
# LASER SAFETY MANUAL

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# LASER SAFETY PROGRAM PURPOSE AND SCOPE

Grand Valley State University's Laser Safety Program establishes policies and procedures necessary to protect students and employees from the hazards associated with lasers in educational or research laboratories. Lasers are capable of causing eye and skin injuries, releasing hazardous fumes or gasses, and ignition of flammable materials, This Manual provides procedures for identifying and controlling hazards, recommendations for proper use, training requirements, and individual responsibilities for safe use of lasers.

This Laser Safety Program applies to individuals who operate or work in proximity to Class 3B or Class 4 lasers in teaching, research, or any other university-related activities at GVSU.

In addition to the provisions of this manual, all individuals responsible for safe use of any laser must also be familiar with and comply with the applicable provisions of the following:

- US Food and Drug Administration, Center for Devices and Radiological Health regulations at 21 CFR 1040.10 (Appendix I).

- American National Standards Institute Standards for Safe Use of Lasers (ANSI Z136 series) as they relate to hazard evaluation and classification, control measures, training, emergency response, and non-beam hazards. (Available in Padnos 105 or for purchase from ANSI)

- GVSU's Lab Safety and Chemical Hygiene Plan and any other applicable plans or policies (i.e.: radiation safety, biosafety, animal care, etc.). Available at www.gvsu.edu/labsafety

# ROLES & RESPONSIBILITIES

## Laser Safety Committee

The use of lasers for research and academic demonstration at GVSU is governed by the Laser Safety Program as set forth by the Laser Safety Committee (LSC) to ensure safe operation in compliance with federal and state regulations. In addition to drafting the content and policies of this Laser Safety Manual, the LSC is also tasked with overseeing the general implementation and enforcement of the program. The LSC has the authority to temporarily shut down any laser lab where a substantial violation of the University's laser safety policies has occurred until the situation has been remedied.

The members are appointed to alternating 3 year terms by the Research Integrity Officer and shall meet not less than once annually. In order to conduct official business of the LSC, a majority of the committee, including the Laser Safety Officer must be present. The Research Integrity Officer shall elect a Chair, who will hold the position for a 3-year term. The Chair approves agendas, presides at all meetings, calls for motions and seconds, and closes the meeting. The Chair may also assign additional duties to other members as deemed necessary for the conduct of the work of the LSC.

In the absence of a University Laser Safety Officer, individuals from the LSC membership will fulfill the LSO's responsibilities as assigned by the Committee Chair.

## Laser Safety Officer

The Laser Safety Officer (LSO), is a member of the LSC and coordinates oversight of the day-to-day implementation of the requirements of the University's Laser Safety Manual. These responsibilities include the following:

- Upkeep of the laser safety web page, providing a source of information for those working with lasers on campus.
- Maintain an updated database on the inventory of lasers in GVSU's labs and the PI's responsible for those labs.
- Track all students and visitors with access to those labs; along with verification of the laser safety training they have received.
- In conjunction with the LSC, the LSO is also responsible for keeping records of any accidents / incidents that may have occurred in any of the laser labs. These records should detail the nature and cause of the event; who was involved; what medical attention, if any, was received; and what steps were taken to prevent a re-occurrence.
- Provide oversight of all laser safety training conducted both in the classroom and in a laser lab.
- Conduct lab inspections to update the laser inventory, as well as ensure compliance with the University laser safety policies.

## Authorized Laser User

The Authorized Laser User, or often the lab supervisor or Principal Investigator (PI), has the responsibility for maintaining safe practices in the day-to-day operation of their laser lab. These responsibilities include:

- Ensure compliance with all elements of the GVSU Laser Safety Manual and applicable university policies, State and Federal regulations, and laser safety standards.
- Provide adequate supervision and restrict lab access to only those students and visitors who have received the proper training.
- Provide hands-on training in the lab for those using the lasers. This would include the implementation of all appropriate Control Measures, as well as full knowledge of the SOP's (Standard Operating Procedures) specific to those lasers, as well as how best to shut down the equipment in the event of an accident.
- Maintain all records and documentation pertaining to the specifications, user guides, and maintenance or modifications made to the laser system.
- Assist with investigation and resolution of any accident or incident that may have occurred in their lab.
- Ensure appropriate engineering controls and personal protective equipment are available and/or worn when laser systems and devices are operating.

## Member Conflicts of Interest

No LSC member may participate in the LSC review or approval of an activity in which that member has a conflicting interest, except to provide information requested by the LSC.

LSC members and advisors are required to disclose any conflicts of interest according to the applicable GVSU Policies.

Any LSC member is said to have a conflict of interest whenever that person, their spouse, domestic partner, or dependent child falls under any of the following conditions:

- Is an investigator or sub-investigator on the protocol.
- Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest.
- Acts as an officer or a director of the sponsor or an agent of the sponsor.
- Has an equity interest in the sponsor.
- Has received payments or other incentives from the sponsor that when aggregated for the member and spouse/domestic partner/dependent children exceeds $5000 annually.
- Is involved in a potentially competing research program.
- Has a philosophical or moral objection to the study itself.
- Has identified themselves for any other reason as having a conflict of interest.

Members holding a financial or non-financial conflict of interest with the study or investigators shall:

- Announce the presence of a conflict and recuse themselves from participating in the review of the protocol, except to provide information requested by the LSC.
- Leave the meeting during the discussion and the vote on any motion to approve, require changes, or disapprove the research in questions. (Note: When a person with a conflict of interest leaves the room, they cannot be counted towards quorum. If quorum is lost, the protocol will be tabled. Those who recuse themselves during a meeting will be identified as doing so in the minutes.)

If a member is unsure if they have an actual or perceived conflict of interest with the research under review, the member shall inform the LSC Chair of the potential conflict prior to engaging in the review of the research. The Chair will review the potential conflict, consulting with the Office of Research

Compliance and Integrity (ORCI) as needed, and determine if the member should recuse themselves from protocol review. In cases where the presence or appearance of conflict remains unclear following Chair/ORCI review, the member with the perceived or actual conflict of interest shall recuse themselves from protocol review.

# WORKING WITH LASERS

## Laser Registration and Inventory

The Principal Investigator, Authorized Laser User or Unit Head must be able to provide documentation of each laser's classification. Notification must be made to the Laser Safety Officer of the intent to purchase a Class 3B or Class4 laser or any use of lasers that may pose a risk of use to students or the public. The LSC will designate an Authorized User responsible for the safe use and recordkeeping of the laser. The Authorized User must maintain a current inventory of all Class 3B and Class 4 lasers along with all records and manuals. The Authorized User will notify the LSC or designated individual when a Class 3B or Class 4 laser is taken out of use or disposed.

Where product labelling and manufacturer's specifications are inconsistent, precautions for the higher classification will be followed. In absence of labels or manufacturer specifications, or where there is reason to believe the classification is inaccurate, the classification will be determined either by laser beam power analysis or verification by an individual with knowledge of the laser specifications. For all lasers a hazard evaluation must clearly define hazards and appropriate control measures.

## Laser Controlled Areas

Class 3b/4 lasers with an open beam configuration may only be operated in a designated laser controlled area. If the entire beam path of the Class 3b/4 laser is completely enclosed the laser is considered a Class 1 laser and is not required to be used in a laser controlled area. However, where removal of protective housings or interlocks are necessary, a temporary laser-controlled area must be established and coordinated with the LSO.

Requirements for laser controlled area include the following:

a. Entrances must be posted with appropriate warning signs.
b. Laser operation by qualified personnel.
c. Beams must be terminated by and appropriate beam stop.
d. Personnel must wear appropriate eye protection and lasers should be mounted so that the beam is below eye level.
e. The beam must be restricted within the room through the use of window coverings, curtains, or other barriers.
f. Laboratories classified as laser controlled areas must remain locked and access will be provided to Authorized Users and laser workers upon completion of Laser Safety Training.
g. Class 4 laser controlled areas must be equipped with visible signage indicating active beam, limited access to the beam, and an emergency deactivation device.

Due to the nature of working in a laser lab, as well as the level of sophistication of the instruments themselves, it is University policy that the doors to all laser labs remain locked, preventing access to the room by any unauthorized individuals. This requires that the default setting on the door locks themselves must remain in the locked position, and lab doors cannot be left propped open.

## Laser Safety Training Program

Laser safety training is required for anyone working with Class 3B or 4 lasers and anyone working in a designated laser controlled area. In addition, individuals responsible for safe use of enclosed beam Class 3b/4 lasers must complete laser safety training. There are two parts to GVSU Laser Safety training program.

a. Part one consists of either online or in-the-classroom training. An additional quiz or test may also be required. Once completed, the student will be allowed to apply for a key request through the building facilities manager. The training and completion documentation will be maintained in GVSU's Blackboard online system.
b. Part-2 consists of hands-on training in the lab with the respective PI. The content and documentation of this training is left to the discretion of the PI.

## Lab Inspections

Periodic inspections of laser controlled areas and Class 3b/4 enclosed beam lasers will be coordinated by the Laser Safety Committee or a designated individual to ensure that practices in the lab are consistent with Federal and State safety standards and this manual. A report of the inspection should also include an update of the inventory of lasers located in the lab, as well as a current list of everyone that has access to the lab – to ensure that they have successfully completed LS training.

Any violation of safety measures should be identified and a deadline set for correcting the situation. After that date, if the issue still has not been resolved the matter is brought before the LS Committee. Failure to address safety violations may result in loss of access to laser controlled areas or equipment.

Documentation of the inspection will be maintained in the Environmental, Health and Safety document retention system. A copy should also be supplied to the respective PI for his/her own records.

## Warning Signs and Equipment Labels

ANSI or FDA (see Appendix) approved signs and equipment labels must be conspicuously displayed in locations where they best serve to warn onlookers. The Authorized User is responsible for ensuring proper signage and labelling. Personnel who may need to enter areas where lasers are used, must be provided appropriate instructions as to the meaning of warning signs and labels. The Authorized User is responsible for identifying and training such personnel.

## Non-Beam Hazards

Non-beam hazards often exist in laser-related operations and can pose significant health and safety risks. The Authorized User must evaluate non-beam hazards and adequately address them in Standard Operating Procedures and ensure relevant safety training has been completed. Non-beam hazards may include:

- Electrical hazards from high voltage connections and switches
- Laser-generated air contaminants from heated materials or gasses used in the laser (ex: carbon monoxide, chlorine, fluorine, etc.)
- Fire or explosion hazards
- Chemical exposures from laser dyes or solvents

- Compressed gasses
- Physical hazards from working in tight or cluttered labs (ex: tripping, bruises, cuts, heavy lifting)

## Standard Operating Procedures

All Principal Investigators that use lasers are required to write standard operating procedures (SOP) for all laser operations involving Class 3b and 4 lasers detailing operation, alignment and maintenance procedures for each laser. The SOP's should be available to all laser users in the laboratory. This SOP shall address specific safety considerations during normal operations, beam alignment, servicing and any non-beam hazards that might exist.

