Laser Safety Manual

Standard Operating Procedures for Medical Center Use of Class 3B and Class 4 Lasers

*Type of Laser: (CO2 or Holmium, NdYAG/etc*

*Prepare one safety manual for each laser in your area*

*Location of Laser Use (if multiple areas, each area must be addressed)*

*University of Virginia Medical Center*

*[Department]*

*[Messenger Mail Address]*

*[Preparation Date]*

*Revision Date: one year after Preparation Date*

Table of Contents

[PURPOSE 4](#_Toc370898300)

[BACKGROUND 4](#_Toc370898301)

[ROLES & RESPONSIBILITIES 4](#_Toc370898302)

[DESCRIPTION OF FACILITIES 5](#_Toc370898303)

[LASER SPECIFICATIONS 6](#_Toc370898304)

[GENERAL LASER SAFETY 8](#_Toc370898305)

[EQUIPMENT 8](#_Toc370898306)

[Performance Checks 8](#_Toc370898307)

[Laser Alignment 8](#_Toc370898308)

[Electrical Hazards 9](#_Toc370898309)

[Emergency Shutoff 9](#_Toc370898310)

[Laser Handpiece 9](#_Toc370898311)

[Instrument Draping 9](#_Toc370898312)

[Fibers 9](#_Toc370898313)

[Fiber Calibration 9](#_Toc370898314)

[Fiber Cooling 9](#_Toc370898315)

[PROCEDURES 10](#_Toc370898316)

[General 10](#_Toc370898317)

[Qualified Personnel 10](#_Toc370898318)

[Standard Operating Procedures (SOPs) 10](#_Toc370898319)

[Key Control 10](#_Toc370898320)

[Delivery Control 10](#_Toc370898321)

[Controlled Area 11](#_Toc370898322)

[Warning Signs 11](#_Toc370898323)

[Fire and Explosion Hazards 11](#_Toc370898324)

[Smoke and Plume Control 12](#_Toc370898325)

[Eye Protection 13](#_Toc370898326)

[Reflection Hazards 13](#_Toc370898327)

[Lateral Damage 14](#_Toc370898328)

[Laser Safety Checklist 14](#_Toc370898329)

[Laser Procedural Documentation 14](#_Toc370898330)

[Incidents 14](#_Toc370898331)

[TRAINING 14](#_Toc370898332)

[EMERGENCY PHONE NUMBERS 16](#_Toc370898333)

[EMERGENCY PROCEDURES 16](#_Toc370898334)

[VALIDATION AND HISTORY FOR LASER SAFETY MANUAL 17](#_Toc370898335)

[APPENDIX A: FLOOR DIAGRAM(S) 18](#_Toc370898336)

[APPENDIX B: EXAMPLES OF PROPER LASER SIGNAGE 20](#_Toc370898337)

[APPENDIX C: LASER SAFETY TIME-OUT CHECKLIST 21](#_Toc370898338)

# **PURPOSE**

Training in laser and laser safety practices for the physician and technical support staff is distinguished from merely learning the methods and techniques for using the laser device. All Health care personnel who will be entering and/or working in the Nominal Hazard Zone, delineated by the Medical Center as the room in which the laser is operated, must be thoroughly familiar and cognizant of the specific hazards contained herein and presented by the operation of the *[identification of your specific laser device]* and the precautions required when it is in use.

Additional training requirements are referenced in the ***American National Standard for Safe Use of Lasers in Health Care Facilities, (ANSI Z136.3-2011).***

This document provides a source of information covering the use of Class 3B and Class 4 Laser Devices in diagnostic and therapeutic medical applications. Specifically, it describes the protocols and precautions which must be followed during the use of *[your device(s)]* in *[your facility]*. This manual will be used as a training guide for new Laser Operators and Licensed Independent Practitioners and shall be reviewed annually by the Laser Safety Designee for changes or corrections to ensure that it is timely and accurate.

**Acknowledgement & Signatures**

We, the undersigned, understand that the use of laser devices for diagnostic and therapeutic applications in health care facilities present unique dangers when adequate precautions area not observed. Our signatures designate that we have read this Laser Safety Manual. We understand its content and we intend to comply with the instructions provided.

