CHAPTER

1 BUILDING BLOCKS OF LASER SAFETY

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LASER HAZARD CLASSIFICATION

The role of laser hazard classification cannot be understated:

- It gives the user a heads-up on the potential hazard of the laser or laser system.
- The classification sets the product safety requirements required by regulatory bodies.
- It tells the safety professional the level of training and controls that need to be in place or considered.

Of course, in a research setting, laser classification is only the start. Once the beam leaves the laser or lasers, all sorts of manipulations can take place that affect the actual hazard of the setup.

In simple terms, the overall laser hazard classification is based on output and visibility of the beam. As to who classifies lasers, while there is much agreement on class definitions, we have competing groups.

In their respective laser standards, the American National Standards Institute (ANSI) in the United States and the International Electrotechnical Commission (IEC) in the rest of the world define the meanings of each laser class. But for many, the most important organizations on laser hazard classification are the regulatory bodies who set laser product requirements.

Take the Center for Devices and Radiological Health (CDRH), an agency under the U.S. Food and Drug Administration (FDA). While the ANSI standard allows Class 3R lasers to be visible or invisible, CDRH only recognizes visible Class 3R lasers (a laser system CDRH still calls 3A). So, if I am manufacturing 3R lasers and hope to sell them, they will all be visible, regardless of what ANSI allows. With that said, let's give the most useful definition of each laser class. But before that, Laser Notices 50 and 56 need to be explained. For years, manufacturers of laser devices faced a dilemma—the CDRH did not use the same laser classification numbering as did the rest of the world. To CDRH's

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defense, they were using the labeling protocol the rest of the world used, which was Roman numerals, but when the world moved to Arabic numbers, CDRH stood still. The common explanation for this is that the process to make this change in the Code of Federal Regulations (CFR) is difficult. So, we were left with two sets of labeling for laser classification—Roman and Arabic. After many years, the CDRH made a move to address this and released Laser Notices 50 and 56. These two notices informed laser product manufacturers that the United States would accept the IEC classification scheme, and dual labeling was no longer required.

Class 1

All groups that have criteria for laser classification consider a Class 1 laser to be harmless. It does not produce sufficient output to be an eye or skin hazard. Class 1 lasers are in the general range of 35–40 mW max.

Class 1 Product

Once again there is universal agreement, regardless if one calls it a Class 1 Product or Embedded Laser as ANSI likes to refer to this type of system. The key is that during "Normal" operation, it does not present any hazard. A simple example is a laser diode inside a laser printer or a Class 4 laser inside a laser cutter. As long as there is no possible exposure hazard, the device, system, or product (pick your name) is termed a *Class 1 Product*. Of course, all that changes if the device is opened for service and then an exposure potential exists (more on this later).

> Note: The CDRH will consider a protective housing to be doing its job if it takes more than two internal bounces to escape the housing.

Class 1C

At the time of the writing of this book, only the IEC recognized the 1C classification. It will most likely find its way into the Z136 ANSI laser standard and sometime afterward into the CDRH classification through a "Laser Notice" or other administrative means.

Class 1C refers to a laser product that is safe for direct exposure of body tissue excluding the eye. The key feature is that the laser must be in contact with the skin in order for the beam to fire. Hence, "C" stands for *Contact*. Laser output can be in the Class, 2, 3R, or 4 range. This class of laser products is typically used in home medical systems (i.e., for wrinkle removal, etc.).

Class 1M

Class 1M laser products or devices use invisible wavelengths and are safe, sometimes termed "eye safe," which is a terrible term. They can be hazardous to the eyes if viewed using optical instruments. The beam is expanded or there are diverging beams so the irradiance is below a hazardous level. The classification came out of free space communications needed to classify its transmission beams in open space.

Class 2

A Class 2 laser or laser product uses visible wavelengths that have an output no more than 1 mW, and the laser mode is continuous wave. The concept is that exposure to the beam will induce the aversion response, meaning that one will turn away from the beam in less than 0.25 s. While burly vision or a residual image may occur, it is a transient effect, not permanent, meaning that some retinal cells have been oversaturated, and vision will return to normal as the energy is dissipated.

Class 2A

This is a CDRH product classification that was generated for bar code scanners. You will not find it in use in the ANSI or IEC standards. The classification is similar to Class 2, but CDRH Class 2a, written as Class IIa, are products that have emissions in the visible spectrum (400–710 nm) and are nonhazardous for viewing durations up to 1000 s. Viewing for longer than 1000 s presents the risk of chronic impairment. By the way, 1000 s equals 16.6 min, a rather unrealistic direct viewing time, but not for diffuse reflections that a cashier might face.

Class 2M

The companion to Class 1M, Class 2M is just for visible wavelengths. An aversion response is typically generated, and like 1M, 2M can be hazardous if viewed through optical instruments. Once again, it traces its development from free space communications. This class is found in the ANSI Z136 series and the IEC 60825 series of standards.

Class 3R

For Class 3R laser products, output is limited to 5 mW, continuous wave mode. This is considered safe for momentary viewing, unless viewed through optics. The most common devices that are Class 3R are laser pointers (in particular, those with green output), construction level devices, and a number of alignment devices found in a wide variety of medical and industrial equipment. Although one should not look directly at this beam, the most common problem is startle or surprise from exposure. Large numbers of these lasers have been tied to pilot illumination incidents. Once again, you will find this classification in ANSI and IEC laser standards. An interesting item is that in the ANSI 136 series, Class 3R can be visible or invisible, while per CDRH it can only be a visible beam. "R" stands for *Reduced* requirements.

Class IIIa

This is the classification associated with Class 3R, but from a CDRH perspective, IIIa is the official classification. Defined as products that have emissions in the visible spectrum and that have an emission power of more than 5 mW for continuous discharge of more than 0.38 ms. A Class IIIa product can be a potential eye hazard from direct viewing or viewing through optical instruments.

Class 3B
This is the real starting point for laser safety. Class 3B covers visible and invisible wavelengths, continuous wave or pulse mode of operation. Direct exposure is a potential eye hazard. The output range for a Class 3B laser system is 5–500 mW for continuous wave and no more than 125 mJ, pulsed in less than 0.25 s. By the way, the "B" has no meaning.