## Emergency procedures

In the unlikely event of an accident involving a laser, don't wait to seek medical attention. This is true even if it is not clear if any injury took place. Not all injuries to the eye will have an immediate, noticeable impact on one's vision - and prompt treatment may mitigate the degree to which tissue is affected.

In the event that the PI is not present at the time of the incident, attempts should be made to notify other faculty or staff. Emergency facilities and contact information are posted in each lab.

After receiving medical attention, contact the PI to notify them of what has happened, as well as the LSO. In addition, fill out the Incident Report Form posted in labs or at the Lab Safety web page. The LSO should coordinate any follow-up that may be necessary, and keep a copy of the Accident Report. The lasers in the lab should be shut down until the cause of the accident can be determined and corrected.

# LASER CLASSIFICATION

Lasers are divided into different levels, based on their hazard potential to biological tissue. Laser manufacturers are required to attach a sticker to a laser denoting its classification level. In addition, warning signs on a lab door need to display this information as well. Class 1, 2, and 3R lasers are exempt from regulation except in the cases of optically aided (magnified) viewing, intentional direct viewing, and unattended operations where the beam can be directly viewed by the public. The designations as established by ANSI 316.1 (2014) are as follows:

## Class-1

All lasers or laser systems that cannot under any operating conditions, produce optical radiation that can damage the eye. Apart from very low power lasers, this could also include some that are higher but that are built into an enclosure such that no potentially damaging radiation can exit (for example laser printers, CD players).

**Class 1**

- Not capable of emitting in excess of the Class 1 Accessible Emission Limit (AEL) (Note: AEL's vary by laser wavelength and pulse duration). See appendix.
- Most lasers in this class are lasers which are in an enclosure which prohibits or limits access to the laser radiation.
- Not capable of producing damage to the eye (unless disassembled).

**Class 1M**

- Same criteria for classification as Class 1 but where beam may be hazardous for viewing with magnification

## Class-2

Lasers that are in the visible part of the spectrum (400-700nm) and of such intensity that a normal, automatic response of the eye (0.25 sec) prevents staring into the source for an extended period of time. Visible low power lasers; either with large beam diameter or highly divergent short-term exposure is insufficient to cause any damage. A longer exposure time (>1000 secs) could exceed this level though. Bar code scanners are an example of a Class-2 laser.

**Class 2**

- Continuous wave (CW) and repetitive-pulse lasers in the visible region of the spectrum (0.4 to 0.7 μm) which can emit accessible radiant energy exceeding the Class 1 AEL for the maximum duration inherent in the laser, but not exceeding the Class 1 AEL for any pulse duration < 0.25 s (the time estimated to blink or look away) and less than an average radiant power of 1 mW.
- The output of the laser is not intended to be viewed.
- An example of a Class 2a laser is a supermarket point-of-sale scanner.

**Class 2M**

- Same criteria for classification as Class 2 but where beam may be hazardous for viewing with magnification.

## Class-3R

A laser in this category is in a power range that under normal conditions would be insufficient to cause any damage, but potentially could if focused by a lens or mirror system. They are typically safe when handled carefully. Only small hazard potential for accidental exposure. Direct viewing of the beam or its specular reflection may result in eye damage. Other characteristics of 3R lasers include:

- Have output between 1 and 5 times the Class 1 acceptable exposure limit (AEL) for wavelengths shorter than 0.4 μm or longer than 0.7 μm, or less than 5 times the Class 2 AEL for wavelengths between 0.4 μm and 0.7 μm.
- 3R is only a hazard if collected and focused in the eye.
- Most laser pointers are 3R lasers. (Note that often laser pointers are untested and may be Class 3b or Class 4)
- Previously this classification was known as 3a.

## Class-3B

Class 3B lasers require approval of appropriate control measures by the Laser Safety Officer. Lasers in this category have sufficient intensity to cause damage when viewed not only directly but also from specular (mirror-like) reflections, as well as from diffuse (scattered) reflections at close range.

An example of a Class-3b laser is a CW laser with an output power up to 0.5w, or a pulsed laser that emits energy less than 125 mJ in 0.25 seconds. 3B lasers are defined as:

- Ultraviolet and infrared lasers and laser systems that can emit accessible radiant power in excess of the Class 3a AEL during any emission duration within the maximum duration inherent in design of the laser or system, but that cannot emit an average radiant power in excess of 0.5 W for greater than or equal to 0.25 s or cannot produce a radiant energy greater than 0.125 J within an exposure time > 0.25 s.
- Visible or near-infrared lasers or systems that emit in excess of the 3a AEL but that cannot emit an average radiant power in excess of 0.5 W for greater than or equal to 0.25 s and cannot produce a radiant energy greater than 0.03 $C_a$ J per pulse. ($C_a$ is a correction factor that increases the maximum permissible exposure values in the near infrared spectral band based upon reduced absorption propertied of melanin pigment granules found in skin and in the retinal pigment epithelium).

## Class-4

Class 4 lasers emit accessible radiation greater than Class 3B and require approval of appropriate control measures by the Laser Safety Officer. A Class-4 laser can cause ocular tissue damage not only from exposure to the full beam but from specular and diffuse reflections as well. These lasers can also cause skin burns, ignite fires, and vaporize certain materials. Even a partial reflection of a Class-4 beam may be sufficient to cause permanent eye damage, as well as 2$^{nd}$ or 3$^{rd}$ degree burns to the skin, and set fire to a lab wall or curtain.

# CONTROL MEASURES FOR CLASS 3B & 4 LASERS

The safe operation of laser labs, especially the higher powered Class-3 and Class-4 lasers, necessitate the pro-active implementation of a variety of Control Measures. This are broken down into three categories: Engineering, Administrative, and Personal Protective Equipment (PPE). The following include controls for lasers, however many laser labs may have potential chemical exposures, so a full hazard assessment should be conducted for each laser laboratory.

## Administrative Controls

These are procedural in nature, such as providing training courses, restricting lab access, and the use of SOP's (Standard Operating Procedures). SOP's should supplement information contained in the laser user manuals and highlight day-to-day operation of the lasers, including how best to shut down the laser or block beams in the event of an emergency.

- Posting of the appropriate laser warning signs outside in the hallway indicating if the laser is on.
- Restricted access into the lab to only qualified (trained and authorized) individuals.
- Procedures for a quick and safe procedure to disable the laser in the event of an emergency.
- Readily accessible copies of the laser's SOP.
- Perform initial alignment of routing optics and experiment at as low energy as possible.
- Keep the ambient light at appropriate levels for safe occupancy.

## Engineering Controls

Engineering controls physically control the ability to access or turn on the laser, or notify others that it has been turned on. Examples would include door locks, power supply key switches, shutters, or warning lights.

- Avoid beam heights at eye level for someone sitting or standing in the experimental area. Computer workstations need shielding from any potentially hazardous beam exposure.
- External covering of all windows and doorways to prevent propagation of the beam out of the lab.
- Proper use of all safety interlocks.
- Clear walking space around the laser table.
- Controls to prevent the unauthorized use of the laser (e.g.: removal of keys).
- Keep objects with reflective surfaces away from beam path area (such as oscilloscopes and computer monitors). All users should remove any jewelry when working near the beam path.

## Personal Protective Equipment

PPE includes laser safety goggles, laser curtains and barriers to contain beams.

- Laser safety glasses should be well labeled and stored near the entrance to the lab.
- Proper safety glasses for **everyone** within the Nominal Hazard Zone.
- If potential for skin injury exists, appropriate skin covering should be worn

- All eyewear must be clearly labeled with the optical density and wavelength. Different wavelengths require appropriate protective eyewear. Color-coding or other distinctive identification is recommended in multi-laser environments.
- All beams need to be safely terminated and confined, using only appropriate material.
- Keep the covers on the lasers. Exposure to beams with higher intensity, as well as stray reflections - normally contained by the cover-is possible. When it is necessary to remove the covers for routine maintenance, do so **only** if you have been properly trained. Ensure that all back reflections have been contained, and other people within the Nominal Hazard Zone are aware that the laser is uncovered. The covers should be put back on the lasers as soon as the work has been completed.

# APPENDIX

## Appendix A: Core Concepts of Laser Safety

**Maximum Permissible Exposure (MPE):**

The MPE values are the demarcation between what exposure levels are safe and what may cause damage to unprotected eye or skin tissue. Exposure levels over an MPE line are considered potentially hazardous. As such, the lower the MPE value, the more hazardous the scenario.

But knowing the MPE level is only one part. More important is the ratio of a laser's output (Irradiance or Radiant Exposure) ***to*** the MPE value. If the Irradiance (or Radiant Exposure) is greater than the MPE level, then Control Measures must be utilized for the safe operation of the laser.

*Consequently, the ratio of a laser's Irradiance to its MPE level plays a significant role in determining the hazard level of a laser beam.*

In fact, this ratio shows up in a variety of LS equations - such as the calculation of the NHZ (Nominal Hazard Zone); as well as the attenuation needed for laser safety glasses; and even what type of beam dumps or barriers should be used to safely terminate a beam.

MPE values can be calculated for a specific laser system (taking into account a number of variables such as: pulsed vs cw operation, repetition-rate, wavelength, pulse-width, exposure time, beam-size vs pupil diameter, etc.). However, there are a number of MPE charts that are readily available for a large number of lasers that are prevalent in laser labs today (see the Appendix). The values on these charts reflect what the exposure level would be to the cornea and skin, but also take into consideration what they would be at the retina for wavelengths that undergo the full focusing ability of the cornea and lens combination. This is seen in the dip in the lines, particularly in the 400-700 nm region.

Regions outside of this wavelength range have concerns of their own - in particular, the NIR (near infrared, from 700-1400nm). The cornea, lens, aqueous humor, and the vitreous humor are all transparent to this region of the spectrum. As a result, this light will undergo the full focusing of the cornea/lens combination – coming to a very tight focus on the retina. However, the photo-receptor cells in the upper layers of the retina have very little, to no sensitivity in this region. So, the eye is unable to see this light. As a result, there is an increased hazard when working with lasers operating at these wavelengths; two in particular – Titanium-Sapphire lasers, operating at 700-900nm (typically), and Q-switched Nd:YAG lasers, operating at 1064nm.

There are similar concerns for UV light. Not only are there retinal sensitivity issues again, but there is also a special issue due to an accumulative effect – called the UV Hazard. With this hazard, the tissue of the cornea and lens can be adversely affected by exposure to UV light over extended periods of time – even from low intensity beams. This effect is addressed by the continued dipping of UV light MPE lines for with longer and longer exposure times.

