

DUKE UNIVERSITY
DUKE UNIVERSITY MEDICAL CENTER

Laser Safety Policy



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1. Laser Safety Program Elements

1.1 Abbreviations Used

ANSI Z136.1 – American National Standards Institute Z136.1-2000 (or latest version thereof)
Standard for the Safe Use of Lasers

ANSI Z136.3 – American National Standards Institute Z136.3-2005 (or latest version thereof) *Safe Use of Lasers in Health Care Facilities*

CFR – Code of Federal Regulations

CW – Continuous wave laser (laser operating with continuous output for more than 0.25 seconds)

DU – Duke University

DUMC – Duke University Medical Center

GCFI – Ground Fault Interruption Circuit

IEC – International Electrotechnical Commission. This group establishes standards for the safe use of lasers that are similar to the ANSI Z136 series of standards and which, like the ANSI standards, are recognized by the various U.S. government agencies regulating laser use in this country

IR – Infrared light (> 760 nm wavelength)

LO – Laser Operator

LSC – Laser Safety Committee.

LSM – Laser Safety Manager

MPE – Maximum Permissible Exposure, i.e. the laser radiation level to which a person can be exposed without hazardous effect or adverse biological changes in the eye or skin.

MSDS – Material Safety Data Sheet

OESO – Duke Occupational and Environmental Safety Office

OSHA – Occupational Safety and Health Administration

PLU – Principal Laser User

RSO – Radiation Safety Officer and Director of the OESO Radiation Safety Division

SOP – Standard Operating Procedure

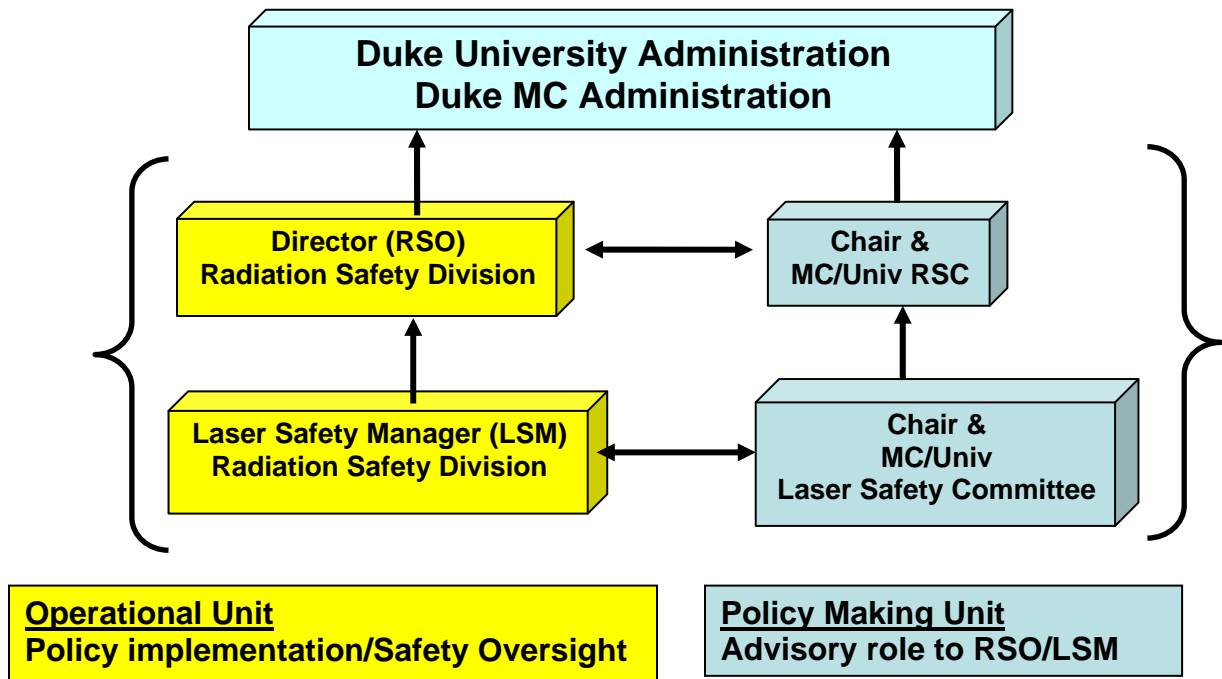
UV – Ultraviolet light (100 – 400 nm wavelength)

1.2 Purpose

The Duke University laser safety policy is based on the recommendations of ANSI Z136.1 and the applicable federal and state regulations. The laser safety program's primary objective is to ensure that no laser radiation in excess of the MPE reaches the human eye or skin. This program is also intended to ensure adequate protection against laser-related non-beam hazards.

1.3 Roles and Responsibilities

1.3.1 Laser Safety Program Oversight Organizational Chart



1.3.2 Laser Safety Committees (LSC)

While the two institutional Radiation Safety Committees are ultimately responsible for laser safety oversight, two LSCs, one for Clinical Use and another for Research Use, directly oversee the laser safety programs at Duke. Each LSC is a subcommittee of the corresponding Radiation Safety Committee (see the *Radiation Safety Manual for Duke University and Duke University Medical Center*). Each LSC consists of the Committee Chairman, the LSM, laser users, management representatives, persons knowledgeable in laser safety and/or laser technology, and others as needed. The LSCs' responsibilities include:

- Establish and maintain internal policies/procedures to ensure they comply with applicable regulations and standards.
- Resolve conflicts or issues identified by the LSM, laser users, or other parties.
- Perform annual program reviews.
- Maintain an awareness of all applicable new or revised laser safety standards.

1.3.3. Radiation Safety Officer (RSO)

The RSO has the responsibility to establish, monitor, and enforce control of laser hazards and is responsible to the Radiation Safety Committee and LSC for the laser safety program's management and administration. The RSO designates the LSM.