**NAME SIGNATURE DATE**

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# **BACKGROUND**

[This section should include a detailed discussion of:

1) laser product name, common name if applicable, manufacturer,

2) specific operations and activities performed with the laser device (e.g. ablation, vaporization, excision of skin; ablation, vaporization of brain tumors, treatment of vascular lesions, etc.)

3) special safety considerations for this particular laser (e.g. near infrared laser with an invisible beam, a visible beam with a high voltage flashlamp, mobil device, etc.

The information provided herein is useful for training new Laser Operators and Licensed Independent Practitioners in the way things are done at your facility, in addition to revealing potential hazards. A good source for this information is the manufacturer’s manual as well as the LIP and LSD knowledge of how this laser is used; types of procedures, operating conditions etc ]

# **ROLES & RESPONSIBILITIES**

*Primary department contact*: Manager of the area where the laser is primarily located. The primary department contact has oversight responsibility for all aspects of laser safety for each laser located in the area(s) for which they have primary responsibility. *Put your manager’s name here and contact info.*

*Laser Safety Designee (LSD):* The manager of each area where a laser is located will designate an LSD to have primary responsibility and accountability for safety of that laser. A Registered Nurse is preferred for this position. Responsibilities include training and documentation. Each LSD will complete the AORN Laser Safety Module*. Put your LSD’s name here and contact info.*

*Licensed Independent Practitioner (LIP):* Physician, nurse practitioner, or physician’s assistant trained and privileged to fire the laser. *. Put your LIP’s name here and contact info.*

*Laser Operator:* Team members in each area where a laser is located trained to assist in laser procedures. *. Put your laser operators’ names here.*

*Clinical Staff Office*: Location and maintenance of credentialing records related to laser safety training and competency for LIPs. *As of 10/22/2014 this is: Stephanie Allen, Director of Clinical Staff Office, UVA Health System, Clinical Staff Office, McKim Hall, Room 1094, PO Box 800547, Charlottesville 22908-0547. Update as needed.*

*Vendor*: Representative of the laser manufacturer*. Put your manufacturers’ reps name here with contact information.*

# **DESCRIPTION OF FACILITIES**

[Describe the layout and configuration of the location(s) in which the laser device will be operated. Describe means of controlling access and all means to maintain a safe environment for patients and health care personnel].

*[Procedures to include]:*

1. Regulation Danger laser signs shall be posted at eye level on all doors that access a room where Class 3b and/or Class 4 laser will be operated. These signs will state all required information as described in the ANSI Z136.3 standard, and shall be removed when the laser is not in use. An example of an acceptable laser door sign is shown in Appendix B
2. Safety eye wear labeled with the appropriate wavelength and optical density shall be available at the entry where each door sign is posted.
3. Glass windows shall be covered with shades or filters of appropriate optical density on the laser side of the window whenever a fiberoptic laser system is operational.
4. All safety procedures shall be followed during service and demonstrations.
5. No one will be allowed into a laser room unless properly authorized and protected.
6. The laser should not be activated when it is necessary to open the door, if the Nominal Hazard Zone (NHZ) extends to the doorway.
7. Laser keys will be kept in a secured area and accessible only by those authorized to utilize them by the Laser Safety Designee.

Floor diagrams are displayed in Appendix A.

# **LASER SPECIFICATIONS**

Table 1 contains variables essential for the completion of a proper hazard analysis by the University of Virginia Laser Safety Officer. Hazard analyses include (1) the calculation of the **maximum permissible exposure (MPE)[[1]](#footnote-1),** (2) the **nominal hazard zone (NHZ)[[2]](#footnote-2),** and (3) the confirmation that the appropriate protective eye wear has been selected by calculating the required **optical density (O.D. or Dλ)[[3]](#footnote-3)**.