MPE charts are segregated into two different varieties – those that plot the power density (the units for the vertical scale are $W/cm^2$) as a function of exposure time, and those that plot the energy density as a function of pulse duration and wavelength (here the units are $J/cm^2$). To simplify matters, the first can be used for cw-lasers (continuous wave) and the latter for pulsed lasers. In the latter case, the effect of pulsed duration is very evident, as the shorter the pulse-width, the lower the MPE values for a given wavelength. So, the MPE lines for a femto-second laser are lower than those for a nano-second laser. In effect this is saying that all things being equal, the shorter the pulse-width of a laser - the more dangerous it is – as the pulses being emitted have higher peak-power.

As mentioned earlier, once the MPE values for a laser have been determined (whether by calculation or the use of charts), the pertinent number to know is the ratio of the power density output of a given laser compared to its MPE value.

For a cw laser, all that needs to be known is the average output power of the laser (what is measured with a power meter) and the approximate beam size. It is usually sufficient to just use the area: $\pi r^2$ - where the beam radius or diameter is given by the manufacturer in the manual for the laser.

The ratio of the output power to beam size is known as the Irradiance **(E**). [so $E = P/\pi r^2$] and the units will be in $W/cm^2$. The Irradiance for a specific laser then, can be plotted on the MPE chart.

For pulsed lasers it is very similar, only it is called the Radiant Exposure or **(H)** which is the energy per unit area. The energy '**Q'** - (which appears in the numerator of the equation) is the energy in an individual pulse. If the Radiant Exposure for multiple pulses is needed, then '**Q'** is multiplied by the pulses per second, then multiplied by the exposure time.

So, whether it is a cw laser or a pulsed laser, it's the ratio of **'E'** or **'Q'** to the MPE value that's of ultimate interest.

**Nominal Hazard Zone**

The Nominal Hazard Zone (NHZ) is the region surrounding a laser whereby exposure levels can exceed the MPE value. It is a measure of how far away from a laser that you need to be such that safety control measures no longer need to be employed. Outside of the NHZ, exposure levels are less than the MPE values and as such, even safety glasses would no longer be required.

Calculations of the NHZ for typical Class-3 and Class-4 lasers can yield distances on the order of tens of miles. Needless to say, just entering the doorway to a lab with one of these lasers means that you are well within the NHZ, and pro-active Control Measures need to be in place.

With such large distances involved, it is illustrative to consider what the NHZ would be for back reflections from one of these lasers (a specular reflection off of the surface of an optic or shiny post can contain 5% of the energy of the full beam). Depending on the laser, the NHZ for such a reflection could still be up to a mile.

Clearly, for high-powered lasers, not only must the full beam be properly blocked, but all back reflections and scattered beams need to be accounted for.

(The parameters that appear in the calculation for the NHZ are: the output power of the laser, the beam size, the beam divergence, and the MPE value).

**Optical Density**

Optical Density (OD) refers to the attenuation of light as it passes thru a material. With regard to Laser Safety, it is used to rate the filters for safety glasses. The rating is a function of wavelength and all safety glasses or goggles should have these values inscribed on them. The higher the OD number – the greater the level of attenuation. Once again, it is the ratio of the Irradiance or Radiant Exposure to the MPE value that comes into play. Specifically, it is the '$\log_{10}$' of that ratio. So, if the Irradiance of a laser exceeds its MPE value by 100, then an OD of 2 is needed (and if by a 1000, then an OD of 3).

A chart detailing the OD for different power ranges for both CW and pulsed lasers is included in the Appendix.

*As a side note, safety glasses should never be considered as the 'end-all' for protecting your eyes. Close scrutiny of many manufacturer's specification sheets show that they are only designed for at most a 10 second exposure time.

## Appendix B: Glossary

**AEL** – Accessible Emission Level - *The AEL is used to define the different levels of laser classification. It is a measure of the hazard potential of a beam as a function of power or energy, wavelength, MPE values, exposure time, and beam divergence.*

**ANSI** – American National Standards Institute - *National organization tasked with setting industry standards for a number of fields. Publication ANSI Z136.1 is the recognized standard for lasers*

**Attenuation** - *commonly used in the discussion of filters used in laser safety glasses it is a measure of the reduction in energy or power due to absorption or scattering as a beam passes through a material or tissue.*

**Aversion Response** - *a natural reaction that causes someone to look away from a bright beam of light in the visible part of the spectrum (especially yellow-green wavelengths). The reaction time can be as quick as a quarter of a second. This response can limit the amount of light that reaches the retina and therefore can be a factor in determining MPE values*

**Cataracts** - *a clouding of the tissue in the lens from a breakdown of the protein structure as a result of excessive exposure of UVA light (315-400nm, which mostly passes thru the Cornea)*

**CDRH** – Center for Devices and Radiological Health - *a part of the Food & Drug Administration, with standards similar to ANSI Z316 but slightly more stringent.*

**Coherence** - *a property often ascribed to laser light and one that makes it unique from most other light sources. It is a measure of the degree of correlation in the oscillation of multiple waves. Because light is made up of E&M fields propagating as waves of energy, when the waves are in phase or peaking at the same time it is said to be coherent. Coherent waves can add together - resulting in light with higher peak intensity.*

**Control Measures** - *a combination of measures to address the hazards of working with lasers. There are three categories: Engineering, Administrative, and Personal Protective Equipment.*

**Cornea** - *the outer tissue layers of the eye, the Cornea is transparent to light in the visible and near-infrared part of the spectrum, but absorbs UV and IR light. Excessive exposure to IR light can cause 'corneal burns.' Because of its high index of refraction, the Cornea plays a major role in the eye's ability to bring an image to focus.*

**CW laser** - continuous-wave laser - *a laser with a constant or continuous output of power (as opposed to a pulsed laser).*

**Diffuse reflection** - *a reflection off of a rough, uneven surface. This results in the beam breaking up or scattering in different directions.*

**Divergence** - *the angular spread of the beam-size as it propagates away from the laser*

**Embedded laser** - *a laser enclosed into a system, preventing exposure to the full beam directly out of the laser.*

**Energy – (Q)** - *the output of pulsed lasers is often expressed in terms of energy – with units of joules (J)*

**Erythema** - *short-term injury to skin as a result of excessive exposure to intense light. Similar to sunburn*

**Fovea Centralis** - *a very small area within the Macula Lutea of the Retina that has a very high concentration of photo-receptor cells and is responsible for acute vision*

**High radiance** - *a term used to describe light that has very high intensity contained in a very narrow beam*

**IEC** – International Electro-technical Commission - *similar to ANSI in function, the IEC is a global organization that publishes standards for a variety of technological fields. IEC 60825-1 pertains to lasers*

I**ndex of Refraction** - *a measure of the optical density of a material. When light passes through an interface between two materials with a substantial difference in the Index of Refraction, it will diffract or change the direction of its path.*

**Infrared** - *the part of the EM spectrum with wavelengths longer then visible light. The photo-receptor cells of the Retina are not sensitive to these wavelengths and therefore they are not visible to the human eye.*

**Intrabeam viewing** - *the full or direct exposure to the eye from a beam*

**Iris -** *the part of the eye that controls the amount of light entering into the eyeball itself. As the ancillary muscles expand or tighten, the opening in the iris, or the pupil, changes in size. In dim light conditions it opens up to a diameter of about 7mm. Under bright conditions it collapses down to 2-3mm.*

**Irradiance** - *refers to power either emitted or absorbed. The units are watts per cm squared. It is equal to the Radiant Exposure divided by the exposure time.*

**IR viewer** - *a device that allows the viewing of infrared light by use of a phosphorescent screen that glows with green light when absorbing IR.*

**Joule - (J)** - *a unit for energy. The number of joules per second equals one watt.*

**Laser Classification** - *the grouping of lasers according to hazard potential, from Class-1 to Class-4, with the latter being more dangerous*

**Lens** - *the element of the eye responsible for fine-focusing of an image (the process is called 'accomadation'). Although the lens is crystalline in nature, it is also pliable and can be bent and contorted by the constricting of the Zonular Fibers.*

**LGAC's** – Laser Generated Air Contaminants - *the release of toxic, potentially carcinogenic, airborne contaminants as a result of the interaction between high-intensity laser light and certain materials*

**LSO** – Laser Safety Officer - *the individual charged with the implementation and oversight of a Laser Safety program*

**Macula Lutea** - *the part of the Retina that is responsible for acute vision. It is a brown-pigmented region, about 5-6mm in diameter, containing a high concentration of (cone) photo-receptor cells.*

**Monochromatic** - *light emitted at a single wavelength or narrow-band of the EM spectrum, in contrast to broadband light such as white light*

**MPE –** Maximum Permissible Exposure - *the maximum amount of energy an unprotected person may be exposed to without the risk of injury to the eye or skin tissue*

**NHZ** – Nominal Hazard Zone - *the area surrounding a laser where exposure levels in excess of the MPE values are possible.*

**Non-beam Hazards** - *a number of hazards, separate from the beam itself, associated with lasers. Examples include exposure to toxic gases , dyes or chemicals, compressed gases, high-pressure arc lamps, and electric shock.*

**OD -** Optical Density - *a measure of the attenuation of a material to light as a function of wavelength. The term is used to describe filters for laser safety glasses*

**Optical Feedback** - *the deliberate reflection of light off of the mirrors within a laser cavity for a number of purposes, such as increasing the light intensity*

**OSHA** –Occupational Safety and Health Administration - *A part of the Department of Labor, OSHA is involved in promoting safe work environments*

**Photokeratitis -** *or 'welder's flash' - an inflammation in the Corneal tissue (similar to a sunburn) as a result of excessive exposure to UV light (UVB/C 180-315nm).*

**Plasma Radiation -** *the generation of UVA light (180-315nm) from a high-intensity beam interacting with certain metals*

**Population Inversion** - *a situation describing the energy states of an atom where more electrons occupy a higher energy level then a lower (intermediate or ground) level. This condition is essential for generating large numbers of photons thru Stimulated Emission, and at the core of why laser light is so intense.*

**Power -** *the amount of energy emitted or received per second. Units are watts (w).*

**Prf** – Pulse Repetition Frequency (or Rep-Rate) - *the number of pulses emitted per second by a pulsed laser.*

**Pulsed duration** - *the temporal extent of an individual pulse emitted by a pulsed laser, usually measured at the full-width-half-max points. With the development of laser technology, pulsed durations have gone from micro-seconds, to nano-seconds, to pico-seconds, to femto-seconds. As a general rule, the shorter the pulse duration – the higher the peak power.*

**Pulsed laser** - *a laser where the emission has been deliberately modulated to produce a string of pulses as opposed to continuous output (cw). No energy is emitted in between pulses, so most of that stored up energy results in pulses with very high peak powers.*

**Pupil** - *the opening in the Iris that controls the amount of light entering into the eyeball itself. Its diameter can change from 2-7mm, to adjust for a bright or dim light environment.*

**Q-switch** - *one of the methods for pulsing a laser. An electro-optic or acousto-optic element is used that is able to modulate the gain/ loss of the cavity very quickly. The result is a string of pulses with pulse durations on the order of nano-seconds.*

**Radiant Exposure -** *the amount of light energy per surface area striking a surface( or layer of tissue). The term is usually used when dealing with pulsed lasers, and the units are in joules per cm-squared. It is equal to the Irradiance multiplied by the exposure time.*

**Retina -** *the lining on the back and sides of the eyeball, containing the photo-receptor cells (cones and rods) that convert light energy to chemical energy – and then to electrical energy. The retina consists of as many as 15 layers.*

**Scotoma -** *a blind spot or diminished vision in the field of view*

**SOP -** Standard Operating Procedure - supplements the information contained in a laser user manual. It is specific to a particular laser system and highlights day-to-day operation of the lasers, such as: how to turn the laser on and off, how to optimize the system, how the laser is aligned into the experimental setup, and how best to shut down the laser or block the beams in the event of an emergency.