1.3.4 Laser Safety Manager (LSM)

The LSM is designated by the RSO. The LSM's responsibilities include:

- (a) Administer the day-to-day operation of the Laser Safety Program.
- (b) Maintain a current inventory of Class 3b and 4 lasers.
- (c) Function as liaison between PLUs and the LSCs.
- (d) Accompany outside inspectors/regulators on laser safety inspections.
- (e) Perform laser hazard analyses and audits; ensure, by follow up and additional audits as necessary, that all laser safety deficiencies are addressed and resolved.
- (f) Make recommendations to improve laser safety.
- (g) Restrict or terminate use of lasers that present an imminent danger or excessive hazard.
- (h) Ensure the availability of proper laser safety training.
- (i) Make recommendations for selection of proper personnel protective equipment.
- (j) Investigate laser accidents and near misses.
- (k) Update laser safety policy and procedures as needed.
- (l) Review, approve, and maintain a copy on file of all laser SOPs.
- (m) Review, approve, and maintain a copy on file of all Non-Clinical Laser Laboratory Pre-Operational Checklists; coordinate with the responsible PLU to ensure compliance prior to approval.
- (n) Review, approve, and maintain a copy on file of all Non-Clinical Laser Laboratory Authorizations; coordinate with the responsible PLU to ensure compliance prior to approval.
- (o) Ensure maintenance of laser user's most recent laser safety training records until that user is no longer involved with laser use at Duke.
- (p) Provide periodic reports on the status of laser safety to the LSC and RSO, and promptly inform the RSO of any serious laser safety concerns.

1.3.5 Principal Laser User (PLU)

Every class 3b or 4 laser system on site must be assigned to a PLU. If no PLU has been formally identified for a particular laser/laser system, the Departmental Chairman may designate a PLU, and inform the LSM of the designation. The PLU's responsibilities include:

- (a) Planning and implementation of all safety measures required for safe laser operation for all lasers under their control, and prior to introducing additional laser equipment to their area.
- (b) Complete a Laser Registration Form for each Class 3b or 4 laser and send the form(s) to the LSM.
- (c) Prior to non-clinical use of a Class 3b or 4 laser, complete and obtain the LSM's approval signature on a Laser Laboratory Pre-Operational Checklist. This checklist is available on the OESO Laser Safety Web Site.

- (d) For every non-clinical area using class 3b and 4 lasers under the PLU's control, complete and submit to the LSM a Non-Clinical Laser Laboratory Authorization form (available on the OESO web site). Coordinate with the LSM to obtain approval of the Non-Clinical Laser Laboratory Authorization before operating a Class 3b or 4 lasers for non-clinical applications. Resubmit each Non-Clinical Laser Laboratory Authorization to the LSM for renewal every four years, or upon major changes (e.g. room relocation, different laser types, etc.) to the laser laboratory.
- (e) Post a written SOP (as described in section 9 of this Policy) in a location readily available to laser operators, for all unenclosed Class 3b and 4 lasers; ensure compliance with the SOP. Provide a current copy of the SOP to the LSM and obtain LSM approval for the SOP before operation of the laser.
- (f) Supervise the safe use of lasers in the laser environment.
- (g) Ensure that all lasers under his/her control are properly classified and labeled.
- (h) Establish and maintain a current list of those personnel approved to operate specific types of Class 3b or 4 lasers under their supervision and provide a copy of the list to the LSM.
- (i) Complete the applicable OESO Laser Safety course at the interval specified in this Manual.
- (j) Immediately notify OESO in the event of a suspected overexposure to the output beam from a Class 3b or 4 laser.
- (k) Ensure that safety controls are not disabled, removed, or modified without written authorization from the PLU, and notify the LSM immediately of any changes in the status of safety controls.
- (l) Notify the LSM of any OEM lasers (i.e. lasers that do not comply with all requirements of the Federal Laser Product Performance Standard, e.g., warning labels, interlock shutter, etc. because they are designed for incorporation into larger devices) that the PLU is using in an open beam configuration.
- (m) Ensure the safe and responsible disposition of their unneeded, but potentially hazardous, class 3b or 4 lasers and laser components. See chapter 3 for a list of appropriate disposal options.

1.3.6 Laser Operator (LO)

Only a PLU or an LO may operate a Class 3b or 4 laser. Each LO must work under the supervision of a PLU. LO responsibilities include:

- (a) Complete the applicable OESO Laser Safety course, before operating a Class 3b or 4 laser and again at the interval specified in this Policy manual.
- (b) Use lasers safely.
- (c) Comply with established policy, SOPs and other procedural requirements.
- (d) Promptly report to the PLU any malfunctions, problems, accidents, or injuries, which may have an impact on safety.
- (e) Do not disable, remove, or modify any safety control systems without prior written approval from the PLU.

1.3.7 Escalated Enforcement Policy

(a) Purpose

This section specifies the actions of the Radiation Safety Officer (RSO) and the Research Use Laser Safety Committee to correct specific items of non-compliance, ensuring that laser users work with the RSO and the Committee to maintain safety and compliance. This enforcement policy does not apply to patient care areas. Instead, for these areas, the RSO will work with the Division Director or Departmental Chair to resolve any uncorrected compliance issues.

(b) Enforcement Process

- i. Radiation Safety staff will provide the PLU with written notification of any items of non-compliance discovered in that PLU's area of responsibility. If appropriate, Radiation Safety staff may request a written response from the PLU regarding corrective measures for any items of non-compliance discovered during routine laser laboratory audits. Any such written response shall be provided by the PLU to the auditor on or before the date specified in the written notification.
- ii. Documented compliance issues should be resolved between the PLU and the RSO or his/her designee.
- iii. If routine Radiation Safety staff surveys show a repeat violation (i.e. same item cited on last inspection) or other pattern of multiple violations, the PLU must, within one week of notification, send the Radiation Safety Officer a brief written explanation of:
 - what caused the item(s) of non-compliance,
 - steps taken to date by the PLU to correct the item(s),
 - further steps to be taken by the PLU, and
 - measures the PLU took or will take to prevent recurrence.
- iv. If the PLU has not achieved compliance to the Radiation Safety Officer's satisfaction within one week of notification, the Radiation Safety Officer and the PLU will discuss the matter with the PLU's Departmental Chair or Faculty Dean, or other representative of the Institutional Administration as appropriate.
- v. If satisfactory resolution still cannot be obtained, the matter will be escalated to the Research Use Laser Safety Committee and, if necessary, senior Institutional Administration.