*Laser Safety Hazard Calculation Results:*

**MPE = \_\_\_\_\_\_\_\_\_\_\_\_\_**

**NHZ = \_\_\_\_\_\_\_\_\_\_\_\_\_**

**O.D. = \_\_\_\_\_\_\_\_\_\_\_\_\_**

TABLE 1: LASER SPECIFICATIONS

|  |  |
| --- | --- |
|  | **Laser** |
| Device Location(s): Building |  |
| Room |  |
| Laser Type |  |
| Wavelength (μm) |  |
| Laser Class |  |
| Aiming Laser Class |  |
| Application |  |
| Manufacturer |  |
| Model |  |
| Serial # |  |
| Control # |  |
| Active? (Y/N) |  |
| Mode (CW/Single Pulse/Multi-Pulse?) |  |
| Beam Shape (Circular/Elliptical/etc.?) |  |
| Beam Diameter @ Laser Aperture (mm.) |  |
| Beam Divergence (mrad) |  |
| Average Power (watts) |  |
| Exposure Time (seconds) |  |
| Pulse Energy (joules) |  |
| Pulse Length (seconds) |  |
| Pulse Rate (hertz) |  |

***[This page will be submitted to the UVA Laser Safety Officer and the UVA Health Systems Clinical Engineering Department to be entered into the Institutional Medical Laser Inventory. The information you provide will also be used to perform the appropriate safety calculations. It is, therefore, imperative that you provide all of the requested information].***

# **GENERAL LASER SAFETY**

[The following sections have been excerpted, with minimal editorial change, directly from ANSI Z136.3. If your facility and/or operations necessitate additional entries, you are encouraged to include them.]

The use of lasers has many technical advantages in surgical and other medical specialties. However, there are both laser and non-beam hazards which must be understood and controlled by acquired training either during a residency program, an acceptable in-service seminar, or postgraduate courses. These hazards can be avoided by a proper understanding of the equipment and by following safe procedures. Guidance is available for a number of medical specialties in the ANSI document, but this does not eliminate the need for hands-on laser training.

# *EQUIPMENT*

## Performance Checks

Test all lasers, delivery systems, and safety equipment prior to having the patient in the room. Appropriate eyewear should be worn during such tests. The Health Care Laser System (HCLS) should be calibrated in accordance with manufacturer’s directions, and if the procedure is prolonged, it may be prudent to recalibrate during treatment.

Check the power output of the laser frequently with an appropriate power meter, especially before beginning the procedure. Appropriate eyewear should be worn during such checks. The laser should be placed in a standby mode when not in use, to prevent inadvertent exposure to power/energy.

## Laser Alignment

HCLS should not be activated if there is a faulty aiming system from a misaligned beam or if infrared lasers such as CO2 and Nd:YAG are used without an aiming beam. Coincidence of the aiming and treating beams is very important for articulated arm instruments. Alignment of the beam may be checked by testing laser modes on a wet wooden tongue depressor (a TEM00 mode is desirable). Alternatively, the focused beam of a CO2 laser set at 10 W for 0.1 s will just penetrate a dry tongue depressor leaving a pinhole aperture seen under bright light. The equipment manufacturer is required to provide written standard procedures detailing alignment methods.

## Electrical Hazards

Use of any electrical system may give rise to electrical hazards, and consequently, proper grounding and insulation are imperative. For example the potential hazard is increased during endoscopic urological procedures in which the irrigating solution may wet the floor or equipment. Ensure that operating areas remain as dry as possible. (See ANSI Z136.3, Section 7.2 for additional electric safety information).

## Emergency Shutoff

An emergency shutoff switch must be available to the operator or the assistant to rapidly shutdown the equipment.

## Laser Handpiece

When using the laser handpiece in a sterile field, the sterile drape on the laser handpiece should be taped at least four cm above the aperture of the handpiece to prevent slippage and ignition of the sterile covering.

## Instrument Draping

The use of microscope-linked laser directing systems require careful attention to the probability of fallout dust and debris on the surgical field. Accordingly, appropriate draping techniques should be utilized to minimize the possibility of contamination from equipment as it is brought into the sterile operating field.

## Fibers

Examine all fibers prior to use, for breakage or damage to the distal tip, proximal connector, or catheter sheath. Monitor fibers for distortion of the beam, accumulation of debris on the tip, loosening of the connector, or decreased power delivery.

## Fiber Calibration

Calibrate fibers according to manufacturer’s directions, to verify adequate transmission of power, prior to procedure.

## Fiber Cooling

Always use coaxial cooling appropriate to the fiber and procedure. Never use air or gas to cool a fiber in the uterus.