**Specular reflection -** *the reflection off of a shiny or smooth surface. Unlike a diffuse reflection, where the beam is broken up and the energy scattered, with a specular reflection the reflected beam largely retains the shape and energy distribution of the incident beam.*

**Spontaneous Emission -** *the process whereby a photon is generated as a result of an atom losing some of its energy. The process is random and the photon has the energy or wavelength directly related to the amount of energy lost by the atom.*

**Stimulated Emission -** *like Spontaneous Emission, a photon is emitted when an atom loses energy as a result of one of its electrons dropping to a lower energy state. In this case however, rather than being random, the transition is 'triggered' as a result of an interaction between the atom and another incident photon. The amount of energy lost by the atom is exactly equal to the energy or wavelength of the incident photon, and as such the newly emitted photon has the same wavelength as the incident one. The phrase 'Stimulated Emission' is at the core of the acronym for laser (Light Amplification by the Stimulated Emission of Radiation) in that as a result of the process, another photon has been generated - yielding two, spectrally-identical photons.*

**Transmittance -** *the amount of light energy that passes thru an optic, or material, or layer of tissue.*

**UV hazard -** *deep UV light can have an accumulating effect on the tissue of the Cornea and Lens, resulting in damage from long-term exposures from even low power beams. As a result, the MPE values (what's considered safe) go lower as exposure time increases.*

**UV light -** *the short-wavelength portion of the spectrum (100-400nm). The photo-receptor cells of the Retina are very insensitive to this region and as a result, intense UV beams may appear to be low in power.*

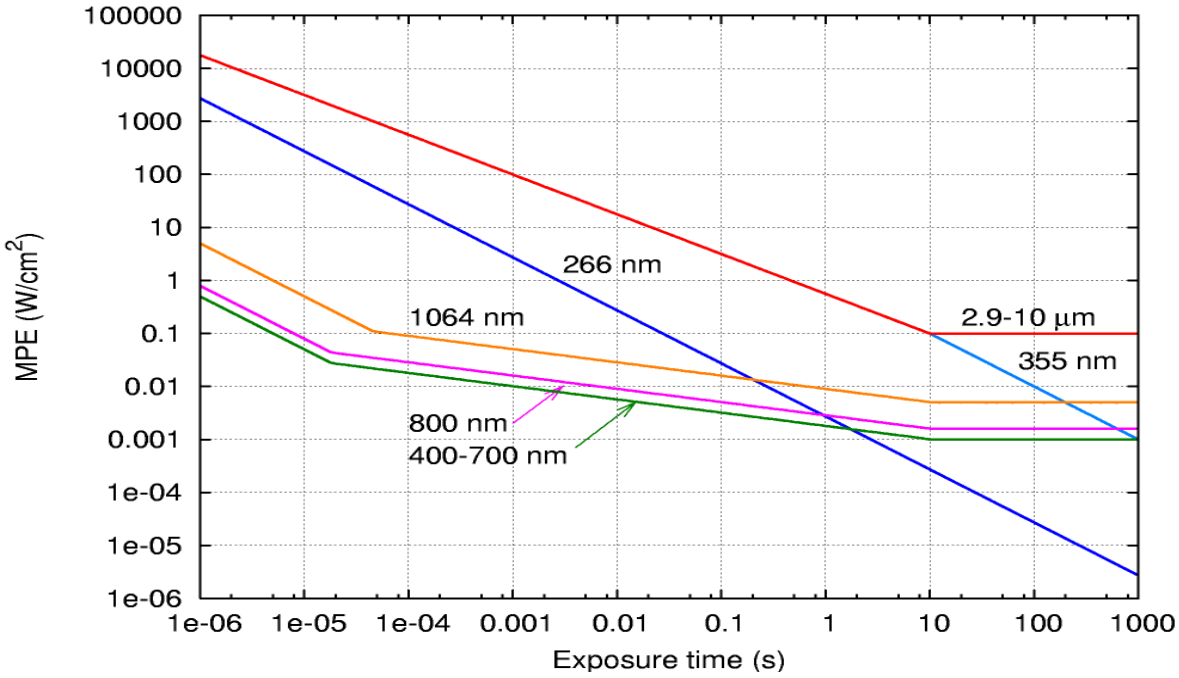
**Visible light -** *the part of the spectrum (400-700nm) that the front end of the eye is transparent to, allowing the light energy to reach the Retina. Photo-receptor cells in the Retina are also sensitive to this wavelength range.*

**Watt – (**W**) -** *the unit for power or Radiant Flux. One watt is equal to the number of joules passing per second.*

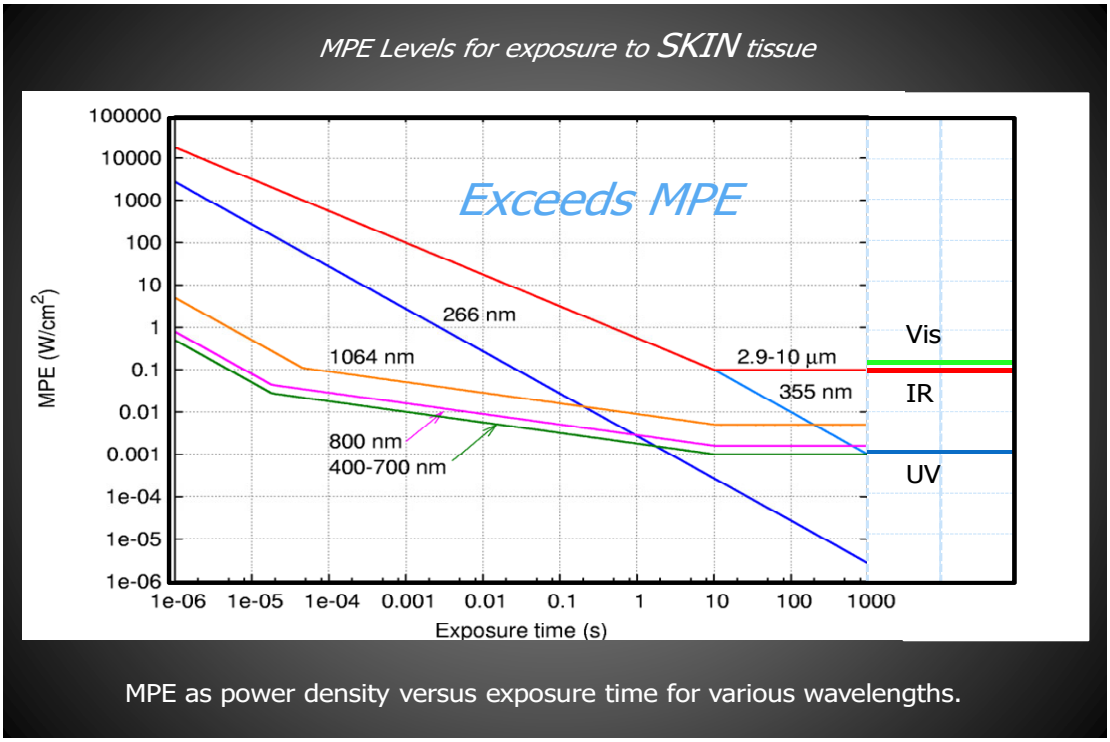
**Wavelength -** *light is the oscillation of propagating E-M waves (Electro-Magnetic) with a sinusoidal waveform. The distance between peaks determines the wavelength and for light it is on the order of nano-meters. UV light has a wavelength from 100-400nm, visible light from 400-700nm, near-infrared light (NIR) from 700-1400nm, and infrared light (IR) from 1400 to > 10,000 nm (1.4 to > 10 microns).*

## Appendix C: MPE Charts

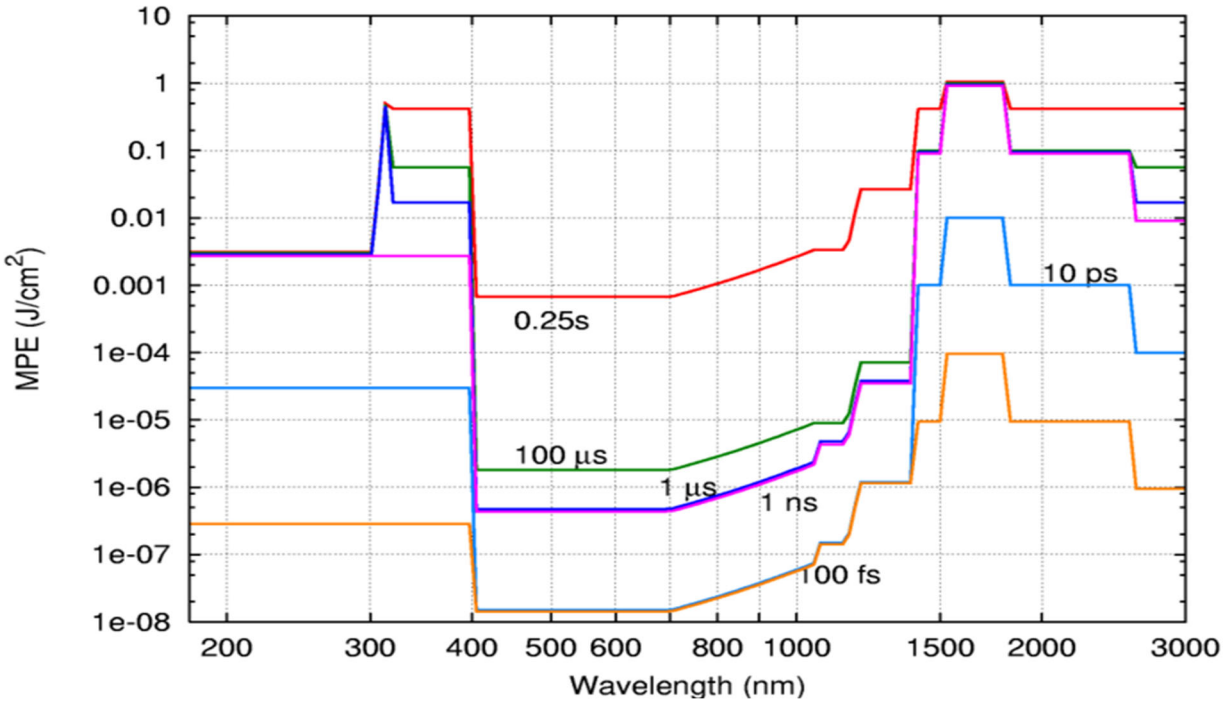
This chart plots the Maximum Permissible Exposure to ocular tissue from cw (continuous-wave) lasers, as a function of wavelength and exposure time. Radiant exposure above an MPE line for a particular wavelength can result in damage to eye tissue.