Class 4
Any laser output greater than Class 3B is a Class 4 laser, laser system, or laser product. Because there is no upper limit, Class 4 is considered an eye and skin hazard for direct exposure and diffuse exposure as well as a fire hazard. Many non-beam hazards are associated with Class 4 laser systems.

Class 5
When the first ANSI Z136.1 standard was published in 1973, few expected laser outputs to be in the range available today (expect the laser fusion folks). The issue has been raised that with MegaWatt, PetaWatt, and similar systems becoming common, should we have a classification to distinguish them from lower-power systems. Many of these "Class 5" lasers have unique non-beam hazards as well as special beam containment challenges. There has been resistance from standard committee members to go down this path, but I am sure that over time, that will change. Whether it becomes Class 5 or Class 4A or maybe Class 4L (L for lethal), a classification to represent these lasers will be coming.

Note from CDRH
The FDA recognizes four major hazard classes (I–IV) of lasers, including three subclasses (IIa, IIIa, and IIIb). The higher the class, the more powerful the laser is and the greater the potential to pose serious injury if used improperly. The labeling for Classes II–IV must include a warning symbol that states the class and the output power of the product. Roughly equivalent IEC classes are included for products labeled under the classification system of the International Electrotechnical Commission. (See the Regulation section for additional information about **Notices 50, 56, and 14**.)

CDRH Laser Notices 50 and 56 allow manufacturers of laser products to use the IEC labeling scheme, rather than dual labeling products.

ROLE OF THE LASER SAFETY OFFICER

The first ANSI standard, Z136.1 Safe Use of Lasers, was published in 1973. That standard formally introduced the position of the laser safety officer (LSO). It is clear that no facility can say it has a laser safety program without someone fulfilling the role or position of LSO.

Before describing the duties of the LSO, let me clearly state that the existing laser standards allow the LSO to delegate responsibilities. The task of LSOs is to see that laser safety is addressed, either by themselves, others, or a combination. An interesting difference between the U.S. ANSI laser standards and the international IEC laser standards is that in the United States, the role of the LSO is established with responsibilities and authority. This means that the LSO can stop work if safety considerations call for such action. The IEC approach gives the LSO responsibilities but states the LSO must negotiate authority with the employer; in other words, the employer can limit the authority of the LSO, for example, saying that lab shutdown is not allowed as their independent call.

The LSO's role is rather simple, it is to see that laser safety is addressed. Hazards are evaluated and control measures put into place. The LSO does not have to perform all the traditional tasks of the LSO but needs to see that they are addressed. Following is a listing of the LSO duties per laser safety standards, both ANSI and IEC. Additional items are listed and explained that many LSOs overlook or do not take advantage of. (This is a teaser to get you to read this section.)

The LSO takes responsibility, on behalf of its management, for the administration of day-to-day matters of laser safety. Critical LSO duties may include, but are not limited to:

- Evaluating laser use of Class 3B and Class 4 laser systems.
- Developing control measures and solutions.
- Monitoring compliance to laser safety procedures.
- Reviewing specifications of laser protective eyewear and other laser safety devices and or barriers.
- Recommending laser protective devices (i.e., eyewear, beam blocks).
- Ensuring that laser safety training is adequate for the laser risks.
- Reviewing laser safety assessments.
- Leading any laser-related incident investigations.

Note: To be an effective LSO, the person must want to do the job; it is that simple. If one feels like they are just stuck with it, they will never do a good job. To achieve laser safety, it takes effort, and management must realize it takes resources, and most of all, time has to be allotted to do the job.

What about a laser safety committee?

The laser safety committee (LSC) can fulfill an important role in the overall safety approach for any facility. It should be composed of members who represent laser use areas, the Environmental Health and Safety (EHS) Department, and a management representative.

The goal of the LSC is to

- Establish and maintain internal policies and procedures to ensure they comply with applicable regulations and standards.

- Meet on a regular basis (quarterly at a minimum).
- Receive updates on laser-related activities from the LSO or laser safety advisor.
- Evaluate proposals for technology and procedure changes.
- Review appeals and concerns from laser users (e.g., issues that may be conflict with LSO determinations) and make recommendations for their resolution.
- Assist the LSO in investigating incidents that caused or potentially could have caused injury or equipment damage.

Laser safety supervisor

In the research or academic setting, the laser safety supervisor (LSS) is critical to achieving laser safety. Their role is to be the boots on the ground, the local person who sees that laser safety is performed. The LSO will not be everywhere or a constant observer. The LSS is not the “safety cop” but is to set the safety culture and make sure new people get an orientation to the lab, get protective eyewear, etc. The individual who is the LSS needs to recognize the responsibility and want to do it, otherwise safety will not happen.

BIOLOGICAL EFFECTS OF LASER EXPOSURE

If not for the potential to cause harm to tissue, skin, or eye, laser safety would be of minor or no concern. Unfortunately, laser exposure has the potential to cause minor to major injury to an individual, as well as varying risk perception issues. Therefore, an awareness of these effects is certainly to the advantage of the user.

While skin is by far the largest target for a laser beam, it is the eyes that are of the greatest concern. The eye is just a marvel of bioengineering. Let’s start with a review of the major components of concern in the world of laser safety as well as the trip that light takes through the eye. Figures 1.1–1.4 illustrate the information discussed in the chapter.

The path of visible light

Light from an object (such as a tree) enters the eye first through the clear cornea and then through the pupil, the circular aperture (opening) in the iris. Next, the light is converged by the lens to a point immediately behind the lens; at that point, the image becomes inverted. The light progresses through the gelatinous vitreous humor and, ideally, back to a clear focus on the retina, the central area of which is the macula. In the retina, light impulses are changed into electrical signals and then sent along the optic nerve and back to the occipital (posterior) lobe of the brain, which interprets these electrical signals as visual images.