(c) Enforcement Options

i. Radiation Safety Intervention

The RSO is authorized to immediately order the termination or limitation of any procedure or other laboratory activity that in his/her professional opinion constitutes an immediate danger to life, health, property, or the environment. The RSO is also authorized to order the termination or limitation of any procedure or laboratory activity of a PLU who willfully violates the Duke Laser Safety Policy. Such intervention may include, but is not necessarily limited to, the suspension of laser use, the withholding of pending deliveries of lasers and the disabling of lasers (e.g. by confiscation of the laser

on/off switch key). The RSO will notify the PLU, the chair of the Research Use Laser Safety Committee and appropriate senior management.

ii. Restriction and Revocation

- The Chairman of the Research Use Laser Safety Committee may, upon the RSO's recommendation, restrict the authority of a PLU as a result of repeated or serious violations of Duke University/Medical Center policy. Radiation Safety staff must immediately notify the PLU, the PLU's Departmental Chair or Faculty Dean, and the appropriate Institutional Administrators of any restriction and of the reason for that restriction.
- Such restriction remains in effect until review by the Research Use Laser Safety Committee either reinstates, modifies, or revokes the restricted privileges by a majority vote.

2. Laser Classification

All lasers and laser systems in the U.S. are categorized into one of several hazard classes. Corresponding labels affixed to the laser or laser system positively identify the class. These laser classifications are detailed in ANSI Z136.1, ANSI Z136.3; the Federal Laser Products Performance Standard, 21 CFR 1040.10 and 1040.11; and the International Electrotechnical Commission (IEC). See Appendix B for a summary of the classification schemes of these three organizations. The manufacturer provides the classification for most lasers. For custom-built and modified lasers, the LSM can assist with classification.

2.1 Class 1

- Do not emit harmful levels of radiation during normal operation.
- Also includes higher class lasers completely enclosed and interlocked to prevent beam access, allowing a Class 1 laser system designation; any time the higher class laser is accessible (e.g. during alignment or servicing), the higher laser class controls must be observed.
- Can be used without restriction in the manner intended by the manufacturer and without special operator training or qualification.

2.2 Class 2

- Emit accessible laser light in the visible wavelength region.
- Capable of creating eye damage through chronic exposure.
- In general, the human eye will blink within 0.25 second when exposed to Class 2 laser light; this blink reflex provides adequate protection.
- Can be used without restriction in the manner intended by the manufacturer and without special operator training or qualification.

2.3 Class 3a

- Normally not hazardous when viewed momentarily with the unaided eye, but may pose severe eye hazards when viewed through collecting optics (e.g., microscopes and binoculars).
- Power levels 1-5 milliwatt (mW).
- Same controls as Class 1 and Class 2 lasers for normal operations; if viewed through optical instruments (e.g., binoculars, telescopes, or microscopes), contact the LSM for a hazard review.

2.4 Class 3b

- Will cause injury upon direct viewing of the beam and specular reflections.
- Power output 5-500 mW for CW or less than 0.03 joule (J) for a pulsed system (i.e. pulse width less than 0.25 second).
- Must implement specific control measures covered in this chapter.

2.5 Class 4

- Includes all laser systems with power levels greater than 500 mW CW or greater than 0.03 J for a pulsed system.
- Pose eye hazards, skin hazards, and fire hazards. Viewing the beam or specular reflections or exposure to diffuse reflections can cause eye and skin injuries.
- All control measures explained in this document must be implemented.

2.6 Embedded Lasers

Lasers are often embedded in laser products or systems with a lower hazard class. When the laser system is used as intended, the controls for the system's class apply. When the system is opened (e.g. for service or alignment) and the embedded laser beam is accessible, a temporary control area must be established. The controls for the temporary control area must be based on the classification of the embedded laser. The user and LSM must determine adequate controls. Confirmation of a system classification is the responsibility of the LSM, and therefore necessitates registering the system. An abbreviated SOP may be required, as in the case of such commercially available enclosed laser systems as a laser scanning confocal microscope.

2.7 IEC Classification Scheme

The IEC has established a hazard classification scheme similar to that described in this section, but with some minor differences. Laser products encountered at Duke may be labeled using this alternate system. Laser systems bearing the IEC 1M, 2M, or 3R classification require the same control measures as Class 3a lasers. See Appendix B [Summary of Laser Hazard Classification Schemes] for further information regarding these laser classification schemes

3. Laser Acquisition, Transfer, and Disposal

Notify the LSM of any decision to purchase, fabricate, or otherwise acquire a Class 3b or Class 4 laser. The LSM will review with the user the hazards of the proposed operation and make recommendations regarding the specific safety requirements that pertain to the proposed use, including requirements for SOPs, laser control areas, training, and personnel protective equipment. Also notify the LSM of any class 3b or 4 laser or laser system relocated, transferred to another PLU or institution, or sent offsite as surplus equipment.

Laser users have an obligation to ensure safe and responsible disposition of their unneeded, but potentially hazardous, class 3b or 4 lasers and laser components. Appropriate means of laser disposal include:

- Donate the laser to an organization (e.g. school, industrial company, hospital) with a need for such a device. The donor should ensure that the donated laser system complies with all applicable product safety standards, such as the Federal Laser Product Performance Standard, and is provided with adequate safety instructions for operations and maintenance. The donor should also verify that the receiving organization has a viable laser safety program.
- Return the laser to the manufacturer, or to a vendor specializing in re-selling used laser equipment.
- Eliminate the possibility of activating the laser by removing all means by which it can be electrically activated. Once this has happened the laser could then be discarded.
- Destroy the laser.

The last two methods also require proper disposal of any hazardous materials found inside the laser components, such as mercury switches, oils, dyes, etc. Users should contact the LSM if they need further information or assistance with proper disposal.