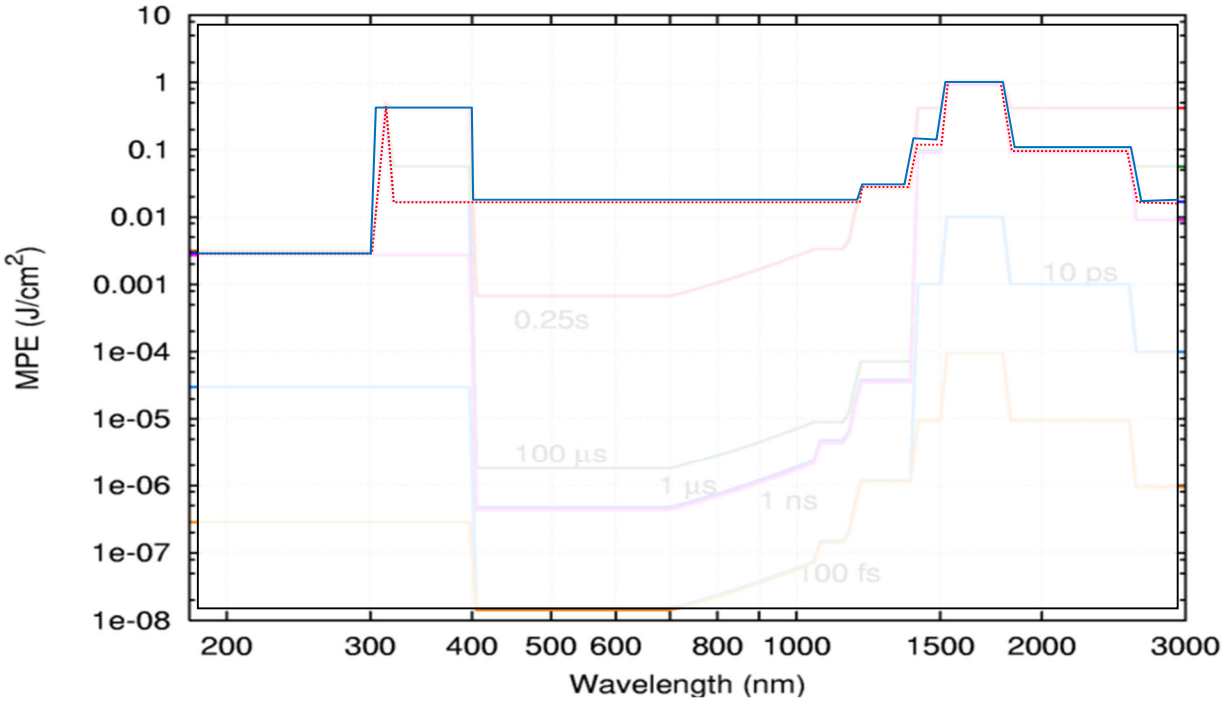

Similarly, this chart plots the MPE lines for exposure to skin tissue



MPE chart for pulsed lasers as a function of wavelength and pulse duration for ocular tissue. These values are appropriate for lasers with a repetition rate up to 1 kHz. (For higher rep-rates, the MPE values are lower by at least a factor of 10).




MPE lines for exposure to skin tissue from nano-second laser pulses. The blue line is from thermal effects and the red line from photo-chemical.



# Appendix D: Safety Glass Selection

**OD Filter Selection for Laser Safety Glasses for Intra-Beam viewing**

Wavelength range 400 - 1400 nm

Adapted from ANSI Z136.1 1993

| Pulsed lasers | | | | | cw lasers | | | | Attenuation | |
|---|---|---|---|---|---|---|---|---|---|---|
| Mode-locked (psec, fsec) | | | Q-switched (nsec) | | short-term exposure | | long-term exposure | | | |
| Repitition Rate | | | max | max | < 10 sec | | > 10 sec | | | |
| 80 MHz | 250 kHz | 1 kHz | Energy | Radiant | max | max | max | max | Attenuation | OD |
| max Energy | | | | Exposure | Power | Irradiance | Power | Irradiance | factor | |
| nJ | μJ | mJ | (joules) | J/cm$^2$ | watts | W/cm$^2$ | watts | W/cm$^2$ | | |
| $10^6$ | $10^3$ | 100 | 10 | 20 | $10^5$ | $2x10^5$ | 100 | 200 | $10^8$ | 8 |
| $10^5$ | 100 | 10 | 1 | 2 | $10^4$ | $2x10^4$ | 10 | 20 | $10^7$ | 7 |
| $10^4$ | 10 | 1 | 0.1 | 0.2 | $10^3$ | $2x10^3$ | 1 | 2 | $10^6$ | 6 |
| $10^3$ | 1 | 0.1 | $10^{-2}$ | $2x10^{-2}$ | 100 | 200 | 0.1 | 0.2 | $10^5$ | 5 |
| 100 | 0.1 | $10^{-2}$ | $10^{-3}$ | $2x10^{-3}$ | 10 | 20 | $10^{-2}$ | $2x10^{-2}$ | $10^4$ | 4 |
| 10 | $10^{-2}$ | $10^{-3}$ | $10^{-4}$ | $2x10^{-4}$ | 1 | 2 | $10^{-3}$ | $2x10^{-3}$ | $10^3$ | 3 |
| 1 | $10^{-3}$ | $10^{-4}$ | $10^{-5}$ | $2x10^{-5}$ | 0.1 | 0.2 | $10^{-4}$ | $2x10^{-4}$ | $10^2$ | 2 |
| 0.1 | $10^{-4}$ | $10^{-5}$ | $10^{-6}$ | $2x10^{-6}$ | $10^{-2}$ | $2x10^{-2}$ | $10^{-5}$ | $2x10^{-5}$ | 10 | 1 |

## Appendix E: Comparison of Laser Classifications

The following charts have been created to illustrate the various similarities and differences between the classification criteria of the different laser standards.

| Class | IEC 60825 (Amend. 2) | U.S. FDA/CDRH | ANSI-Z136.1 (2000) |
|---|---|---|---|
| Class 1 | Any laser or laser system containing a laser that cannot emit laser radiation at levels that are known to cause eye or skin injury during normal operation. This does not apply to service periods requiring access to Class 1 enclosures containing higher class lasers. | | |
| Class 1M | Not known to cause eye or skin damage unless collecting optics are used. | N/A | N/A |
| Class 2a | N/A | Visible lasers that are not intended for viewing and cannot produce any known eye or skin injury during operation based on a maximum exposure time of 1000 seconds. | N/A |
| Class 2 | Visible lasers considered incapable of emitting laser radiation at levels that are known to cause skin or eye injury within the time period of the human eye aversion response (0.25 seconds). | | |
| Class 2M | Not known to cause eye or skin damage within the aversion response time unless collecting optics are used. | N/A | N/A |
| Class 3a | N/A | Lasers similar to Class 2 with the exception that collecting optics cannot be used to directly view the beam<br><br>Visible Only | Lasers similar to Class 2 with the exception that collecting optics cannot be used to directly view the beam |
| Class 3R | Replaces Class 3a and has different limits. Up to 5 times the Class 2 limit for visible and 5 times the Class 1 limits for some invisible. | N/A | N/A |
| Class 3b | Medium powered lasers (visible or invisible regions) that present a potential eye hazard for intrabeam (direct) or specular (mirror-like) conditions. Class 3b lasers do not present a diffuse (scatter) hazard or significant skin hazard except for higher powered 3b lasers operating at certain wavelength regions. | | |
| Class 4 | High powered lasers (visible or invisible) considered to present potential acute hazard to the eye and skin for both direct (intrabeam) and scatter (diffused) conditions. Also have potential hazard considerations for fire (ignition) and byproduct emissions from target or process materials. | | |

(source: Rockwell Industries)

# Appendix F: Overview of Laser Safety Classes

| Class | Type of lasers | Meaning | Relationship to MPE | Hazard Area | Typical AEL for CW Lasers |
|---|---|---|---|---|---|
| Class 1 | Very low power lasers or encapsulated lasers | Safe | MPEs are not exceeded, even for long exposure duration (either 100 s or 30000 s), even with the use of optical instruments | No hazard area (NOHA) | 40 μW for blue |
| Class 1M | Very low power lasers; either collimated with large beam diameter or highly divergent | Safe for the naked eye, potentially hazardous when optical instruments are used | MPEs are not exceeded for the naked eye, even for long exposure durations, but maybe exceeded with the use of optical instruments | No hazard area for the naked eye, but hazard area for the use of optical instruments (extended NOHA) | Same as Class 1, distinction with measurement requirements |
| Class 2 | Visible low power lasers | Safe for unintended exposure, prolonged staring should be avoided | Blink reflex limits exposure duration to nominally 0.25 seconds. MPE for 0.25 seconds not exceeded, even with the use of optical instruments. | No hazard area when based on unintended exposure (0.25 seconds exposure duration) | 1 mW |
| Class 2M | Visible low power lasers; either collimated with large beam diameter or highly divergent | Same as Class 2, but potentially hazardous when optical instruments are used | MPE for 0.25 seconds not exceeded for the naked eye, but maybe exceeded with the use of optical instruments | No hazard area for the naked eye when based on accidental exposure (0.25 sec exposure, but hazard area for the use of optical instruments (extended NOHA) | Same as Class 2, distinction with measurement requirements |
| Class 3R | Low power lasers | Safe when handled carefully. Only small hazard potential for accidental exposure | MPE with naked eye and optical instruments may be exceeded up to 5 times | 5 times the limit of Class 1 in UV and IR, and 5 times the limit for Class 2 in visible, i.e. 5 mW | 5 times the limit of Class 1 in UV and IR, and 5 times the limit for Class 2 in visible, i.e. 5 mW |
| Class 3B | Medium power lasers | Hazardous when eye is exposed. Wear Eye Protection within NOHA. Usually no hazard to the skin. Diffuse reflections usually safe | Ocular MPE with naked eye and optical instruments may be exceeded more than 5 times. Skin MPE usually not exceeded. | Hazard area for the eye (NOHA), no hazard area for the skin | 500 mW |
| Class 4 | High power lasers | Hazardous to eye and skin, also diffuse reflection may be hazardous. Protect Eye and skin. Fire hazard. | Ocular and skin MPE exceeded, diffuse reflections exceed ocular MPE | Hazard area for the eye and skin, hazard area for diffuse reflections | No limit |