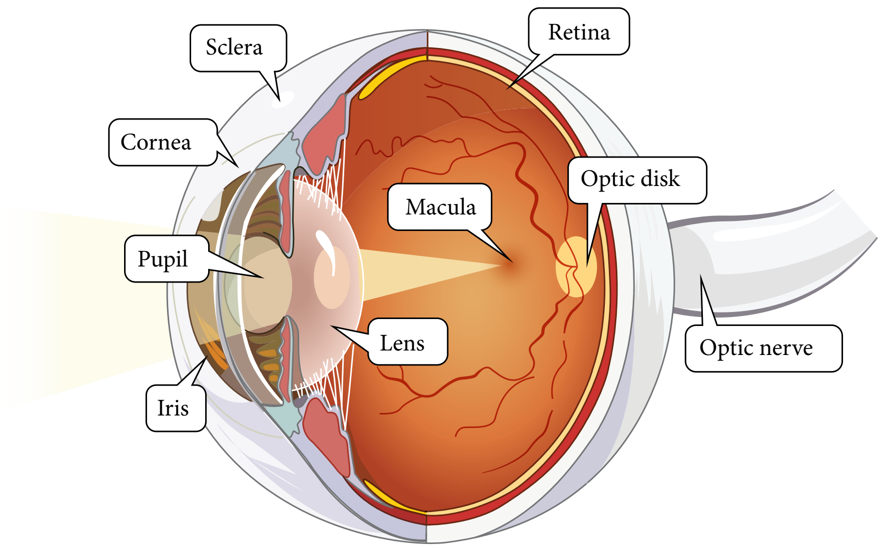


FIG. 1.1
Parts of the eye.

Cornea

The **cornea** is the transparent layer of tissue covering the eye. Damage to the outer cornea may be uncomfortable (like a gritty feeling) or painful but will usually heal quickly. Damage to deeper layers of the cornea may cause permanent injury.

> Note: Accidental injury to the cornea is common from excessive rubbing of the eyes in cases of suspected laser injury.

Lens

The **lens** focuses light to form images onto the retina. Over time, the lens becomes less pliable, making it more difficult to focus on near objects. With age, the lens also becomes cloudy and eventually opacifies. This is known as a cataract. Every lens develops cataracts eventually.

Retina

The part of the eye that provides the most acute vision is the fovea centralis (also called the macula lutea). This is a relatively small area of the retina (3%–4%) that provides the most detailed and acute vision as well as color perception. This explains why eyes move when you read, as the image has to be focused on the fovea for detailed perception. The balance of the retina can perceive light and movement.

If a laser burn occurs on the fovea, some level of fine (reading and working) vision may be lost. If a laser burn occurs in the peripheral vision, it may produce little or no effect on vision.

Looking at exposure from a wavelength point of view

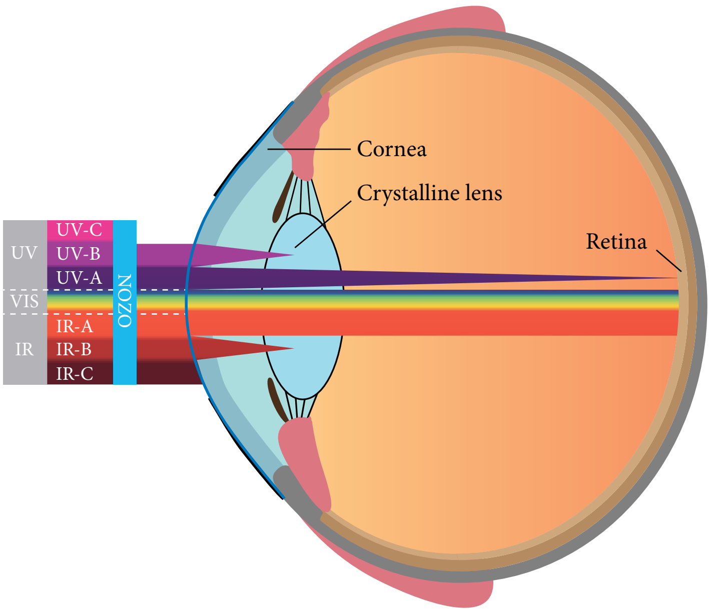


FIG. 1.2
Wavelength journey through the human eye.

180–400 nm (Ultraviolet) is absorbed by the cornea and lens, and the damage mechanism is "photokeratitis"

Ultraviolet-B + C (100–315 nm)
The surface of the cornea absorbs all UV wavelengths that produce a photokeratitis (welder's flash) by a photochemical process, which cause a denaturation of proteins in the cornea. This is a temporary condition because the corneal tissues regenerate very quickly.

> Note: Wavelengths below 180 nm are not considered laser wavelengths due to their electron volt energy, and no safe exposure guidance levels will be found in laser standards for these wavelengths.

Ultraviolet-A (315–400 nm)
The cornea, lens, and aqueous humor allow ultraviolet radiation of these wavelengths, and the principal absorber is the lens. Photochemical processes denature proteins in the lens resulting in the formation of cataracts.

400–700 nm (Visible spectrum) Visible light passes through the cornea and is focused onto the retina at the back of the eye. This macula/fovea tissue is a small zone (2%–4% of your retinal surface) made up of 1 million cone cells and is where all critical vision takes place. The rest of the retina is primarily for motion detection, and laser damage outside the macula/fovea may have little to no adverse effect on vision.

For visible light, 400–700 nm, the aversion reflex, which takes 0.25 s, may reduce exposure, causing the subject to turn away from a bright light source. However, this will not occur if the intensity of the laser is great enough to produce damage in less than 0.25 s.

700–1400 nm (Near infrared) Infrared (IR) energy, like visible light, is focused on the retina but is not interpreted into vision. However, IR energy is still absorbed by the retina and can cause injury. One of