4. Laser Hazard Control Measures

4.1 Controls for Class 1, 2, and 3a Lasers

- Class 1, 2, and 3a laser beams may not be intentionally directed at a law enforcement officer or the head or face of another person, except for:
 - law enforcement purposes by police, or
 - medical use by authorized medical personnel.
- Class 3a laser beams must not be viewed with collecting optics (e.g. microscopes) unless the optical system is specifically designed and constructed to prevent eye exposure exceeding the applicable MPE.
- Otherwise, no other specific laser safety requirements apply to Class 1, 2, and 3a lasers.

4.2 Controls for Class 3b and Class 4 Lasers

Class 3b and Class 4 lasers may be operated only in designated laser control areas, including operative suites, patient treatment rooms and patient examination rooms, or in other laser control areas approved by the LSM. The purpose of laser control areas is to confine laser hazards to well-defined spaces that are under the control of the laser user, thereby preventing injury to those visiting and working near the control area. All personnel authorized to enter a Class 3b or Class 4 laser controlled area shall be appropriately trained, and must follow all applicable administrative and operational controls.

4.2.1 Posting

The area must be posted with appropriate warning signs that indicate the nature of the hazard. The wording on the signs will be specified by the LSM and conform to the ANSI Z136.1 guidelines. Such signs shall be posted at all entrances to the laser control area during the time a procedure utilizing the active beam is in progress, and shall be removed when the procedure is completed. In addition, an SOP approved by the LSM must be posted in a location readily available to laser operators.

4.2.2 Authorization

Only personnel who have been authorized by the PLU may operate the laser. Personnel may be authorized upon completing the applicable OESO laser safety training. The PLU may stipulate additional authorization requirements. For Non-Clinical Applications, Class 3b and 4 lasers may only be operated upon the LSM's approval of the responsible PLU's applicable Non-Clinical Laser Laboratory Authorization.

4.2.3 Beam Stop

All laser beams, other than those applied to tissue for surgical or therapeutic purposes, must be terminated at the end of their useful paths by a material that is non-reflective and (for class 4 lasers) fire resistant.

4.2.4 Eye Protection

Laser protective eyewear of adequate optical density and threshold limit for the beams under manipulation must be provided and worn at any point where laser exposure could exceed the MPE. This includes provision and use of M-rated eyewear in labs using unenclosed class 3b or 4 laser systems capable of <1 ns pulses, and R-rated eyewear in labs using unenclosed class 3b or 4 Q-switched laser systems (see Appendix D for further information). In addition:

- (a) Procedures and practices must ensure that optical systems and power levels are not adjusted upstream during critical open beam operations, such as beam alignment.
- (b) In clinical use, patients must also be provided with eye protection. If the patient is conscious or under conscious sedation, appropriate protective eyewear is to be used. If the patient is under general anesthesia, the eyes are to be protected with wet gauze pads or similar non-flammable material.
- (c) The need for laser eye protection must be balanced by the need for adequate visible light transmission. It is the responsibility of the PLU to obtain appropriate laser protective eyewear. For assistance in selecting laser eye protection, contact the LSM. The LSM can assist the user in determining the proper parameters of such eyewear, and can provide contact numbers for vendors.
- (d) Laser eye protection should be inspected periodically to ensure that it is in good condition. Damaged or faded eyewear must be removed from service.

4.2.5 Light Containment

Laser light levels in excess of the MPE must not pass the boundaries of the control area. All windows, doorways, open portals, and other openings through which light might escape from a laser control area must be covered or shielded in such a manner as to preclude the transmission of laser light. Where feasible, the laser user is required to keep all laser beams within the operating field, on the optical table or within the experimental envelope at all times. To maintain this control it is essential to be aware of all beams, including stray beams and/or reflections, and to terminate them with beam stops at the end of their useful paths. When a beam traverses to other tables or across aisles, the beam must be enclosed or the access to the aisle must be blocked to prevent personnel from exposure to the beam. Lasers should be mounted so that the beam path is not at eye level for standing or seated personnel. Special rules apply for outdoor use and laser control areas that do not provide complete containment. Contact the LSM for details.

4.3 Additional Controls for Class 4 Lasers

Only appropriately trained personnel may enter a Class 4 laser controlled area during the time a procedure utilizing the active beam is in progress. All personnel within the control area must be provided with appropriate protective equipment and are required to follow all applicable administrative controls. Class 4 laser control areas must meet all of the requirements that apply to Class 3b control areas and also the following requirements:

4.3.1 Rapid Egress and Emergency Access

There must be provisions for rapid egress from a laser control area under all normal and emergency conditions. Any control area interlock system must not interfere with emergency egress. In addition, access control measures must not interfere with the ability of emergency response personnel (fire, paramedical, police) to enter the laser control area in the event operating personnel become injured or incapacitated.

4.3.2 Laser Activation Warning Systems and Entry Controls

Procedural area or entryway controls must be in place to prevent inadvertent entry into a laser control area, or inadvertent exposure to the active laser beam. These measures should include:

- (a) a visible sign or audible warning sign or signal must be at the entrance to the control area to indicate when the laser is energized and operating;
- (b) provision of personnel with proper training and laser protective eyewear;
- (c) doors or blocking curtains/barriers that attenuate the laser beam to below the MPE at the entranceway.
- (d) Entryway control (e.g. interlocks, shutters, illuminated “Laser On” warning signs, barrier curtains) shall be checked periodically to verify proper operation
- (e) If entryway controls must be disabled for any reason, administrative and procedural controls providing the same level of protection must be instituted prior to the operation of the laser or laser system. Any such changes to entryway controls and alternate control measures must be pre-approved in writing by the PLU and communicated to all personnel working in the laser area. The PLU and all personnel in the laser area must also be notified upon restoration of the entryway controls.

The results of a formal hazard evaluation by the LSM may require more rigorous entryway controls to be put into place, depending upon the level of the hazard. These may include door interlocks or other entryway safety controls.

Locking entryway doors as a means of access control is not acceptable, because it is contrary to the principle of permitting rapid egress or emergency access (see 2.2.1 above).

4.3.3 Key Switches

For those laser systems equipped with a key switch to prevent unauthorized use, the key must not be left in the switch when the laser system is unattended.