(Source: Rockwell Industries)

## Appendix G: Laser Lab Inspection Checklist

*This inspection checklist should be used accordance with the Laser Safety Manual. PI's and Lab Supervisors are responsible for ensuring that each Class 3B and 4 laser in their laboratory is registered with EH&S and that their employees who use the lasers are trained in laser safety.*

Principal Investigator _____Department _____

Telephone #_____Email _____

Campus Address_____Lab Room Number _____

Purpose or Intended Use: _____

**Personnel who use laser system**

| NAME | JOB TITLE | TRAINING RECEIVED |
|---|---|---|
| | | ___Yes |
| | | ___Yes |
| | | ___ Yes |

**Laser Safety Control Measures**

| Control Measures | Yes | No | Comments |
|---|---|---|---|
| The laser system has been classified appropriately with a label, manual or other documentation stating the class designation | | | |
| For open beams, a nominal hazard zone has been identified for areas that may exceed maximum potential exposure | | | |
| Beam alignment procedures have been developed and beam path is below eye level, and directed away from doors, windows and reflective surfaces | | | |
| A protective housing and beam shutter safety interlock system available, functioning and used | | | |
| For laboratories with open beam lasers, access doors are secured, labeled laser with hazards, and illuminated hazard sign present | | | |
| Open beam lasers and optics are secured to the table and beam stops and barriers (curtains, window coverings, etc.) are in place | | | |
| Protective eyewear approved for specific wavelength/optical density and other hazards are available for all lab personnel and other PPE is provided as necessary | | | |

| | | | |
|---|---|---|---|
| Gasses, vapors and fumes are controlled and gas detection systems (if present) are properly functioning | | | |
| Laser Safety Training has been completed by all individuals with access to Class 3b/4 open beam lasers and by personnel supervising the use of Class 3b/4 enclosed beam lasers | | | |
| Non beam hazards such as high voltage electricity, chemical hazards, compressed gasses, and fire hazards have been identified and controlled | | | |
| The laser(s) are registered with the Laser Safety Committee and included in the laser inventory | | | |
| SOP's consistent with the Laser Safety Manual, ANSI standards, equipment manuals or Laser Safety Committee special conditions are available | | | |

**COMMENTS:**

_____

_____

_____

Inspected By:_____ Date _____

## Appendix H: Additional references

OSHA
Laser safety www.osha.gov/dts/osta/otm/otm_iii/otm_iii_6.html
Laser hazards www.osha.gov/SLTC/laserhazards/

**American National Standards Institute**
www.ansi.org

**Laser Institute of America**
www.lia.org

**Rockwell Laser Industries**
www.rli.com/default.aspx

# Appendix I: FDA Laser Regulations (21 CFR 1040.10)

Code of Federal Regulations
Title 21 - Food and Drugs - SUBCHAPTER J - RADIOLOGICAL HEALTH
PART 1040 - PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

§ 1040.10
Laser products.

(a) Applicability. The provisions of this section and § 1040.11, as amended, are applicable as specified to all laser products manufactured or assembled after August 1, 1976, except when:

(1) Such a laser product is either sold to a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, or

(2) Sold by or for a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, provided that such laser product:

(i) Is accompanied by a general warning notice that adequate instructions for the safe installation of the laser product are provided in servicing information available from the complete laser product manufacturer under paragraph (h)(2)(ii) of this section, and should be followed,

(ii) Is labeled with a statement that it is designated for use solely as a component of such electronic product and therefore does not comply with the appropriate requirements of this section and § 1040.11 for complete laser products, and

(iii) Is not a removable laser system as described in paragraph (c)(2) of this section; and

(3) The manufacturer of such a laser product, if manufactured after August 20, 1986:

(i) Registers, and provides a listing by type of such laser products manufactured that includes the product name, model number and laser medium or emitted wavelength(s), and the name and address of the manufacturer. The manufacturer must submit the registration and listing to the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, 2094 Gaither Rd., Rockville, MD 20850.

(ii) Maintains and allows access to any sales, shipping, or distribution records that identify the purchaser of such a laser product by name and address, the product by type, the number of units sold, and the date of sale (shipment). These records shall be maintained and made available as specified in § 1002.31.

(b) Definitions. As used in this section and § 1040.11, the following definitions apply:

(1) Accessible emission level means the magnitude of accessible laser or collateral radiation of a specific wavelength and emission duration at a particular point as measured according to paragraph (e) of this section. Accessible laser or collateral radiation is radiation to which human access is possible, as defined in paragraphs (b) (12), (15), and (22) of this section.

(2) Accessible emission limit means the maximum accessible emission level permitted within a particular class as set forth in paragraphs (c), (d), and (e) of this section.

(3) Aperture means any opening in the protective housing or other enclosure of a laser product through which laser or collateral radiation is emitted, thereby allowing human access to such radiation.

(4) Aperture stop means an opening serving to limit the size and to define the shape of the area over which radiation is measured.

(5) Class I laser product means any laser product that does not permit access during the operation to levels of laser radiation in excess of the accessible emission limits contained in table I of paragraph (d) of this section.1 (Footnote(s): 1 Class I levels of laser radiation are not considered to be hazardous.)

(6) Class IIa laser product means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in table I, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in table II-A of paragraph (d) of this section.2. (Footnote(s):2 Class IIa levels of laser radiation are not considered to be hazardous if viewed for any period of time less than or equal to

1 × 103 seconds but are considered to be a chronic viewing hazard for any period of time greater than 1 × 103 seconds.)

(7) Class II laser product means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in table II-A, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in table II of paragraph (d) of this section.3 (Footnote(s): 3 Class II levels of laser radiation are considered to be a chronic viewing hazard.)

(8) Class IIIa laser product means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in table II, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in table III-A of paragraph (d) of this section.4 (Footnote(s): 4 Class IIIa levels of laser radiation are considered to be, depending upon the irradiance, either an acute intrabeam viewing hazard or chronic viewing hazard, and an acute viewing hazard if viewed directly with optical instruments.)

(9) Class IIIb laser product means any laser product that permits human access during operation to levels of laser radiation in excess of the accessible emission limits of table III-A, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in table III-B of paragraph (d) of this section.5 ( Footnote(s): 5 Class IIIb levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct radiation.)

(10) Class III laser product means any Class IIIa or Class IIIb laser product.

(11) Class IV laser product means any laser that permits human access during operation to levels of laser radiation in excess of the accessible emission limits contained in table III-B of paragraph (d) of this section.6 (Footnote(s): 6 Class IV levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct and scattered radiation.)

(12) Collateral radiation means any electronic product radiation, except laser radiation, emitted by a laser product as a result of the operation of the laser(s) or any component of the laser product that is physically necessary for the operation of the laser(s).

(13) Demonstration laser product means any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition. The term “demonstration laser product” does not apply to laser products which are not manufactured, designed, intended, or promoted for such purposes, even though they may be used for those purposes or are intended to demonstrate other applications.

(14) Emission duration means the temporal duration of a pulse, a series of pulses, or continuous operation, expressed in seconds, during which human access to laser or collateral radiation could be permitted as a result of operation, maintenance, or service of a laser product.

(15) Human access means the capacity to intercept laser or collateral radiation by any part of the human body. For laser products that contain Class IIIb or IV levels of laser radiation, “human access” also means access to laser radiation that can be reflected directly by any single introduced flat surface from the interior of the product through any opening in the protective housing of the product.

(16) Integrated radiance means radiant energy per unit area of a radiating surface per unit solid angle of emission, expressed in joules per square centimeter per steradian (Jcm−2 sr−1).

(17) Invisible radiation means laser or collateral radiation having wavelengths of equal to or greater than 180 nm but less than or equal to 400 nm or greater than 710 nm but less than or equal to 1.0 X 106 nm (1 millimeter).

(18) Irradiance means the time-averaged radiant power incident on an element of a surface divided by the area of that element, expressed in watts per square centimeter (W cm−2).

(19) Laser means any device that can be made to produce or amplify electromagnetic radiation at wavelengths greater than 250 nm but less than or equal to 13,000 nm or, after August 20, 1986, at

wavelengths equal to or greater than 180 nm but less than or equal to 1.0X106 nm primarily by the process of controlled stimulated emission.

(20) Laser energy source means any device intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries shall not be considered to constitute laser energy sources.

(21) Laser product means any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system that is intended for use as a component of an electronic product shall itself be considered a laser product.

(22) Laser radiation means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph (b)(19) of this section that is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the appropriate aperture stop and within the appropriate solid angle of acceptance, as specified in paragraph (e) of this section.

(23) Laser system means a laser in combination with an appropriate laser energy source with or without additional incorporated components. See paragraph (c)(2) of this section for an explanation of the term “removable laser system.”

(24) Maintenance means performance of those adjustments or procedures specified in user information provided by the manufacturer with the laser product which are to be performed by the user for the purpose of assuring the intended performance of the product. It does not include operation or service as defined in paragraph (b) (27) and (38) of this section.

(25) Maximum output means the maximum radiant power and, where applicable, the maximum radiant energy per pulse of accessible laser radiation emitted by a laser product during operation, as determined under paragraph (e) of this section.

(26) Medical laser product means any laser product which is a medical device as defined in 21 U.S.C. 321(h) and is manufactured, designed, intended or promoted for in vivo laser irradiation of any part of the human body for the purpose of: (i) Diagnosis, surgery, or therapy; or (ii) relative positioning of the human body.

(27) Operation means the performance of the laser product over the full range of its functions. It does not include maintenance or service as defined in paragraphs (b) (24) and (38) of this section.

(28) Protective housing means those portions of a laser product which are designed to prevent human access to laser or collateral radiation in excess of the prescribed accessible emission limits under conditions specified in this section and in § 1040.11.

(29) Pulse duration means the time increment measured between the half-peak-power points at the leading and trailing edges of a pulse.

(30) Radiance means time-averaged radiant power per unit area of a radiating surface per unit solid angle of emission, expressed in watts per square centimeter per steradian (W cm−2 sr−1).

(31) Radiant energy means energy emitted, transferred or received in the form of radiation, expressed in joules (J).

(32) Radiant exposure means the radiant energy incident on an element of a surface divided by the area of the element, expressed in joules per square centimeter (Jcm−2)

(33) Radiant power means time-averaged power emitted, transferred or received in the form of radiation, expressed in watts (W).

(34) Remote interlock connector means an electrical connector which permits the connection of external remote interlocks.

(35) Safety interlock means a device associated with the protective housing of a laser product to prevent human access to excessive radiation in accordance with paragraph (f)(2) of this section.

(36) Sampling interval means the time interval during which the level of accessible laser or collateral radiation is sampled by a measurement process. The magnitude of the sampling interval in units of seconds is represented by the symbol (t).