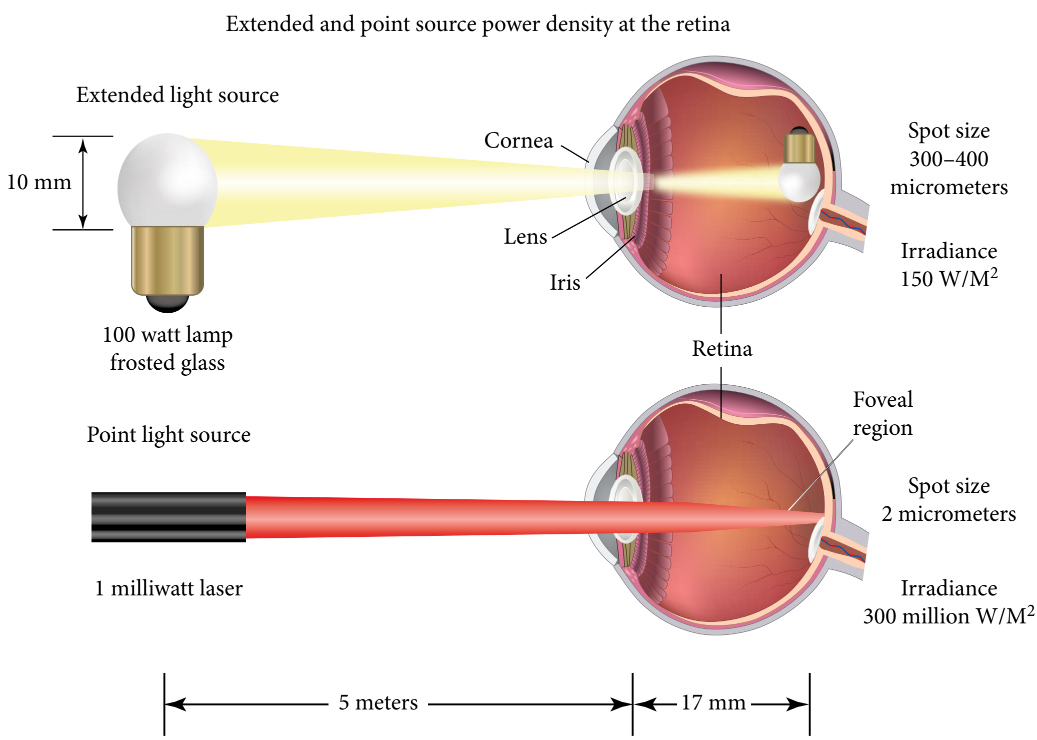


FIG. 1.3
Spot size factor.

the documented effects is the causation of a bubble that then bursts, damaging your retinal cells with a "POPPING" sound from inside your eye.

Note: The cornea, lens, and vitreous fluid are transparent to wavelengths. Damage to the retinal tissue occurs by absorption of light and its conversion to heat by the melanin granules in the pigmented epithelium or by photochemical action to the photoreceptor. The focusing effects of the cornea and lens will increase the irradiance on the retina by up to 100 000 times.

Infrared-B and Infrared-C (1400 to 1.0×10^6 nm)
Corneal tissue **will** absorb light with a wavelength longer than 1400 nm. Damage to the cornea results from the absorption of energy by tears and tissue water causing a temperature rise and subsequent denaturation of protein in the corneal surface.

The major danger of laser radiation is harm from beams entering the eye. The eye is the organ most sensitive to light. A laser beam (400–1400 nm) with low divergence entering the eye can be focused down to an area 10–20 μm in diameter.

The energy density (measure of energy per unit of area) of the laser beam increases as the spot size decreases. This means that the energy of a laser beam can be intensified up to 100 000 times by the focusing action of the eye for visible and near-infrared wavelengths. If the irradiance entering the eye is 1 mW/cm^2, the irradiance at the retina will be 100 W/cm^2. Even a 4% reflection off an optic can be a serious eye hazard. Remember that a low-power laser in the milliwatt range can cause a burn if focused directly onto the retina. A 40 mW laser is capable of producing enough energy (when focused) to instantly burn through paper.

Blink and aversion response

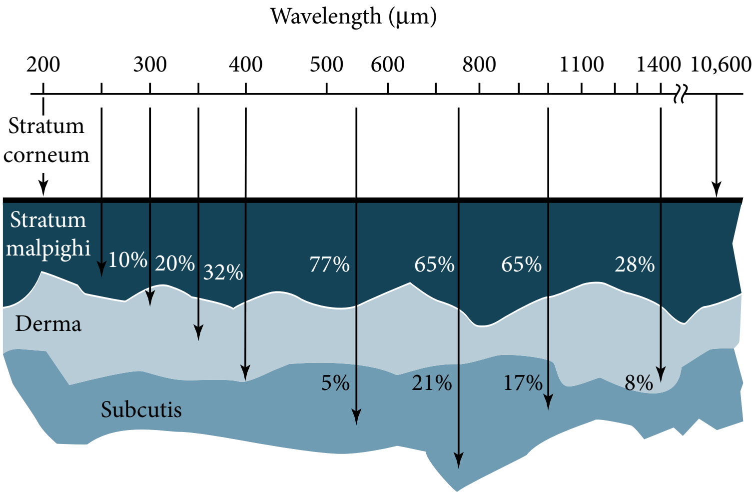
Fortunately, the eye has a self-defense mechanism—the blink and aversion response. Aversion response is the closing of the eyelid or movement of the head to avoid exposure to bright light. The aversion response is commonly assumed to occur within 0.25 s and is only applicable to visible laser wavelengths. This response may defend the eye from damage where lower-power lasers are involved but cannot help where higher-power lasers are involved. With high-power lasers, the damage can occur in less time than a quarter of a second.

Signs of eye exposure

Symptoms of a laser burn in the eye include a headache shortly after exposure, excessive watering of the eyes, and sudden appearance of *floaters* in your vision. Floaters are those swirling distortions that occur randomly in normal vision most often after a blink or when eyes have been closed for a couple of seconds. Floaters are caused by dead cell tissues that detach from the retina and choroid and float in the vitreous humor. Ophthalmologists often dismiss minor laser injuries as floaters due to the very difficult task of detecting minor retinal injuries. Minor corneal burns cause a gritty feeling, like sand in the eye.

SKIN HAZARD

Laser radiation injury to the skin is normally considered less serious than injury to the eye, since functional loss of the eye is more debilitating than damage to the skin, although the injury thresholds for both skin and eyes are comparable (except in the retinal hazard region, 400–1400 nm). In the far-infrared and far-ultraviolet regions of the spectrum, where optical radiation is not focused on the retina, skin injury thresholds are about the same as corneal injury thresholds. Obviously, the possibility of skin exposure is greater than that of eye exposure because of the skin's greater surface area.



Values are percentages of incident radiation reaching a given layer of the skin.
Source: WHO 1982.

FIG. 1.4
Human skin and wavelength penetration.