## *EYE PROTECTION*

The greatest risk for personnel using lasers is eye injury to the cornea or retina from direct or reflected laser beams. Splash guards and face shields should be used in conjunction with proper laser eyewear when protection is needed against blood borne pathogens. Eye protection should be worn by the surgeon, all personnel in the operating room (within the NHZ specifically), and the patient. OSHA and State Regulations concerning eye protection during procedures should be strictly observed, due to the potential risk of contamination by bloodborne pathogens. **Caution**: Laser Safety Eyewear is not designed for looking directly at a laser beam.

**Protective Eyewear.** Protective eyewear with adequate optical density (OD) at the particular wavelength in use must be clearly labeled and worn by all members of the operating team within the NHZ. It must be emphasized that using endoscopes, microscopes, or video monitors do not preclude the laser beam being emitted from a break in the optical fiber.

**Side Shields.** It is recommended that built-in side shields be used to protect the eyes from tangential beams and scattered reflections.

**Filters.** Use appropriate filters, permanently fastened in place, for eyepieces of endoscopes, flexible and rigid bronchoscopes, and microscopes to protect against the back reflection of the laser beam.

**Eye Shields.** Patient eye protection requires metal and acrylic eye shields be placed on top of the cornea to protect the eye during laser treatment of facial areas; particularly around the eyes. Protective glasses may interfere and/or allow leakage of laser radiation around the edges. When a patient is anesthetized, a double layer of saline moistened eye pads placed over the eyes may provide adequate protection with CO2 laser use.. For other laser wavelengths, other shielding material, especially black felt, may be used.

# *PROCEDURES*

## General

It is the responsibility of the Laser Safety Designee to monitor the safety of the patient, the environment, the staff, and the equipment during laser procedures. This individual is empowered with the authority to enforce compliance with safety policies and procedures.

## Qualified Personnel

Only qualified and authorized staff should operate the laser or be responsible for the care and management of the optical delivery system. Adequate warning should be given by the laser surgeon before commencement of lasing.

## Standard Operating Procedures (SOPs)

Written policies and procedures (SOPs), such as this one, should cover laser beam and non-beam hazards. They shall be included in laser educational programs, and be available within the practice setting. They should be reviewed annually, and revised if warranted, to conform with current standards, procedures, and instrumentation.

## Key Control

The HCLS key shall be stored in a secured area to prevent misuse by unauthorized personnel.

## Delivery Control

Control delivery systems at all times, whenever not being used in the operative field. Do not lay hot fibers or tips on drapes.

All foot-controlled switches must be covered to prevent accidental activation of the HCLS. The operator should remove his/her foot from the shutter pedal and place the laser on standby while conversing or changing position.

In light of common usage of foot pedal to activate both surgical equipment, e.g., bipolar cautery and the bovey cautery, an effort should be made to obviate the need for an operating surgeon to use more than one pedal. Ideally this would be the laser pedal. The inadvertent activation of the laser pedal can also be minimized by immediate disabling of the HCLS when another pedal-operated instrument is used.

## Controlled Area

Authorized personnel, upon entry to an area where lasers are being used, shall be provided with personal protective equipment (see Description of Facilities, above). Such controlled area should contain the NHZ, the extent of which is clearly delineated, and shall be posted with appropriate laser warning signs specific to the wavelength being used (as described in ANSI Z136.3, Section 4.7).

## Warning Signs

Warning signs shall be in view outside the room where the laser procedure is being performed at each point of entry. They must be removed upon completion of the procedure.

## Fire and Explosion Hazards

Fire hazards associated with lasers take many forms. Proper procedure to minimize the hazards should include the following:

1. Use only wet or fire retardant materials in the operative field.
2. Non combustible anesthetic agents should be used in surgery.
3. Do not use alcohol or wet iodophors in the field while firing the laser.
4. Protect tissue adjacent to laser impact site, with wet or fire retardant drapes. Do not use disposable drapes.
5. Inserting a wet sponge above the lesion in the rectal lumen will limit a flash fire from methane or hydrogen gas which may be present.
6. Frequently suction or dab liquefied fat in order to minimize the possibility of a flash fire.
7. Moist towels and biogel wound protective materials will avert the possibility of fire in the immediate proximity of the surgical site and may enhance the effectiveness of fire retardant draping materials.
8. Be aware of the potential for oxygen saturation under gowns and drapes.
9. Keep an open container of water or saline solution available during laser procedures.
10. Know location and operation of nearest fire extinguisher.