4.4 Temporary Laser Control Areas

Temporary laser control areas can be created for the servicing and alignment of embedded lasers, enclosed lasers, and in special cases where permanent laser control areas cannot be provided. They are subject to the normal SOP approval process.

4.5 Special Requirements for Invisible Laser Beams

Since IR and UV laser beams are not within the boundaries of normal human vision, they possess a higher hazard potential than visible light lasers. Because of the invisible nature of the optical radiation, the use of laser eyewear that will protect against worst-case exposures is required at all times.

4.5.1 Infrared Lasers

Infrared laser beams (> 700 nm), other than those applied to tissue for surgical or therapeutic purposes, must be terminated by a highly absorbent, non-specular backstop. Note that many surfaces that appear dull are excellent IR reflectors and would not be suitable for this purpose. Class 4 IR laser beam terminators must be made of a fire-retardant material, or of a material which has been treated to be fire-retardant.

4.5.2 Ultraviolet Lasers

UV radiation causes photochemical reaction in the eyes and the skin, as well as in materials that are found in laboratories. The latter may cause hazardous by-products such as ozone and skin-sensitizing agents. The direct beam and scattered radiation should be shielded to the practical maximum extent to avoid such problems. The use of long-sleeved coats, gloves, and face protectors is recommended. Some medications, including tetracycline, doxycycline, tricyclic antidepressants, and methotrexate, can increase a person's risk to UV radiation. Contact the LSM for more information about this subject.

4.6 Substitution of Alternate Control Measures

Upon documented review by the LSM, the engineering control measures recommended by ANSI Z136.1 for Class 3b and Class 4 lasers or laser systems may be replaced by administrative or other alternate engineering controls that provide equivalent protection. Approvals of these controls are subject to the same review procedure as described in this chapter.

5. Laser Safety Training

5.1 Initial Training

All employees who use Class 3b or Class 4 lasers must complete the appropriate OESO Laser Safety course. Non-Medical laser users must complete the “Laser Safety – Non Clinical Use” course. Healthcare laser users and those nursing and ancillary personnel working in operative or treatment areas during healthcare laser use must complete the appropriate application-specific laser safety course. All of these laser safety courses are available on-line on the OESO Web site or, upon request, by classroom instruction through the LSM.

5.2 Visitors

Guests of DU/DUMC requesting to use or observe Class 3b or Class 4 lasers must contact the LSM regarding the training requirement for non-Duke personnel. New employees and guests may use lasers under the direct supervision of a PLU until completing the training requirement.

5.3 Laser-specific Training

Laser users are also responsible for knowing the safety requirements that apply to their specific laser or laser system and for knowing the contents of the applicable SOP.

5.4 Update Training

Laser users must periodically retake the applicable OESO laser safety course.

(a) Research (non-medical) users: retraining interval not to exceed two years

(b) Healthcare laser users:

- Physicians with Laser Privileges: comply with applicable Credentialing training requirements
- All others: annual retraining interval

6. Laser Related Non-Beam Hazards & Control Measures

While beam hazards are the most prominent laser hazards, other hazards pose equal or possibly greater risk of injury or death. These hazards must be reviewed by the LSM and addressed by the PLU in the SOP for the laser operation where applicable.

6.1 Electrical Hazards

Some lasers use high-voltage power supplies, large capacitors, or capacitor banks that present a lethal shock hazard. Additional hazards of electrical equipment include resistive heating and ignition source. Electrical safety controls include:

- (a) OSHA [29 CFR 1910 S] requires additional controls and training for work on live circuits operating a more than 50 volts; note also that capacitors maintain a lethal charge even in de-energized and unplugged equipment. Use extreme caution if servicing laser power supplies.
- (b) Review and comply with the Electrical Safety chapter of the Duke University Safety Manual.
- (c) Check the condition of electrical insulation and ensure that electrical terminals are covered; repair or replace damaged equipment.
- (d) Ensure good equipment grounding (i.e. chassis/frame resistance to ground limited to a few ohms).
- (e) Follow good wiring practices (e.g. use GFCI outlets, no wires on the floor, no overloaded circuits, etc.).
- (f) Use equipment only for its intended/designed purpose.
- (g) Keep equipment “power up” warning lights clearly visible.

6.2 Laser Dyes

Dyes used as the optically active medium in some laser are often toxic and/or carcinogenic chemicals dissolved in flammable solvents. This creates the potential for personnel exposures above permissible limits, fires, and chemical spills. For each dye used, the PLU must have the MSDS available for staff review and in general ensure compliance with applicable Duke policies governing hazardous chemical use and disposal (see the DU Laboratory Safety Manual).

6.3 Compressed Gases and Cryogenics

Hazardous gases may be used in laser applications; i.e. excimer lasers (fluorine, hydrogen chloride). Cryogenic fluids are used in cooling systems of some lasers. The SOP should contain references for the safe handling of compressed gases. See the applicable section of the Duke Laboratory Safety Manual for further guidance.

6.4 Laser Generated Air Contaminants

Air contaminants may be generated when Class 3b and Class 4 laser beams interact with matter. When target irradiance reaches a threshold of about 10^7 W/cm², target materials including plastics, composites, metals, and tissues may liberate toxic and noxious airborne contaminants. Generally, the PLU must ensure that any laser operation that creates visible smoke or plume has adequate local exhaust ventilation in place and included in the SOP; respiratory protection is not an acceptable alternative to local exhaust ventilation. If, in addition to local exhaust ventilation, respiratory protection is required or worn voluntarily, consult the Duke Respiratory Protection Policy in the Duke University Safety Manual.

6.5 Plasma Radiation

Interactions between very high power ($\sim 10^{12}$ W/cm²) laser beams and target materials may produce a *plasma*, which in turn generates "blue light" and UV emissions that pose an eye and skin hazard. Similarly, targets heated to very high temperatures (e.g. in laser welding and cutting) emit an intense light. The PLU must ensure adequate control measures are in place and addressed in the SOP for such operations.

6.6 UV and Visible Radiation

Laser discharge tubes and pump lamps may generate sufficient UV and visible radiation to pose an eye and skin hazard. To address this issue, maintain the integrity of the laser housing and avoid operating any laser with the housing removed.