The layers of the skin, which are of concern in a discussion of laser hazards to the skin, are the epidermis and the dermis. The epidermis layer lies beneath the stratum corneum and is the outermost living layer of the skin. The dermis mostly consists of connective tissue and lies beneath the epidermis.

Skin composition

Epidermis

The epidermis is the outer layer of skin. The thickness of the epidermis varies in different types of skin. It is the thinnest on the eyelids at 0.05 mm and the thickest on the palms and soles at 1.5 mm.

Dermis

The dermis also varies in thickness depending on the location of the skin. It is 0.3 mm on the eyelid and 3.0 mm on the back. The dermis is composed of three types of tissue that are present throughout—not in layers. The types of tissue are collagen, elastic tissue, and reticular fibers.

Subcutaneous tissue

Subcutaneous tissue is a layer of fat and connective tissue that houses larger blood vessels and nerves. This layer is important in the regulation of the temperature of the skin and the body. The size of this layer varies throughout the body and from person to person.

Skin damage

There is quite a variation in depth of penetration over the range of wavelengths, with the maximum occurring around 700–1200 nm. Injury thresholds resulting from exposure of less than 10 s to the skin from far-infrared and far-ultraviolet radiation are superficial and may involve changes to the outer dead layer of the skin. A temporary skin injury may be painful if sufficiently severe, but it will eventually heal, often without any sign of injury. Burns to larger areas of the skin are more serious, as they may lead to serious loss of bodily fluids. Hazardous exposure of large areas of the skin is unlikely to be encountered in normal laser work.

A sensation of warmth resulting from the absorption of laser energy normally provides adequate warning to prevent thermal injury to the skin from almost all lasers except for some high-power far-infrared lasers. Any irradiance of 0.1 W/cm^2 produces a sensation of warmth at diameters larger than 1 cm. Only one-tenth of this level can be readily sensed if a large portion of the body is exposed. Long-term exposure to UV lasers has been shown to cause long-term delayed effects such as accelerated skin aging and skin cancer.

> Note: Safe skin exposure levels, Maximum Permissible Exposure levels for skin, are based on an exposure spot size of 3.5 mm. Little data are available for larger spot sizes.

To the skin, UV-A (0.315–0.400 μm) can cause hyperpigmentation and erythema. UV-B and UV-C, often collectively referred to as “actinic UV,” can cause erythema and blistering, as they are absorbed in the epidermis. UV-B is a component of sunlight that is thought to have carcinogenic effects on the skin. Exposure in the UV-B range is most injurious to skin. In addition to thermal injury caused by ultraviolet energy, there is the possibility of radiation carcinogenesis from UV-B (280–315 nm) either directly on DNA or from effects on potential carcinogenic intracellular viruses.

Exposure in the shorter UV-C (0.200–0.280 μm) and the longer UV-A ranges seems less harmful to human skin. The shorter wavelengths are absorbed in the outer dead layers of the epidermis (stratum corium), and the longer wavelengths have an initial pigment-darkening effect followed by erythema if there is exposure to excessive levels.

IR-A wavelengths of light are absorbed by the dermis and can cause deep heating of skin tissue.

REGULATIONS AND STANDARDS

To give users and purchasers of lasers and laser products some guidelines, a number of standards and regulations have been developed over the years. Some standards have taken on near regulatory status, such as ANSI Z136.1 Safe Use of Lasers, while other standards have been ignored.

While it may be obvious to most, let's define the difference between a "regulation" and a "standard."

Regulation

From a laser user or manufacturer perspective, there are rules made by a government or regulatory body with the purpose of controlling the way something is done or the way people act. In the United States, the US Food and Drug Administration's Center for Devices and Radiological Health sets the product requirements. In the rest of the world, IEC sets the tone for national regulations on laser product safety requirements.

The US Food and Drug Administration's Center for Devices and Radiological Health (CDRH) mandates are released as federal code in Title 21 of the Code of Federal Regulations (21CFR). The subsections of this title list the required elements to which manufacturers must comply if they are offering a product for sale in the United States:

21 CFR Chapters related to laser products, bolded are the most important.

21CFR 1000–1005 Broad scope list of devices regulated and the records and reports that must be produced and kept by a manufacturer, and the import/export requirements.

21CFR 1010 General performance standards, certifications, and variances.

21 CFR 1040.10 Performance standards for manufacture of laser products. Information on laser housing interlocks, remote electrical interlocks, labeling, and power classification can be found. Also has information for user when building their own Class 1 enclosure.

21 CFR 1040.11 Performance standards for specific-use laser products. Medical, survey, leveling, alignment, and demonstration laser products must meet criteria listed in this chapter as well as items in 21 CFR 1040.10.

Laser Notices

Laser Notices are guidance from the CDRH; even though technically they are not regulations, they take on that level of authorization. Many times, Laser Notices are a CDRH response to an industry question, such as define a manufacturer or can we use IEC labeling only? Due to the administrative burden to propagate new federal regulations, the Laser Notice approach allows the CDRH to update or harmonize some of its regulations. Two of the most important to the general laser user population are the following:

Laser Notice 50, which has been replaced by Laser Notice 56. Laser Notice 56 allows laser manufacturers to use IEC labeling rather than having to put a dual set of labels on their products. One of the key lines in the Notices Introduction is bolded.

Here is the introduction on Laser Notice 56:

> This guidance describes the Food and Drug Administration's (FDA) approach regarding manufacturers' compliance with FDA's performance standards for laser products. FDA recognizes that while there are many similarities between International Electrotechnical Commission (IEC) standards 60825-1: Safety of laser products - Part 1: Equipment classification, and requirements, Edition 3.0 and 60601-2-22: Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment, **Edition. 3.1 and FDA's laser performance standards, there are clauses of these IEC standards that differ significantly from FDA's performance standards for laser products. For the manufactures that conform to the clauses of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 that FDA identifies as comparable with 21 CFR 1040.10 and 1040.11, FDA does not intend to enforce the applicable requirements in 21 CFR 1040.10 and 1040.11.**

Walking the tightrope, following is the last paragraph of Laser Notice 56's introduction:

> FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

Laser Notice 14, which dates to 1976, addresses the question of could I be a manufacturer in the eyes of CDRH:

Laser Notice 14 answers this question in this way:
You are not considered engaged in the business of a manufacturer under the following conditions:
If you assemble a product for your own personal non-commercial use.
Repair of a laser product to its original condition and it does not result in a modification.
Now comes the really import part of the notice:
Laser products constructed on a onetime basis by a particular company for use by that company in it manufacturing process at the place where constructed is not considered "manufacturing".
But now comes the part that gets people's attention.