(11)Store highly combustible or explosive materials in the laser area in closed cabinets. Wall coverings and draperies should be fire retardant.

## Smoke and Plume Control

Lasers capable of vaporization can result in a plume ejected from the impact site. Care should be taken to evacuate this plume with the proper device (see ANSI Z136.3, Section 7.3). Evacuation also eliminates cellular debris providing greater visibility.

Personal Equipment**.** Surgical masks are not designed to provide protection from plume contents. They are intended to protect the patient from the surgeon’s contamination. During procedures that generate surgical smoke, an N95 filtering face piece respirator or a high-filtration surgical mask should be worn by all personnel in the room while the laser is in use. Local exhaust ventilation techniques should be the first line of protection.

Noxious Fumes**.** Noxious odors from the plume may induce nausea and vomiting. Irritating fumes may cause coughing and lacrimation. Offensive odors must be rapidly exhausted from the operating room not only to be rid of the offensive odor but also to remove bacterial, viral (i.e., HIV, HPV, HBV) that may be found in the plume. Surgical preparations applied to the operative site should be allowed to dry before starting the laser procedure to reduce the possibility of noxious or toxic plumes.

Smoke Evacuation**.** As recognized in ANSI Z136.3, Section 7.3, tissue vaporization due to laser created reactions cause formation of methemoglobin and carboxyhemoglobin when these are absorbed via the peritoneum. Due to this occurrence at laparoscopy, it is recommended that specified laser parameters be used to accomplish the desired task, i.e., coagulation, ablation or vaporization. It is further recommended that the plume be evacuated as soon as it is created to reduce deleterious effects.

Suction. To be effective, the wand from the smoke evacuator should be kept within 2 inches (or 5 cm) of the operative site.

Filters**.** To ensure optimal functionality, follow the manufacturer’s specification for inspection and replacement of the charcoal HEPA and/or ULPA filters. Filters from portable plume evacuators are considered a possible biohazard and shall be disposed of properly.

## Reflection Hazards

Use anodized blackened or matte (beaded or roughened) retractors and other instruments with visible and near infrared lasers to minimize reflection hazards. This will ensure low specular or diffuse reflection from a direct or scattered laser beam which inadvertently strikes the instrument. Alternate forms of protection to adjacent tissue include wrapping retractors with wet sponges and packing off the intestines or tissue with wet packing.

Only diffusely reflective metals should be placed behind adhesions which are to be severed by a laser. Glass rods should not be used as thermal stress may cause breakage and fragments may get lost in the abdominal cavity.

Waving the surgical suction or other instruments in front of the impacting beam should be avoided. This position of instruments relative to the laser should be consistently monitored.

## Lateral Damage

In order to limit the amount of lateral thermal damage to surrounding tissue, lasers should be used at the highest controllable settings and rapidly maneuvered. Carbonized impact sites must not be repeatedly irradiated while carbon remains at the site, as this will increase the temperature to more than 1000 °C causing increased lateral and deep thermal tissue damage at the impact site.

## Laser Safety Checklist

A checklist shall be utilized as part of a timeout procedure to insure that safety considerations have been addressed to include laser signage, staff eye protection, smoke evacuation, draping, fire protection, window coverings, etc. (refer to Appendix C).

## Laser Procedural Documentation

Patient record documentation shall include wattage and total joules, confirmation of the laser safety timeout, patient safety considerations (eye wear and skin prep) and anesthesia precautions.

## Incidents

Any incident including fire, inadvertent patient or personnel harm by the therapeutic laser use must be reported through the Quality Reporting Process ([Medical Center Policy 0132](http://www.healthsystem.virginia.edu/documentation/manuals/mc/0132TheQualityReportingProcess.pdf)). Incidents should be noted of personnel not following safety procedures, not applying smoke evacuators properly, not wearing masks, or refusing to wear or use safety glasses of the proper OD and wavelength.

# *TRAINING*

Health Care Personnel authorized to be present during the use of HCLS must be aware of the dangers involved. Participation in a laser training course is a prerequisite before any laser use.