6.7 Explosion Hazards

High-pressure arc lamps, filament lamps, and capacitors may explode if they fail during operation. Keep these components enclosed in the laser housing, which will withstand the maximum explosive forces that may be produced. Laser targets and some optical components also may shatter if heat cannot be dissipated quickly enough. Ensure adequate mechanical shielding when exposing brittle materials to high intensity lasers.

6.8 Ionizing Radiation (X-rays)

X-rays could be produced from two main sources: high voltage vacuum tubes of laser power supplies such as rectifiers and thyratrons and electric discharge lasers. Any power supplies that require more than 15 kilovolts may produce enough x-rays to be a health concern. Consult Radiation Safety for review and control of such hazards.

7. Medical Surveillance

Personnel working with Class 3b and/or Class 4 lasers or laser systems are not required to obtain either a pre- or post-employment medical examination specific to laser use. Following any suspected laser injury, employees must report to a supervisor and the Employee Occupational Health & Wellness if they believe that they have been injured.

8. Laser Accidents

8.1 Immediate Response and General Procedures

8.1.1 General Laser Accident Reporting

Laser users must report all laser accidents on site, no matter how minimal, to the PLU responsible for the laser system involved. The PLU must report any accidents causing injury or property damage to the LSM. If immediate assistance from the LSM is required, dial 911 (on DU & DUMC sites), indicate to the Duke Police that a laser accident has occurred, and direct them to notify the Radiation Safety On Call contact person, who will contact the LSM to respond to the situation.

8.1.2. Known or Suspected Laser Overexposure

If a known or suspected overexposure to laser radiation occurs within DU or DUMC:

- (a) Seek medical care for the individual(s) exposed without delay from Employee Occupational Health and Wellness (EOHW), located in Duke Hospital South and open between the hours of 8:00 AM and 5:00 PM. If an incident occurs outside the operating hours of EOHW, seek assistance from the Emergency Department. Take all seriously injured persons directly to the Emergency Department.
- (b) Notify the supervisor of the injured individual(s) to ensure action is taken to prevent any further injury to other personnel. The supervisor shall notify the LSM within 24 hours after the initial reporting of the incident. The LSM will inform OESO and other relevant personnel of actions being taken or required as part of the medical investigation.
- (c) Complete an injury report form (AO-16).

8.2 Laser Accidents in Duke University Hospital

In addition to the general procedures outlined in Section 8.1, the following actions will also be undertaken if a laser accident occurs in Duke University Hospital.

8.2.1 Occurrence Reporting

- (a) Notify Risk Management immediately of any incident involving serious injury (i.e. life threatening, resulting in permanent impairment of a body function or permanent damage to a body structure, or necessitating medical or surgical intervention to preclude such impairment or damage) to a patient or visitor. Contact Risk Management at:
Telephone: 684-3277 (8 AM - 5 PM, Monday - Friday)
Risk Manager on-call pager: 970-2404 (evenings, nights, weekends, & holidays)
- (b) If laser equipment is involved, maintain all control settings, if possible, when discontinuing use of the equipment and notify Clinical Engineering and OESO Radiation Safety Division for assistance with equipment evaluation. If settings cannot be maintained, document the settings prior to discontinuing use (if possible within safety limits) and include those settings in the occurrence report.
- (c) Risk Management will coordinate regulatory reporting and root cause analysis, with the assistance and at the direction of Counsel's office, and in concert with the Office of Accreditation and Patient Safety.

- (d) Report any other occurrence (event not consistent with the standard of care of a patient or safety of a patient, visitor, or volunteer, whether or not injuries are sustained) to the supervisor responsible for the laser system involved.
- (e) For assistance or directions concerning incident documentation, call Risk Management at 684-3277 (8 AM - 5 PM, Monday - Friday) or page the risk manager on-call at 970-2404 (evenings, nights, weekends, and holidays).

8.2.2 Follow-up Procedures by the Laser Safety Manager

The following guidelines describe the initial procedure to be followed by the LSM in the event of a laser accident or incident:

If indicated, the LSM will respond on-site to the department reporting the incident.

The LSM will document the following information for future review:

- (a) Date and time of call.
- (b) Name and department of caller.
- (c) Name of reporting person's immediate supervisor
- (d) Model, serial number, Duke lot number, manufacturer, and nomenclature of device.

The LSM will contact the caller's supervisor to ensure that he/she is informed, and to remind him/her to report incidents to Risk Management via report or telephone (if indicated).

If the accident occurred in Duke Hospital, the LSM will contact Clinical Engineering and instruct them to sequester equipment involved in the incident.

The LSM will notify Risk Management and provide them with complete documentation (if indicated). Risk Management will provide further guidance to the LSM if any is necessary.

After the LSM has verified that the exposed individual(s) have received the appropriate medical care, and that the appropriate administrative personnel have been notified of the incident, the LSM will continue to investigate the circumstances of the accident by obtaining the following information:

- (a) Name(s) of individual(s) alleged or suspected to have been overexposed.
- (b) Laser nomenclature, characteristics and operating parameters at the time of the incident (wavelength, peak and average power, pulse width and frequency, beam diameter and divergence, etc.).
- (c) Date, location, and time of the incident, as well as the duration of the exposure and the individual's position relative to the laser.
- (d) Description of what happened. If possible, obtain a signed brief description from all individuals who have first-hand knowledge of the incident.
- (e) Protective equipment / clothing in use at the time of the accident, and eyewear transmission characteristics at the wavelength of the laser.
- (f) Facility configuration at the time of the event.
- (g) The name and telephone number of the attending physician.

Following the initial reporting of the alleged or suspected overexposure, the LSM will coordinate with appropriate organizations to prepare a detailed report of the incident. This report shall consist of a summary of the estimated exposure, timetable of medical evaluations, recommendations to prevent recurrence of the incident, and discussion of further medical follow-up recommendations.

When requested by Risk Management/Counsel's Office, the LSM shall provide consulting services on laser incident investigations. When investigation services are requested the investigating individual shall adhere to the following procedures:

- (a) Interview the person reporting the incident using the necessary documentation forms.
- (b) Provide all copies of investigation documentation to Risk Management.
- (c) Obtain signature of Risk Management official who receives the information.

