

PATIENT INJURIES AND LAWSUITS INVOLVING MEDICAL LASERS ARE INCREASING. IS YOUR PRACTICE COMPLIANT WITH SAFETY REGULATIONS?

In 2007, the majority of physicians responding to an American Society for Dermatologic Surgery ("ASDS") survey reported that the number of patients they were treating for complications caused by non-physicians was increasing. These complications frequently involved burns caused by the improper use of lasers, scarring caused by chemical peels, hyperpigmentation caused by laser hair removal and many instances of skin cancer being overlooked due to the removal of malignant tissue that could have otherwise served as a warning sign.

An [article](#) published in the February issue of JAMA Dermatology looked specifically at malpractice litigation from 1985 to 2012 involving dermatologic laser procedures and concluded that litigation has been increasing and is resulting in indemnity payments that exceed the previously reported average across all medical specialties. Like the ASDS survey, the article found laser hair removal, burns, scars and pigmentary alterations to be highly associated with litigation. The article also found that non-physicians were frequently named in the litigation as operators of the laser equipment.

But patient injury is not the only growing concern for physicians who utilize medical lasers in their practices. Employees working near medical lasers can also be injured when exposed to lasers and related radiation. According to a joint [report](#) from the American Association of Physicists in Medicine and the American College of Medical Physics, about 500,000 to 700,000 health care workers in the United States are involved in the use of medical lasers. Some of the major accidents involving employees identified in the report are:

- Available eye protection not used;
- Intentional exposure of unprotected personnel;
- Operators unfamiliar with laser equipment;
- Lack of protection for ancillary hazards;
- Failure to follow standard operating procedures; and
- Accidental eye/skin exposure during use.

REGULATION OF MEDICAL LASERS

Historically, few states have regulated the use of lasers for medical purposes. However, with the increased use of medical lasers in medical spas, combined with the increase in reported patient and employee injuries, many states have reevaluated or are currently reevaluating their laser safety regulatory controls. Some states, including Arizona and Florida, have adopted model regulations developed by the Conference of Radiation Control Program Directors. Other states that have enacted some form of regulation include Alaska, Arkansas, Georgia, Illinois, Massachusetts, Montana, New York, Pennsylvania, Texas and Washington. Other states, such as Indiana, point to the U.S. Occupational Safety and Health Administration's ("OSHA") regulations and [Technical Manuals](#) as the basis for their own oversight.

OSHA, in turn, mostly defers to the Z136 laser standards developed by the American National Standards Institute ("ANSI"), which is a non-regulatory, non-governmental agency that develops voluntary standards used throughout many industries. Similarly, the U.S. Food and Drug Administration ("FDA") regulatory scheme for medical lasers is closely aligned to the standards and risk classifications developed by ANSI. ANSI's Z136.3 standard for medical lasers is even used by The Joint Commission in its accreditation of health care organizations. The standard is also frequently used as an exhibit reference during malpractice and product liability litigation.

Classification of Risk

The ANSI standards are based on the level of risk presented by a laser. Generally lasers can be grouped into one of five categories of risk:

- Class 1: cannot emit laser radiation at known hazard levels.

- Class 2: low-power visible lasers that emit above Class 1 levels but at a radiant power not above 1 mW.
- Class 3A: intermediate power lasers (cw: 1-5 mW). Only hazardous for intrabeam viewing.
- Class 3B: moderate power lasers (cw: 5-500 mW, pulsed: 10 J/cm² or the diffuse reflection limit, whichever is lower).
- Class 4: High power lasers (cw: 500 mW, pulsed: 10 J/cm² or the diffuse reflection limit) are hazardous to view under any condition (directly or diffusely scattered) and are a potential fire hazard and a skin hazard. Significant controls are required of Class 4 laser facilities. **Most medical lasers fall into the Class 4 category.**

Classification of risk may not be as simple as reading the manufacturer's label on the laser machine, however. Risk classification can change when a laser is modified to perform different medical procedures. In those situations, the owner/operator of the laser is responsible for understanding the differing classification potentials based on factors such as measurement of the laser emission, determination of the emission pulse characteristics, evaluation of various performance requirements (protective housing, interlocks, etc.) and taking the appropriate safety measures.

Additionally, with the recent development of non-laser devices for laser-like applications (e.g., vascular anomalies, pigmented lesions, tattoo removal and hair removal), the scheme employed to classify a laser system has also become significant in determining who may legally use this equipment. For example, intense pulsed light ("IPL") sources are technically not lasers because they are not monochromatic and the light is not collimated. As a result, some states' regulations specifying whether non-physicians may perform medical laser procedures may not apply to IPL machines.

Laser Safety Programs

Depending on the risk classification of a laser, different safety activities should be undertaken. Although this article is not intended to be a comprehensive discussion of safety standards relating to the operation of lasers, the following common safety activities are highlighted for illustration purposes:

- Employees are furnished with suitable laser safety goggles, gloves and other protective clothing.
- Only qualified and trained employees are allowed to install, adjust and operate laser equipment.
- The facility develops and regularly maintains written policies and standard operating procedures.
- Regular maintenance and service of laser equipment is performed according to ANSI standards and the Quality Control and Radiation Safety tests as recommended in the 1991 ACMP document, "Radiation Control and QA of Medical Laser Systems."
- A Laser Safety Officer is designated to ensure regulatory compliance, personnel training and general laser safety.
- Laser operators and related personnel are properly trained and have the necessary experience.
- Onlookers to laser procedures are warned, through informed consent documents and/or signage, about the presence of potentially hazardous laser radiation and of relevant safety precautions.
- Adverse events are reported to the manufacturer of the laser equipment and to the FDA as applicable.


Additional responsibilities and recommendations are further explored in ANSI's Z136 standards.

PRACTICAL TAKEAWAYS

As recent injury and subsequent litigation trends have made clear, the use of medical lasers, especially by non-physicians, is a growing concern for patients and regulators. Compliance with applicable regulations and industry best practices may help to reduce the incidences of injury to patients and employees, as well as subsequent litigation. Physicians and other persons offering medical laser procedures at their facilities should consider doing the following:

- Designate an individual to be responsible for laser safety compliance;
- Determine the potential risk classifications of their medical laser(s) under the ANSI Z136 scheme;

- Utilize the ANSI Z136 standards, OSHA regulations and any state regulations to identify and implement the safety practices most appropriate for their laser(s) risk classes; and
- Report to FDA, OSHA and the state, if applicable, any adverse health effects related to the laser's operation.

If you have any questions about the regulation and standards affecting the use or manufacture of medical lasers, please contact Mark Dahlby at 414-721-0902  or mdahlby@hallrender.com.