If the products are made on a continuing basis in the course of a commercial enterprise and **used by employees other than those directly involved in the manufacture of the electronic product**, the company is considered to be "**engaged in the business" of manufacturing subject to the Act.**

Meaning that if I come up with a laser product or solution that is used in multiple locations within my firm, and those folks have not built each themselves, you have become a laser product manufacturer.

Note: Compliance with Laser Notices does not advocate the "certification" process. Manufacturers of laser products must still certify that their products comply with the FDA's performance standards.

Occupational Safety and Health Administration

It is the responsibility of the employer to make sure that their employees have a safe place to work. The role of the US federal and state OSHA programs is to oversee that responsibility. OSHA has minimal regulations concerning lasers, mainly in the construction setting. Most of the lasers used in that setting, while they might be annoying if one is exposed, in themselves are not an eye hazard. The laser used tends to be of Class 2 or 3R.

So how does OSHA deal with the majority of lasers used in the workplace? OSHA rules allow them to perform oversight by referencing recognized consensus standards as a means to demonstrate safety compliance. This falls under the OSHA "General Duty Clause." For lasers, OSHA looks toward the ANSI Z136.1 Safe Use of Lasers standard. This approach is followed by state OSHA programs as well, but under different names. In California, a citation would fall under reviewing a firms' Injury and Illness Plan.

Note: Although ANSI firmly stands behind their position that the standards are just guidance and have no regulatory authority, it is more like a "wink and a nod" since the standard is used as the road map for regulatory agencies.

U.S. state regulations

Some U.S. states have laser regulatory programs. A small number of U.S. states have rules on laser use. They either focus on medical lasers or Class 3B and 4 lasers. In addition, some states and cities have restrictions on handheld lasers (commonly called laser pointers). These later rules apply to the illumination of aircraft. Some states have separate rules affecting medical lasers and who can use them (i.e., physician vs cosmetologist). Overall, the state programs go through swings of activity—at times they are emphasized and at times they seem asleep at the wheel. What you do not want is a state that just has registration fees and provides no services to those who are paying.

The following are states with some level of laser regulations:

- Alaska: Radiological Health Program section of State Laboratories Department of Health and Social Services: Title 18 of the Alaska Annotated Code Part 85, Art. 7, Sect. 670–730 (Oct. 1971 and Apr. 1973)
- Arizona: Arizona Radiation Regulation Agency Regulations, now part of the Department of Health Services: Article 14, Rules for Control of NIR, Sect. R12-1-1421 to 1444
- Florida: Florida Department of Health, Bureau of Radiation Control Regulations: extensive regulations in chapter 10D-89 of FL code
- Georgia: Office of Regulatory Service Department of Human Resources Regulations: registration requirements in chapter 270-5-27, GA Code (9/1/71)

- Illinois: Division of Electronic Products Department of Nuclear Safety Registration Regulations in Laser Systems Act of 1997 (effective 7/25/97)
- Massachusetts: Massachusetts Radiation Control Program Regulations: Registration and Control regulations (ANSI Z136 based); effective 5/7/97
- New York: Department of Labor Radiological Health Unit Regulations: in Industrial Code Rule 50 of Title 12 (cited 12 NYCRR Part 50); amended 3/2/94
- Texas: Bureau of Radiation Control Department of Health Division of Licensing, Registration and Standards; Texas Regulations for the Control of Laser Radiation Hazards (TRCLRH), Parts 50, 60, and 70; 25 Texas Administrative Code (TAC) 289.301

Standards

Are rules or guidance made by a non-governmental body how work should be performed? In many ways, they comprise an approved model of behavior or action. Sometimes they define terms or performance factors.

There are several standards-producing bodies that affect laser users in a research setting.

American National Standards Institute, Z136 series

ANSI Z136 While the American National Standards Institute (ANSI) Z136 laser series is designed only as guidance for laser users, it has taken near regulatory impact since OSHA, US federal agencies, and several state regulatory programs audit against it. The ANSI Z136 laser series is broken down into a Horizontal Standard Z136.1 Safe Use of Lasers which cuts across all laser application standards and application-specific standards (termed *vertical standards*). The rest of the Z136 Laser Series is made up of "Vertical or Application" standards. The Z136 standard body is considering combining some of the application standard, so over time the list that follows may shrink:

- ANSI Z136.1—for Safe Use of Lasers
- ANSI Z136.2—for Safe Use of Optical Fiber Communication Systems Utilizing Laser Diode and LED Sources
- ANSI Z136.3—for Safe Use of Lasers in Health Care
- ANSI Z136.4—RP for Laser Safety Measurements for Hazard Evaluation
- ANSI Z136.5—for Safe Use of Lasers in Educational Institutions
- ANSI Z136.6—for Safe Use of Lasers Outdoors
- ANSI Z136.7—for Testing and Labeling of Laser Protective Equipment
- ANSI Z136.8—for Safe Use of Lasers in Research, Development or Testing
- ANSI Z136.9—Safe Use of Lasers in Manufacturing Environments
- Draft Z136.10—Safe Use of Lasers in Entertainment, Displays and Exhibitions

It is not all or nothing
An overlooked set of sentences in Section 1 of Z136.1 state that control measures in the vertical standard can take precedence over sections in Z136.1 if the LSO deems them to be more appropriate for the laser applications under their review, even if they contradict Z136.1. Therefore, the LSO can choose controls from more than one standard in building the laser safety program. Wording found in the ANSI standard is generally some version of the following: The objective of this standard is to provide reasonable and adequate guidance for the safe use of lasers and laser systems.

Problem with Z136 vertical standards

The greatest weakness of the vertical standards is user awareness. The most commonly used standards are: Z136.1 Safe use of lasers, which is referenced by all regulatory bodies.

Z136.3 Medical Standard, which is believed to be the number two seller in the Z136 series.