9. Standard Operating Procedure (SOP)

The PLU must provide written SOP, approved by the LSM prior to laser use, for all Class 3b and Class 4 laser systems. This SOP must be posted near the laser(s) and include:

- hazard identification and mitigation;
- manufacturer's start up and shut down procedures;
- safe alignment procedures;
- safety procedures;
- protective equipment; and
- emergency procedures.

A general laser SOP template is available via the Duke Laser Safety web site. The use of the template is highly recommended. The template provides a guide for the laser user in identifying the characteristics of the laser operation and collateral hazards, and in formulating set-up and alignment procedures. Clinical and research laser users can also use an interactive "application-specific" on-line template on the OESO Web site. Contact the LSM for assistance in developing control measures and completing the SOP.

In the case of enclosed systems (e.g. laser scanning confocal microscopy) the requirement for an SOP may be reduced or waived entirely after a review by the LSM, who will then determine if which if any SOP sections are required.

All SOPs should be reviewed annually by personnel working with lasers to ensure the accuracy of the procedure(s). If no new hazards have been added to the system, the users can perform the review without notifying the LSM. If new hazards (use of a sub-nanosecond laser system, for example) have been added to the experiment, a review by the LSM is necessary to assure all applicable safeguards have been implemented.

10. Additional Resources

10.1 Glossary (available on line via the OESO web site)

10.2 Standard Operating Procedure (SOP) Template (available on line via the OESO web site)

11. References

- (1) American National Standards Institute (ANSI) Z136.1-2000, American National Standard for the Safe Use of Lasers (or later revision)
- (2) American National Standards Institute (ANSI) Z136.3-2005, American National Standard for the Safe Use of Lasers in Health Care Facilities (or later revision)
- (3) U.S. Department of Labor, Occupational Safety and Health Administration Instruction Publication 8-1.7, "Guidelines for Laser Safety and Hazard Assessment"

APPENDIX A

Use of Lasers Outside of the Clinical or Laboratory Setting

A.1 Introduction

The use of a laser outside of a controlled area can present special hazards. This appendix addresses the control of any Class 3a, 3b, or 4 laser used outside the normal research laboratory or clinical environment. These applications may include; lasers used for telecommunications, laser research being performed outdoors, and lasers used for entertainment or public viewing.

A.2 General Requirements

Any Class 3b, or 4 laser used for entertainment, displays, demonstrations, or any related use intended for public viewing (indoors or outdoors) shall be operated in accordance with federal, state, local, and campus regulations and requirements.*

Any Class 3b, or 4 laser used outdoors for telecommunication applications or for research projects shall be registered with the Laser Safety Manager per the requirements of the Duke Laser Safety Policy.*

The operators of laser systems used for entertainment are required by law to file a “Report on Laser Light Show Display” (or a variance document), with the Food and Drug Administration’s Center for Devices and Radiological Health (FDA/CDRH). No laser light show, display, or device may vary from compliance with 21CFR1040.11(c) in design or use unless an approved Application for a Variance from 21CFR1040.11(c) for a Laser Light Show, Display, or Device has been issued by the FDA per 21CFR1010.4. If the venue is outdoors and the beam(s) may terminate in navigable airspace, then the operators are also required to file a report with the Regional Federal Aviation Administration (FAA) office.

All Class 3a, 3b, or 4 laser systems being used on Duke University property must be used in accordance with the Duke Laser Safety Policy. The Laser Safety Committees must *approve any variation from the Laser Safety Policy.

A.3 Procedures

A.3.1 Laser Light Shows (Indoor or Outdoor)

Duke organizations, departments, or campus affiliated groups (student or otherwise) shall coordinate with Corporate Risk Management on the contracting of outside companies to conduct any laser light show (indoor or outdoor) to be performed on Duke property. Corporate Risk Management will contact the LSM for technical support as needed.

For any light show (indoor or outdoor) conducted by a Duke affiliated entity, that entity must coordinate with the LSM. The LSM will request from the light show operators a copy of the

* The FAA specifies several levels of irradiance; it is not necessary to injure a pilot to disrupt a flight. See App. C for further discussion of outdoor laser use.

required “Report on Laser Light Show Display” (or variance document) prior to the show. Upon receipt, the LSM shall review the description of the show and the operator’s safety procedures. The LSM may require additional safety measures to assure the safety of the operators, performers, or audience. Specific requirements for laser light shows include:

A.3.1.1 The CDRH and ANSI requirements specified by the LSM must be met.

A.3.1.2 Any audience exposure to laser radiation must not exceed the ANSI Class 1 limit.

A.3.1.3 Operators, performers, and employees must be able to perform their duties without having to directly view laser radiation exceeding the ANSI Class 1 limit, and without being exposed to laser radiation exceeding the ANSI Class 2 limit.

A.3.1.4 All laser scanners (including mirror balls) must incorporate proper scanning safeguards.

A.3.1.5 If the laser is not under continuous operator control, any Class 3b, or 4 level of laser radiation cannot be closer than 6 m vertically or 2.5 m horizontally from any standing surface or standing position where the audience may be located.

A.3.1.6 If the laser is under continuous operator control, any Class 3a, 3b, or 4 level of laser radiation cannot be closer than 3 m vertically or 2.5 m horizontally from any standing surface or standing position where the audience may be located.

A.3.1.7 An operator with an accessible control to terminate the beam must be available if conditions become unsafe.

A.3.1.8 FAA notification is required (for Class 3a, 3b, and 4 lasers) if the display is being used in navigable airspace.

A.3.1.9 Additional safety requirements may be needed as specified by the LSM.

A.3.1.10 The CDRH “Report on Laser Light Show Display” forms are available from the LSM.

NOTE: An SOP is not normally required for laser light shows.