(37) Scanned laser radiation means laser radiation having a time-varying direction, origin or pattern of propagation with respect to a stationary frame of reference.

(38) Service means the performance of those procedures or adjustments described in the manufacturer's service instructions which may affect any aspect of the product's performance for which this section and § 1040.11 have applicable requirements. It does not include maintenance or operation as defined in paragraphs (b) (24) and (27) of this section.

(39) Surveying, leveling, or alignment laser product means a laser product manufactured, designed, intended or promoted for one or more of the following uses:

(i) Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement.

(ii) Positioning or adjusting parts in proper relation to one another.

(iii) Defining a plane, level, elevation, or straight line.

(40) Visible radiation means laser or collateral radiation having wavelengths of greater than 400 nm but less than or equal to 710 nm.

(41) Warning logotype means a logotype as illustrated in either figure 1 or figure 2 of paragraph (g) of this section.

(42) Wavelength means the propagation wavelength in air of electromagnetic radiation.

(c) Classification of laser products— (1) All laser products. Each laser product shall be classified in Class I, IIa, II, IIIa, IIIb, or IV in accordance with definitions set forth in paragraphs (b) (5) through (11) of this section. The product classification shall be based on the highest accessible emission level(s) of laser radiation to which human access is possible during operation in accordance with paragraphs (d), (e), and (f)(1) of this section.

(2) Removable laser systems. Any laser system that is incorporated into a laser product subject to the requirements of this section and that is capable, without modification, of producing laser radiation when removed from such laser product, shall itself be considered a laser product and shall be separately subject to the applicable requirements in this subchapter for laser products of its class. It shall be classified on the basis of accessible emission of laser radiation when so removed.

(d) Accessible emission limits. Accessible emission limits for laser radiation in each class are specified in tables I, II-A, II, III-A, and III-B of this paragraph. The factors, k

1 and k

2 vary with wavelength and emission duration. These factors are given in table IV of this paragraph, with selected numerical values in table V of this paragraph. Accessible emission limits for collateral radiation are specified in table VI of this paragraph.

Notes applicable to tables I, II-A, II, III-A and III-B:

(1) The factors k

1 and k

2 are wavelength-dependent correction factors determined from table IV.

(2) The variable t in the expressions of emission limits is the magnitude of the sampling interval in units of seconds.

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(1) Beam of a single wavelength. Laser or collateral radiation of a single wavelength exceeds the accessible emission limits of a class if its accessible emission level is greater than the accessible emission limit of that class within any of the ranges of emission duration specified in tables I, II-A, II, III-A, and III-B of this paragraph.

(2) Beam of multiple wavelengths in same range. Laser or collateral radiation having two or more wavelengths within any one of the wavelength ranges specified in tables I, II-A, II, III-A, and III-B of this paragraph exceeds the accessible emission limits of a class if the sum of the ratios of the accessible emission level to the corresponding accessible emission limit at each such wavelength is greater than unity for that combination of emission duration and wavelength distribution which results in the maximum sum.

(3) Beam with multiple wavelengths in different ranges. Laser or collateral radiation having wavelengths within two or more of the wavelength ranges specified in tables I, II-A, II, III-A, and III-B of this paragraph exceeds the accessible emission limits of a class if it exceeds the applicable limits within any one of those wavelength ranges. This determination is made for each wavelength range in accordance with paragraph (d) (1) or (2) of this section.

(4) Class I dual limits. Laser or collateral radiation in the wavelength range of greater than 400 nm but less than or equal to 1.400 nm exceeds the accessible emission limits of Class I if it exceeds both:

(i) The Class I accessible emission limits for radiant energy within any range of emission duration specified in table I of this paragraph, and

(ii) The Class I accessible emission limits for integrated radiance within any range of emission duration specified in table I of this paragraph.

(e) Tests for determination of compliance—(1) Tests for certification. Tests on which certification under § 1010.2 is based shall account for all errors and statistical uncertainties in the measurement process. Because compliance with the standard is required for the useful life of a product such tests shall also account for increases in emission and degradation in radiation safety with age.

(2) Test conditions. Except as provided in § 1010.13, tests for compliance with each of the applicable requirements of this section and § 1040.11 shall be made during operation, maintenance, or service as appropriate:

(i) Under those conditions and procedures which maximize the accessible emission levels, including start-up, stabilized emission, and shut-down of the laser product; and

(ii) With all controls and adjustments listed in the operation, maintenance, and service instructions adjusted in combination to result in the maximum accessible emission level of radiation; and

(iii) At points in space to which human access is possible in the product configuration which is necessary to determine compliance with each requirement, e.g., if operation may require removal of portions of the protective housing and defeat of safety interlocks, measurements shall be made at points accessible in that product configuration; and

(iv) With the measuring instrument detector so positioned and so oriented with respect to the laser product as to result in the maximum detection of radiation by the instrument; and

(v) For a laser product other than a laser system, with the laser coupled to that type of laser energy source which is specified as compatible by the laser product manufacturer and which produces the maximum emission level of accessible radiation from that product.

(3) Measurement parameters. Accessible emission levels of laser and collateral radiation shall be based upon the following measurements as appropriate, or their equivalent:

(i) For laser products intended to be used in a locale where the emitted laser radiation is unlikely to be viewed with optical instruments, the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within a circular solid angle of acceptance of 1 X 10−3 steradian with collimating optics of 5 diopters or less. For scanned laser radiation, the direction of the solid angle of acceptance shall change as needed to maximize detectable radiation, with an angular speed of up to 5 radians/second. A 50 millimeter diameter aperture stop with the same collimating optics and acceptance angle stated above shall be used for all other laser products (except that a 7 millimeter diameter aperture stop shall be used in the measurement of scanned laser radiation emitted by laser products manufactured on or before August 20, 1986.

(ii) The irradiance (W cm−2) or radiant exposure (J cm−2 equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and, for irradiance, within a circular solid angle of acceptance of 1 x 10−3 steradian with collimating optics of 5 diopters or less, divided by the area of the aperture stop (cm−2).

(iii) The radiance (W cm−2 sr−1) or integrated radiance (J cm−2 sr−1) equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within a circular solid angle of acceptance of 1 X 10−5 steradian with collimating optics of 5 diopters or less, divided by that solid angle (sr) and by the area of the aperture stop (cm−2).

(f) Performance requirements—(1) Protective housing. Each laser product shall have a protective housing that prevents human access during operation to laser and collateral radiation that exceed the limits of Class I and table VI, respectively, wherever and whenever such human access is not necessary for the product to perform its intended function. Wherever and whenever human access to laser radiation levels that exceed the limits of Class I is necessary, these levels shall not exceed the limits of the lowest class necessary to perform the intended function(s) of the product.

(2) Safety interlocks. (i) Each laser product, regardless of its class, shall be provided with at least one safety interlock for each portion of the protective housing which is designed to be removed or displaced during operation or maintenance, if removal or displacement of the protective housing could permit, in the absence of such interlock(s), human access to laser or collateral radiation in excess of the accessible emission limit applicable under paragraph (f)(1) of this section.

(ii) Each required safety interlock, unless defeated, shall prevent such human access to laser and collateral radiation upon removal or displacement of such portion of the protective housing

(iii) Either multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing shall be provided, if failure of a single interlock would allow;

(a) Human access to a level of laser radiation in excess of the accessible emission limits of Class IIIa; or

(b) Laser radiation in excess of the accessible emission limits of Class II to be emitted directly through the opening created by removal or displacement of the interlocked portion of the protective housing.

(iv) Laser products that incorporate safety interlocks designed to allow safety interlock defeat shall incorporate a means of visual or aural indication of interlock defeat. During interlock defeat, such indication shall be visible or audible whenever the laser product is energized, with and without the associated portion of the protective housing removed or displaced.

(v) Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated.

(3) Remote interlock connector. Each laser system classified as a Class IIIb or IV laser product shall incorporate a readily available remote interlock connector having an electrical potential difference of no greater than 130 root-mean-square volts between terminals. When the terminals of the connector are not electrically joined, human access to all laser and collateral radiation from the laser product in excess of the accessible emission limits of Class I and table VI shall be prevented.

(4) Key control. Each laser system classified as a Class IIIb or IV laser product shall incorporate a key-actuated master control. The key shall be removable and the laser shall not be operable when the key is removed.

(5) Laser radiation emission indicator. (i) Each laser system classified as a Class II or IIIa laser product shall incorporate an emission indicator that provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I.

(ii) Each laser system classified as a Class IIIb or IV laser product shall incorporate an emission indicator which provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I, and sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to the laser radiation.

(iii) For laser systems manufactured on or before August 20, 1986, if the laser and laser energy source are housed separately and can be operated at a separation distance of greater than 2 meters, both laser and laser energy source shall incorporate an emission indicator as required in accordance with paragraph (f)(5) (i) or (ii) of this section. For laser systems manufactured after August 20, 1986, each separately housed laser and operation control of a laser system that regulates the laser or collateral radiation emitted by a product during operation shall incorporate an emission indicator as required in accordance with paragraph (f)(5) (i) or (ii) of this section, if the laser or operation control can be operated at a separation distance greater than 2 meters from any other separately housed portion of the laser product incorporating an emission indicator.

(iv) Any visible signal required by paragraph (f)(5) (i) or (ii) of this section shall be clearly visible through protective eyewear designed specifically for the wavelength(s) of the emitted laser radiation.

(v) Emission indicators required by paragraph (f)(5) (i) or (ii) of this section shall be located so that viewing does not require human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and table VI.

(6) Beam attenuator. (i) Each laser system classified as a Class II, III, or IV laser product shall be provided with one or more permanently attached means, other than laser energy source switch(es), electrical supply main connectors, or the key-actuated master control, capable of preventing access by any part of the human body to all laser and collateral radiation in excess of the accessible emission limits of Class I and table VI.

(ii) If the configuration, design, or function of the laser product would make unnecessary compliance with the requirement in paragraph (f)(6)(i) of this section, the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, may, upon written application by the manufacturer, approve alternate means to accomplish the radiation protection provided by the beam attenuator.

(7) Location of controls. Each Class IIa, II, III, or IV laser product shall have operational and adjustment controls located so that human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and table VI is unnecessary for operation or adjustment of such controls.

(8) Viewing optics. All viewing optics, viewports, and display screens incorporated into a laser product, regardless of its class, shall limit the levels of laser and collateral radiation accessible to the human eye by means of such viewing optics, viewports, or display screens during operation or maintenance to less than the accessible emission limits of Class I and table VI. For any shutter or variable attenuator incorporated into such viewing optics, viewports, or display screens, a means shall be provided:

(i) To prevent access by the human eye to laser and collateral radiation in excess of the accessible emission limits of Class I and table VI whenever the shutter is opened or the attenuator varied.

(ii) To preclude, upon failure of such means as required in paragraph (f)(8)(i) of this section, opening the shutter or varying the attenuator when access by the human eye is possible to laser or collateral radiation in excess of the accessible emission limits of Class I and table VI.

