

When you accept the laser rental company's offer to cover your LSO needs, you have given the rental company the authority to run your operating room for all laser procedures. Of all laser company technicians I have come to know in the past years, none truly understands the extent of liability associated with running this equipment. The health care facility

itself must accept that role. Not doing so is a liability and can be detrimental to the practice, your staff and your patients.

The Necessary Skills

Safety guidelines for the laser safety officer are outlined in the Appendix F2 of the ANSI Z136.3 "Safe Use of Lasers in Healthcare Facilities" educational guidelines.

The basic content of the ANSI Z136.3 includes the following 14 areas:

1. Laser physics/biological effects
2. System components/delivery, devices/instrumentation
3. Federal, state, local regulations
4. ANSI Z136.1, Z136.3 standards
5. Institutional policy/procedures
6. Hazard classification
7. Access to laser key
8. Medical surveillance
9. Documentation/incident reporting
10. Anesthesia hazards/controls
11. Personal protective equipment
12. Patient protection
13. Operational skills workshops
14. Procedure for safety audits

To my knowledge, the Laser Institute of America provides the only laser safety officer certification program. The organization drafts particular guidelines and administers the written exam.

For the smaller practitioner, this may be a little more in-depth than needed, but it's still a good idea to take a laser safety course. The American Society of Laser Medicine and Surgery (ASLMS), Laser Institute of America and the Rockwell Laser Institute provide excellent training. Vendor-provided training is also useful in learning specific lasers along with some qualified individuals that can often come to your facility.

No matter what avenue you pursue, be sure to get the background of the instructors, and ask whether they have experience with various lasers. Have they managed a laser safety program in a clinical setting? Do they have the correct qualifications? And have they used many lasers, rather than just a few?

The experience of the instructor can tell you a lot about the quality of the course. In the end, you need to take accountability for these safety aspects. Education is where it all starts.

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PARTNERSHIPS IN LASER SAFETY: LASER RENTAL COMPANIES AND YOUR HOSPITAL

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When lasers are introduced into a health care environment, be it a hospital, surgery center or a physician's office, health care professionals must be prepared to address issues of safety for both the staff and the patient. All lasers present hazards to patients, the individuals utilizing them, as well as anyone present in the area which they are being activated (nominal hazard zone). This equipment should be utilized in accordance with established regulations, standards and recommended practices, manufacturers recommendations, and institutional policies. Laser safety is based on knowledge of the specific laser being utilized, its instrumentation, mode of operation, power densities, action in tissues, and risks.

With the rise in healthcare costs and dwindling reimbursements, many hospitals are considering alternatives to bringing technology into the operating rooms. Over the last decade, the use of laser rental companies has increased and has been a viable solution for providing laser services without incurring the costs of expensive capital requisitions, service contracts, and personnel to operate the laser system. There seems to be a misconception on the part of facilities and hospitals that with the use of this type of contracted service there is no responsibility or accountability on the hospital's side for the safety and validation of the individual operating the laser. Laser rental companies and hospitals both have liabilities and both need to consider and should understand the roles and responsibilities each have to the physician, hospital personnel, and patient.

A laser safety program is a requirement of the hospital facility, as well as the laser rental company. The program establishes and maintains policies and procedures to ensure control of laser hazards. Laser safety programs, policies and procedures should include, but are not limited to the following:

- Laser Safety Officer (LSO) guidelines defining the authority and responsibility for evaluation and control of laser hazards. A laser committee may need to be developed when increased laser usage necessitates maintaining enforcement of Standard Operating Procedures (SOPs).
- Criteria and education for procedures for all personnel working in a nominal hazard zone. All personnel working with lasers should attend laser safety education courses periodically with annual laser safety validation.

- Credentialing and clinical practice privileges of the medical staff are the facilities responsibilities. Credentialing should be for specific laser procedures with specific laser types.
- Implementation of laser hazard control measures.
- A continuous quality improvement program to include appropriate use and maintenance of equipment, management and reporting of accidents as well as prevention.

A laser education program for personnel working with or around lasers must be in place for facilities' and companies' specific laser(s), and must be specific to the procedures being performed in the facility. The program must comply with applicable standards and regulations covering all procedures and uses necessary to provide a safe environment. Personnel should demonstrate and complete competency skills annually.

Laser Rental companies' competencies should be no less stringent than that required of personnel within the facility. The position statement from AORN on "The Role of the Health Care Industry Representative in the Perioperative/Invasive Procedure Setting," states that the competency of an individual who provides direct or indirect patient care should be held to the same requirements as the hospital employee. AORN recognizes the need for a structured process for education, training, and introduction of procedures, techniques, technology, and equipment to healthcare professionals practicing within the facility.

Suggested components of the competencies include, but no limited to:

- Validation of a laser course as recommended by ANSI 136.6 2005 to include laser physics and safety.
- Hands-on demonstration that is wavelength and specialty specific.

Other requirements for credentialing are:

- HIPAA compliance
- Health and Safety, Age Specific competencies
- Immunizations, background checks, and
- Operating Room protocols.

The laser company should appoint a Laser Safety Officer (LSO) for the company with their own policies and procedures, as well as their own laser log. Validation and competencies should be required yearly with their personnel just as a hospital or medical facility would require of theirs. Further more when the laser company brings their laser into the hospital the employee of the company must understand the policies and procedures and credentialing criteria specific to the hospital.

Laser companies have provided an alternative to the purchase of expensive laser systems with either a growing laser service or a laser service with low volumes. Hospitals rely heavily on the companies to provide the expertise for delivering the service and many hospitals assume that the medical legal responsibility and accountability is the liability of the company. Hospitals are not free from liability. The hospital personnel in the laser

treatment area are required to have the same laser competency as the laser operator from the rental company. Even if the laser company provides their validated individual, the facility personnel must be validated. The hospital staff should have validation of a course on laser physics, and safety and their education must be specific to the wavelength and specialty. A hospital should also have an LSO assigned for the hospital. Often hospitals and medical facilities assume there is no responsibility on their end and that the laser companies are accountable, holding them only obligated to pay the service provided.

Laser Safety is the responsibility of both the company and the hospital with a collaborative approach to patient and personnel safety. It is important to understand that regardless of the clinical setting the presence of laser equipment creates a need for unique control measures and work practice controls to be developed and implemented. Whether your setting is a small clinic, a doctor's office or large hospital, laser safety is not the responsibility of one individual, but the obligation and duty of everyone involved in the laser surgery process. All personnel involved in the care of a patient may be in the vicinity of the nominal hazard zone and thus should be educated appropriately to maintain a safe environment for patient care. A well-developed laser safety program that is developed according to the ANSI Z136 series can assure safety when implemented properly. When everyone knows the fundamentals of maintaining a laser-safe environment, risk of accidents, resulting from ignorance or noncompliance with policy, is greatly reduced.

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