Any practitioner who uses a laser must be qualified in laser usage. This qualification is based on proof of adequate basic laser knowledge acquired from an appropriate training course as specified in Appendix C of ANSI Z136.3. Practitioners must keep current by participation in continuing education courses, credentialed and granted laser privileges through the Clinical Staff Office.

# **EMERGENCY PHONE NUMBERS**

Fire and Medical Emergencies 924-2012

Police 9 + 911

Laser Safety Designee *[insert #]*

Occupational Health Services 924-2013

Hospital Emergency Room 924-2231

Clinical Engineering 924-2391

Office of Environmental Health and Safety 982-4911

Office of Patient Safety & Risk Management 924-5595

Marianne Yencken, Laser Safety Officer 243-1725

# **EMERGENCY PROCEDURES**

Consult the University of Virginia Medical Center *Safety & Security Operational Plan & Guide* (available at: <http://www.healthsystem.virginia.edu/docs/manuals/policies/SafetySecurityPlan>)

and the Safety Manual (Unit Red Book) prepared for the department.

All Emergencies and/or accidents must also be reported immediately to the Office of Patient Safety and Risk Management and the Laser Safety Officer.

# **VALIDATION AND HISTORY FOR LASER SAFETY MANUAL**

I hereby certify that I have reviewed the contents of this manual and that it reflects current operating policy for the *[facilities supervised]* located in *[location].*

Departmental Authorized Agent

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Laser Safety Officer

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**History of Manual’s Creation**

Date Created: *[Insert Date Here]*

Author: *[Name]*

# **APPENDIX A: FLOOR DIAGRAM(S)**

(Provide a floor diagram for appendix. A hand drawn plan is sufficient. Be sure to include location of the laser, doors, windows, and any other feature relevant to laser safety.)

**FLOOR DIAGRAM(S) FOR** *[Building Name, Room #]*

# **APPENDIX B: EXAMPLES OF PROPER LASER SIGNAGE**

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# **APPENDIX C: LASER SAFETY TIME-OUT CHECKLIST**

|  |  |
| --- | --- |
| Laser Safety Checklist / Time Out | Action |
| **GENERAL LASER SAFETY STEPS** |  |
| Complete Laser Manufacturer’s Start-Up requirements per manufacturer’s operating manual |  |
| Electrical Cords inspected |  |
| Appropriate Laser Signage on all entrances |  |
| Cover Windows and reflective surfaces |  |
| Staff Eye Protection: Surgeon(s) |  |
| Staff Eye Protection: Support Staff(s) |  |
| Glasses Inspected upon Distribution |  |
| Non-Reflective Instruments |  |
| Laser retardant drapes |  |
| **AREA SPECIFIC PRECAUTIONS** |  |
| Patient laser safety eye protection |  |
| Laser Masks |  |
| Smoke Evacuator |  |
| Rectal Pack |  |
| Check Fiber Integrity |  |
| Cover Fiber Tip Hand Piece |  |
| One Equipment Foot Pedal Access |  |
| **FIRE SAFETY STEPS** |  |
| Fire Extinguisher |  |
| Basin of water or saline |  |
| Wet Towels/4x4s at Surgical Site |  |
| Non-Flammable Prep |  |
| **DOCUMENT TIME-OUT CHECKLIST COMPLIANCE IN PATIENT RECORD** |  |

1. **MPE**: The level of laser radiation to which a person may be exposed without hazardous effects or adverse biological changes in the eye, or skin. The criteria for MPE for the eye and skin are detailed in ANSI Z136.1. [↑](#footnote-ref-1)
2. **NHZ**: The space within which the level of the direct, reflected, or scattered radiation during normal operation exceeds the applicable MPE. Exposure limits beyond the boundary of the NHZ are below the appropriate MPE level. [↑](#footnote-ref-2)
3. **O.D.**: A protection factor assigned to eyewear for a specific wavelength. Generally, it is recommended that engineering controls be employed rather than relying solely on protective eyewear. O.D. is defined as the logarithm to the base ten of the reciprocal of the transmittance: *Dλ = -log10 τλ, where τλ is transmittance at the wavelength λ.* [↑](#footnote-ref-3)