After that, if one equates standards sold to their use, all the other Z136 standards have pitable sales numbers. In this author's opinion, this is not due to the quality of the standards or even the size of their potential audience, but rather to poor promotion and awareness of these standards by their intended user audience.

Outside the United States

The International Electrotechnical Commission (IEC)
The IEC is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. IEC publishes International Standards, Technical Specifications, and Technical Reports. The IEC document that outlines laser user conduct is 60825-14. Once the IEC standard is voted on and approved by the relevant committee, it becomes the responsibility of each member nation to adapt the standard as its national regulations. In doing so, each nation can include national specific items. This may include age limits to work with lasers or accident reporting requirements to national regulatory agencies. The most well-known IEC laser standard is 60825-1, which is a combination of CDRH rules and ANSI Z136 controls. Outside of the United States, users follow IEC standards and regulations, yet within the United States, ANSI Z136 is the dominant user standard.

The most used IEC laser standards for users are:

IEC 60825-1, for the Safety of Laser Products
IEC 60825-2, for the Safety of Fiber Optic Systems
IEC 60825-14, A User's Guide
IEC 60825-5 Manufacturers checklist

Additional IEC 60825 standards exist, covering different aspects of laser use including housing.

SAE International

SAE International is another organization that generates standards. Their focus is on aerospace, automotive, and commercial vehicles. The standards are the outcome of work by volunteers that make up a number of technical subcommittees, and they are based on a technical consensus by committee members. This is the same approach used by other standards bodies.

This is the current list of laser-related standards SAE has generated:

ARP5290A Laser Beam Divergence for Measurements Techniques Comparison
ARP5293A Safety Considerations for Laser Projected in the Navigable Airspace
ARP5535A Observers for Laser Safety in the Navigable Airspace
ARP5560 Safety Considerations for High Intensity Lights (HIL) Directed into the Navigable Airspace
ARP 5572 Control Measures for Laser Safety in the Navigable Airspace
ARP 5674 Safety Considerations for Aircraft Mounted Lasers Projected into the Navigable Airspace
AS6029A Performance Criteria for Laser Control Measures Used for Aviation Safety

USER RESPONSIBILITY

With a technology that is over 50 years old, why do laser accidents still happen? One argument is that it is common for laser users to violate laser safety good practices and nothing happens. Every time a user raises their eyewear to peek at an optic and they are not struck by a beam, it just reinforces that action. The real question is whether such actions are worth the risk of an eye injury. If an injury occurred each time eyewear was raised, the action would stop quickly.

Of course, in scenarios where the power of beams is in the 100 kW range, this might all change as the risk from even diffuse reflections can be hazardous to one's eyes and even skin. The overall theme of this section is that laser safety always comes down to the user. There are motorcycle helmet laws, helmet design has greatly improved, and yet you will find riders who refuse to wear a helmet. This is why hospital emergency room staff call motorcycle riders, donor cycles. Fatal head injuries allow organ donations to go forward.

It all comes down to user compliance with good practices and awareness of the hazards. Let's review some well-worn good practices for users to consider. There is really no commandment-like order to these good practices. For different cases, one may be more important than another and in a new setting be reversed. The reader needs to consider how these apply to the individual work setting.

The good practice list is split between what actions the user needs to follow and what good practices need to be in place for the workspace. Some, of course, will blur that line, so a little open-mindedness is requested of the reader. A number of good techniques, practices, and tricks of the trade are presented.

USER PRACTICES

Remove reflective items from one's person. This includes watches, rings, bracelets, and identification badges. This is of particular importance if the ID badge is hanging from a lanyard. When it comes to ring removal, another option is to cover the ring with something like painter's tape. When removing items from your person, do not forget that smartphone in your pocket.

Beam path below eye level, sitting or standing. This has been listed as a good practice for decades. This may seem rather silly, for if there are beams that one could be exposed to when seated, then steps need to be taken to block the beams. Beam blocks or perimeter guards blocking the beam are better than adjusting chairs to change one's height.

Block potential specular reflections. As optics are set in place and post optical setup, the user needs to consider where reflections can come from. One also needs to consider if there will be transmission through an optic. This is where the placement of beam blocks and enclosures comes into play. Remember that when we talk about upward reflections, one is not just talking of a periscope perpendicular-style beam but also a reflection that is at an angle and leaving the table. Do not forget back-reflections.

Use the correct laser protective eyewear. This sounds rather simple, but several laser injuries in research labs have been traced back to people using the wrong pair of eyewear. In one case, someone picked up a pair of sunglasses rather than laser protective eyewear. In other cases, eyewear with incorrect optical density or wavelength coverage has been worn. Here the LSO has a role in making sure users have the correct eyewear.

Check for stray reflections. This applies not just at initial setup but as things change and during the day. This is especially needed as the number of staff working around the optical tables increases.

750–830 nm trap. One needs to remember that your eye has very poor perception of wavelengths in this range. Less than 1% of photons in this wavelength band are seen by your eye. A faint red dot could easily be a specular reflection of the full 800 nm beam. Once again, a number of laser users have let the instinct that faint equals weak lead them into an eye exposure. While cloth tape, business cards, and Post-it Notes might be a temporary block, they must not become the permanent solution.

Properly terminate beams. All primary beams, picked-off beams, split beams, and reflections need to be terminated. How one does this is generally the role of beam blocks, beam dumps, and power meters. Please keep in mind that these items could be a reflective source, depending on the wavelength(s) with which they are struck.

Unattended lasers left running. Unattended lasers have several meanings. It is common to turn on a laser system and walk away, letting the system reach the required thermal stability. In this case, steps need to be taken to either enclose or block any accessible beams within the system or have an access system robust enough to only allow access by those who know the system. This does not include security or housekeeping—if there are open beams, they must not enter the lab unsupervised. If beams cross an open space, access control is even more important. If the system is all enclosed, the use of unattended laser systems is much more acceptable.

Housekeeping, housekeeping, and yes, housekeeping. I am not talking about those folks who take away your empty pizza boxes, but how neat your lab is. Poor housekeeping leads to lost items, reflection sources, lost time, and an unprofessional look to your work area. The best way to achieve good housekeeping is to set aside a cleaning day. You set the frequency. This way everyone knows and plans not to work that day, but to clean up, put things away, organize items, etc. I have found that if this is planned and carried out by all staff, over time the activity takes less time each cleaning day. People start to put things away. All I can say is to give it a try and be willing to be surprised.