(9) Scanning safeguard. Laser products that emit accessible scanned laser radiation shall not, as a result of any failure causing a change in either scan velocity or amplitude, permit human access to laser radiation in excess of:

(i) The accessible emission limits of the class of the product, or

(ii) The accessible emission limits of the class of the scanned laser radiation if the product is Class IIIb or IV and the accessible emission limits of Class IIIa would be exceeded solely as result of such failure.

(10) Manual reset mechanism. Each laser system manufactured after August 20, 1986, and classified as a Class IV laser product shall be provided with a manual reset to enable resumption of laser radiation emission after interruption of emission caused by the use of a remote interlock or after an interruption of emission in excess of 5 seconds duration due to the unexpected loss of main electrical power.

(g) Labeling requirements. In addition to the requirements of §§ 1010.2 and 1010.3, each laser product shall be subject to the applicable labeling requirements of this paragraph.

(1) Class IIa and II designations and warnings. (i) Each Class IIa laser product shall have affixed a label bearing the following wording: “Class IIa Laser Product—Avoid Long-Term Viewing of Direct Laser Radiation.”

(ii) Each Class II laser product shall have affixed a label bearing the warning logotype A (figure 1 in this paragraph) and including the following wording:

[Position I on the logotype]

“LASER RADIATION—DO NOT STARE INTO BEAM”; and

[Position 3 on the logotype]

“CLASS II LASER PRODUCT”.

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(2) Class IIIa and IIIb designations and warnings. (i) Each Class IIIa laser product with an irradiance less than or equal to 2.5×10−3 W cm2− shall have affixed a label bearing the warning logotype A (figure 1 of paragraph (g)(1)(ii) of this section) and including the following wording:

[Position 1 on the logotype]

“LASER RADIATION—DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS”; and,

[Position 3 on the logotype]

“CLASS IIIa LASER PRODUCT”.

(ii) Each Class IIIa laser product with an irradiance greater than 2.5×10−3 -W cm−2 shall have affixed a label bearing the warning logotype B (figure 2 in this paragraph) and including the following wording:

[Position 1 on the logotype]

“LASER RADIATION—AVOID DIRECT EYE EXPOSURE”; and,

[Position 3 on the logotype]

“CLASS IIIa LASER PRODUCT”.

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(iii) Each Class IIIb laser product shall have affixed a label bearing the warning logotype B (figure 2 of paragraph (g)(2)(ii) of this section) and including the following wording:

[Position 1 on the logotype]

“LASER RADIATION—AVOID DIRECT EXPOSURE TO BEAM”; and,

[Position 3 on the logotype]

“CLASS IIIb LASER PRODUCT”.

(3) Class IV designation and warning. Each Class IV laser product shall have affixed a label bearing the warning logotype B (figure 2 of paragraph (g)(2)(ii) of this section), and including the following wording:

[Position 1 on the logotype]

“LASER RADIATION—AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION”; and,

[Position 3 on the logotype]

“CLASS IV LASER PRODUCT”.

(4) Radiation output information on warning logotype. Each Class II, III, and IV laser product shall state in appropriate units, at position 2 on the required warning logotype, the maximum output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength(s).

(5) Aperture label. Each laser product, except medical laser products and Class IIa laser products, shall have affixed, in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the accessible emission limits of Class I and table VI of paragraph (d) of this section, a label(s) bearing the following wording as applicable.

(i) “AVOID EXPOSURE—Laser radiation is emitted from this aperture,” if the radiation emitted through such aperture is laser radiation.

(ii) “AVOID EXPOSURE—Hazardous electromagnetic radiation is emitted from this aperture,” if the radiation emitted through such aperture is collateral radiation described in table VI, item 1.

(iii) “AVOID EXPOSURE—Hazardous x-rays are emitted from this aperture,” if the radiation emitted through such aperture is collateral radiation described in table VI, item 2.

(6) Labels for noninterlocked protective housings. For each laser product, labels shall be provided for each portion of the protective housing which has no safety interlock and which is designed to be displaced or removed during operation, maintenance, or service, and thereby could permit human access to laser or collateral radiation in excess of the limits of Class I and table VI. Such labels shall be visible on the protective housing prior to displacement or removal of such portion of the protective housing and visible on the product in close proximity to the opening created by removal or displacement of such portion of the protective housing, and shall include the wording:

(i) “CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM.” for Class II accessible laser radiation.

(ii) “CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS.” for Class IIIa accessible laser radiation with an irradiance less than or equal to $2.5\times10^{-3}$ W cm−2.

(iii) “DANGER—Laser radiation when open. AVOID DIRECT EYE EXPOSURE.” for Class IIIa accessible laser radiation with an irradiance greater than $2.5\times10^{-3}$ W cm−2.

(iv) “DANGER—Laser radiation when open. AVOID DIRECT EXPOSURE TO BEAM.” for Class IIIb accessible laser radiation.

(v) “DANGER—Laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.” for Class IV accessible laser radiation.

(vi) “CAUTION—Hazardous electromagnetic radiation when open.” for collateral radiation in excess of the accessible emission limits in table VI, item 1 of paragraph (d) of this section.

(vii) “CAUTION—Hazardous x-rays when open.” for collateral radiation in excess of the accessible emission limits in table VI, item 2 of paragraph (d) of this section.

(7) Labels for defeatably interlocked protective housings. For each laser product, labels shall be provided for each defeatably interlocked (as described in paragraph (f)(2)(iv) of this section) portion of the protective housing which is designed to be displaced or removed during operation, maintenance, or service, and which upon interlock defeat could permit human access to laser or collateral radiation in excess of the limits of Class I or table VI. Such labels shall be visible on the product prior to and during interlock defeat and in close proximity to the opening created by the removal or displacement of such portion of the protective housing, and shall include the wording:

(i) “CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM.” for Class II accessible laser radiation.

(ii) “CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS.” for Class IIIa accessible laser radiation with an irradiance less than or equal to $2.5\times10^{-3}$ W cm−2.

(iii) “DANGER—Laser radiation when open and interlock defeated. AVOID DIRECT EYE EXPOSURE.” for Class IIIa accessible laser radiation when an irradiance greater than $2.5\times10^{-3}$ W cm−2.

(iv) “DANGER—Laser radiation when open and interlock defeated. AVOID DIRECT EXPOSURE TO BEAM.” for Class IIIb accessible laser radiation.

(v) “DANGER—Laser radiation when open and interlock defeated. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.” for Clas IV accessible laser radiation.

(vi) “CAUTION—Hazardous electromagnetic radiation when open and interlock defeated.” for collateral radiation in excess of the accessible emission limits in table VI. item 1 of paragraph (d) of this section.

(vii) “CAUTION—Hazardous x-rays when open and interlock defeated.” for collateral radiation in excess of the accesible emission limits in table VI. item 2 of paragraph (d) of this section.

(8) Warning for visible and/or invisible radiation. On the labels specified in this paragraph, if the laser or collateral radiation referred to is:

(i) Invisible radiation, the word “invisible” shall appropriately precede the word “radiation”; or

(ii) Visible and invisible radiation, the words “visible and invisible” or “visible and/or invisible” shall appropriately precede the word “radiation.”

(iii) Visible laser radiation only, the phrase “laser light” may replace the phrase “laser radiation.”

(9) Positioning of labels. All labels affixed to a laser product shall be positioned so as to make unnecessary, during reading, human exposure to laser radiation in excess of the accessible emission limits of Class I radiation or the limits of collateral radiation established to table VI of paragraph (d) of this section.

(10) Label specifications. Labels required by this section and § 1040.11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during operation, maintenance, or service, as appropriate. If the size, configuration, design, or function of the laser product would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, on the Director's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s) or alternate wording for such label(s) as applicable.

(h) Informational requirements—(1) User information. Manufacturers of laser products shall provide as an integral part of any user instruction or operation manual which is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each laser product:

(i) Adequate instructions for assembly, operation, and maintenance, including clear warnings concerning precautions to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11.

(ii) A statement of the magnitude, in appropriate units, of the pulse durations(s), maximum radiant power and, where applicable, the maximum radiant energy per pulse of the accessible laser radiation detectable in each direction in excess of the accessible emission limits in table I of paragraph (d) of this section determined under paragraph (e) of this section.

(iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and § 1040.11 to be affixed to the laser product or provided with the laser product, including the information required for positions 1, 2, and 3 of the applicable logotype (figure 1 of paragraph (g)(1)(ii) or figure 2 or paragraph (g)(2)(ii) of this section). The corresponding position of each label affixed to the product shall be indicated or, if provided with the product, a statement that such labels could not be affixed to the product but were supplied with the product and a statement of the form and manner in which they were supplied shall be provided.

(iv) A listing of all controls, adjustments, and procedures for operation and maintenance, including the warning “Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.”

(v) In the case of laser products other than laser systems, a statment of the compatibility requirements for a laser energy source that will assure compliance of the laser product with this section and § 1040.11.

(vi) In the case of laser products classified with a 7 millimeter diameter aperture stop as provided in paragraph (e)(3)(i) of this section, if the use of a 50 millimeter diameter aperture stop would result in a higher clsssification of the product, the following warning shall be included in the user information: “CAUTION—The use of optical instruments with this product will increase eye hazard.”

(2) Purchasing and servicing information. Manufacturers of laser products shall provide or cause to be provided:

(i) In all catalogs, specification sheets, and descriptive brochures pertaining to each laser product, a legible reproduction (color optional) of the class designation and warning required by paragraph (g) of

this section to be affixed to that product, including the information required for positions 1, 2, and 3 of the applicable logotype (figure 1 of paragraph (g)(1)(ii) or figure 2 of paragraph (g)(2)(ii) of this section).

(ii) To servicing dealers and distributors and to others upon request at a cost not to exceed the cost of preparation and distribution, adequate instructions for service adjustments and service procedures for each laser product model, including clear warnings and precautions to be taken to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11; and in all such service instructions, a listing of those controls and procedures that could be utilized by persons other than the manufacturers or the manufacturer's agents to increase accessible emission levels of radiation and a clear description of the location of displaceable portions of the protective housing that could allow human access to laser or collateral radiation in excess of the accessible emission limits in tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section. The instructions shall include protective procedures for service personnel to avoid exposure to levels of laser and collateral radiation known to be hazardous for each procedure or sequence of procedures to be accomplished, and legible reproductions (color optional) of required labels and hazard warnings.

(i) Modification of a certified product. The modification of a laser product, previously certified under § 1010.2, by any person engaged in the business of manufacturing, assembling, or modifying laser products shall be construed as manufacturing under the act if the modification affects any aspect of the product's performance or intended function(s) for which this section and § 1040.11 have an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the product in accordance with the provisions of §§ 1010.2. and 1010.3.

(The information collection requirements contained in paragraph (a)(3)(ii) were approved by the Office of Management and Budget under control number 0910-0176)

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