Secure lasers and optics. Lasers and optics in use need to be secured to the optical table or work surface. It is rare that an optic in use cannot be anchored in place. The goal, of course, is to reduce the possibility of an optic moving out of position or falling over.

Never stare at a direct beam. This can be summed up in "Don't look at laser with the remaining eye." If any information is needed from looking at a laser straight on, including the end of a fiber, there is equipment made for that, do not use your eye.

Communications. User communication is vital for user safety. Never turn on a laser system or remove a beam block, optic, etc., without letting others in the room know. Sometimes it is to give them time to put on eyewear, and other times it may be a signal for them to leave the area—many reasons exist. In particular, if removing a control or optic, expect people to be there. The author knows of at least one incident because of this action.

WORKPLACE-FACILITY PRACTICES

Class 4 laser use areas require access control. This does not mean room interlocks are required, but some level of access control is required to keep those not trained or aware of the hazards in the workspace safe. The laser standards allow a range of access controls. The author likes electronic locks the best.

Illuminated warning sign. Many laser labs utilize an illuminated sign to indicate the status of the laser system. There are a variety of illuminated signs to choose from. They range from a simple light (on or off) to a programmable logic digital sign.

Windows—yes or no. Many users find themselves using laboratory space with a window as part of a door or a viewing window on a wall. The usefulness of such windows needs to be evaluated, and it should be determined if they should be covered all the time or just during laser use.

Panel clearance. Knowing electrical safety standards and requirements is important. Electrical panels require an unobstructed clearance of 1 m.

Space planning. When designing a laser lab, one should use a computer-aided design (CAD) software to lay out the lab space. See if optical tables will fit. Does the layout conflict with building safety codes, i.e., electrical panels, eye wash showers, chemical storage, etc.

Exit path. Is there a clear pathway to the exit in case of an emergency, emergency lighting, the required number of exits, etc.?

Posting of warning signs. Access doors require an ANSI-style warning sign, with appropriate information. This is not the same as a hazardous communication sign with a laser logo on it. Wavelength and optical density for eyewear (if eyewear is required) should be posted.

Environmental factors. Lasers systems often require special considerations. These include stable temperature range and water temperature for cooling purposes.

LASER ALIGNMENT GUIDELINES

Laser alignment is a challenge and rarely has a standardized methodology to adhere to. **It is also the most likely time for a laser-induced injury/accident to occur.** When aligning, consider these good practices:

- Follow all laser-specific operating requirements stipulated in the designated standard operating procedure (SOP).
- No unauthorized personnel will be in the room or designated laser control area during the alignment procedure.
- Only appropriately trained personnel should perform or be physically present during laser alignment operations. (Almost the same as the previous line.)
- To make alignment as quick and easy as possible, locate all equipment and materials needed prior to beginning the alignment. An example might be IR viewers, sensor cards, and maybe alignment eyewear.
- If applicable, laser safety curtains/partitions should be put in place.
- Remove all wristwatches, jewelry, ID badges, etc., that may cause unintended stray reflections.
- Clear the laser optic table of any unnecessary equipment and/or materials.
- Ensure beam blocks and stray beam shields are in place and securely mounted.
- Designated protective eyewear will be worn. For visible-wavelength lasers, this may involve designated "laser alignment" eyewear intended to allow the researcher to view the beam while providing a reduced level of eye protection.

- Post the “Laser Alignment in Progress” notice sign outside the laser lab before beginning any alignment procedure.
- It the area is separated by a curtain, check that the laser curtain is securely closed with no gaps.
- Use the lowest practical power during the alignment process.
- If possible, use an alignment laser (e.g., HeNe).
- When using Class 4 laser for alignment, avoid direct viewing of the beam and use cameras.
- Utilize appropriate alignment tools (e.g., fluorescence cards, alignment scopes, etc.). Note that IR cards and Polaroid sheets may be specular reflectors.
- Avoid having beams cross aisleways. If this is unavoidable, ensure the accessible aisleway is appropriately marked and barricaded during laser operations.
- Close the laser shutter while conducting crude adjustments of optics or when entering the beam path. Make sure that the optics and beam blocks are secure prior to opening the shutter.
- Avoid beam alignment out of the horizontal plane.
- Never allow the beam to propagate beyond the point to which you have aligned, and always be aware of the full beam path.
- Always block the beam upstream when inserting/removing anything into/from the beam path, such as alignment irises.
- Whoever moves or places an optical component on an optical table is responsible for identifying and terminating each and every stray beam coming from that component.
- When working with Class 4 lasers, consider using the buddy system (from my experience, this is rarely done).
- When alignment is complete, make sure that all beam blocks, barriers, interlocks, and enclosures are replaced and working.
- Use beam blocks behind optics (mirrors) if there is a possibility beams might miss the mirrors during alignment.
- Check for stray reflections before continuing the next part of the alignment process.

MENTORING/ON-THE-JOB TRAINING

A wide range of good practices have just been listed. Sadly, many are not followed or go unexplained to new users. Some of this is because people feel that at some levels, experience has given the users “skill of the craft.” Unfortunately, this is not always the case. Sometimes it is because no one has shown the individual the correct way to do something, and folks have found their own work-around that seems to work for them. They feel they must be safe or doing it the right way until something happens. It is like stepping over a trip hazard on the floor, rather than fixing it. Until someone trips, there seems to be no reason to spend time correcting the situation.

Just like there is good mentoring, there is also bad mentoring where poor work habits are taught or tolerated. I have come across many, many cases of senior users working in unsafe manners and seeing no problems with it. Sometimes they feel they have so much experience that it overcomes technique shortcomings. Then there are the "Do what I say, not what I do" folks. In addition, there are unspoken bad habits—lifting of eyewear, not looking for stray reflections, and poor housekeeping—that send a message to less-experienced folks that these actions are acceptable. Of course, these folks go on to teach others, and the ripple effect keeps expanding out until someone stands up and resets folks on the right path. Mentoring or on-the-job training should be documented. In requiring this, all parties take their actions more seriously.