A.3.2 Research Projects Involving Outdoor Laser Use

The PLU shall inform the LSM of any lasers used outdoors for research projects. Such laser uses will need to be covered under an SOP approved by the LSM as specified in the Duke Laser Safety Policy. The department will be responsible for informing the LSM of any indoor or outdoor telecommunication applications being pursued by that department. In both cases, the application and operation of the laser system(s) shall be evaluated by the LSM to ensure that appropriate safety measures are in place prior to operation. Specific laser safety requirements for (non-light show) uses of lasers include:

A3.2.1 The PLU must create a written SOP and meet the specified SOP safety requirements.

A.3.2.2 The LSM will establish a Nominal Hazard Zone (any area where the maximum permissible exposure (MPE) is exceeded).

A.3.2.3 The NHZ must be posted and/or restricted as directed by the LSM.

A.3.2.5 The PLU must ensure that only trained personnel enter the NHZ, and that appropriate PPE (personal protective equipment) is issued and used.

A.3.2.6 The PLU must ensure users are properly trained and meet the campus laser safety training requirements.

A.3.2.7 The PLU must ensure only authorized personnel are allowed to operate the laser.

A.3.2.8 The PLU must ensure the use of any required administrative/engineering controls.

A.3.2.9 Laser beams shall not be directed toward structures, automobiles, aircraft, or other vehicles within the NHZ unless adequate training and protective equipment is provided and used by all personnel within these structures/vehicles.

A.3.2.10 The laser beam path shall not be maintained at eye level without LSM approval.

A.3.2.11 FAA notification is required (for Class 3a, 3b or 4 lasers) if the laser is being used in navigable airspace.

A.3.2.12 Additional safety requirements may be needed as specified by the LSM.

A.4 Emergencies

The potential for injuries from a laser light show/display is minimal if the operators observe the CDRH requirements. In the event that an individual suspects an eye injury, the operators of the laser system shall be notified immediately so that the laser beam(s) can be terminated. The event staff shall also be notified and medical attention shall be provided to the injured individual if needed. The LSM shall be informed as soon as possible should any laser injury be suspected. The LSM or his alternate can be contacted at any time by calling 911 and asking for the Duke Radiation Safety Office.

APPENDIX B

Summary of Laser Hazard Classification Schemes

FDA/CDRH 21CFR1040.10	ANSI Z136	IEC/EN 80625
Class I - levels of laser radiation are not considered hazardous	Class 1 – no hazard; exempt from all control measures	Class 1 – no risk, even with viewing instruments Class 1M ^a – no risk except perhaps to eye when viewed through viewing instruments (eye loupes or binoculars)
Class IIa - levels of laser (applies to visible only) radiation are not considered hazardous if viewed ≤ 1,000 seconds but are considered a chronic viewing hazard for any period of time >1,000 seconds	Class 2 – visible (0.4 – 0.7 μm) lasers not considered hazardous for momentary viewing (<0.25 seconds), but for which the Class 1 accessible emission limit may be exceeded for longer exposure durations; avoid prolonged staring	Class 2 – no eye risk for short term exposures, even with viewing instruments; no risk to skin (applies to visible lasers only)
Class II - levels of (visible only) laser radiation considered a chronic viewing hazard		Class 2M ^a – no eye risk for short term exposures, except perhaps with viewing instruments; no risk to skin (visible only)
Class IIIa - levels of laser radiation are considered, 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	Class 3a - with “Caution” label: does not exceed the appropriate irradiance MPE, except perhaps when viewed through collecting optics (e.g. microscopes, telescopes) - with “Danger” label: may exceed the appropriate irradiance MPE	Class 3R ^b – low risk to eyes, no risk to skin
Class IIIb - levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct radiation	Class 3b – emit greater than Class 3a limits and pose an acute eye hazard; more rigorous controls are required to prevent exposure of the unprotected eye	Class 3B – medium to high risk to eyes, low risk to skin
Class 4 - levels of laser radiation are considered an acute hazard to the skin and eyes from direct and scattered radiation	Class 4 – acute eye and skin hazard, plus ignition source (fire) and laser-generated airborne contaminants hazards; strict control measures required	Class 4 – high risk to eyes and skin

- a. The “M” designation in the IEC classification scheme is derived from “magnifying” optical viewing instruments.
- b. The “R” designation in the IEC classification scheme is derived from reduced or relaxed requirements for manufacturers (no key switch or interlock connector required) and users (usually no eye protection required).

APPENDIX C

Additional Considerations for Outdoor Laser Use

A laser need not cause a pilot eye injury to disrupt the normal operation of an aircraft. The FAA identifies three (non-injury) categories of air crew visual impairment:

- **Glare:** dazzling sensation induced by relatively bright light, producing unpleasantness, discomfort, or interference with optimal vision; generally ceases once stimulus removed, but residual effects (spatial disorientation, loss of situational awareness) can persist;
- **Flash blindness:** visual loss during & following exposure to high intensity light flash; may last a few seconds to several minutes; and
- **Afterimage:** persisting sensation or image after stimulus removed.

An FAA study of flight crews in simulators exposed to various levels of laser radiation found that exposure to $\geq 0.5 \mu\text{W}/\text{cm}^2$ causes visual impairment (FAA, 2004). Landing approach is the most critical time, and in fact distractions during this crucial period are limited by law (49CFR121.542, 125.311 & 135.100). To prevent distractions associated with pilot laser exposure, the FAA's Order 7400.2 (Part 6 Chapter 29 "Outdoor Laser Operations") long ago established maximum allowable irradiance levels (flight safe exposure limits) in the area around airports, as follows:

- **Laser Free Zone** – 2 nautical miles (3.7 km) from runway centerline in all directions, plus additional 3 NM along flight path, to 2,000 ft; $50 \text{ nW}/\text{cm}^2$ (distraction)
- **Critical Flight Zone** – 10 NM (18.5 km) from airport center point; $5 \mu\text{W}/\text{cm}^2$ (glare)
- **Sensitive Flight Zone** – (distance established on case by case basis) $100 \mu\text{W}/\text{cm}^2$ (level for significant flash blindness & afterimage)
- **Normal Flight Zone** – $2.5 \text{ mW}/\text{cm}^2$ (exposure $< \text{MPE}$)

Table C.1 indicates the approximate range within which a typical 5 mW red (~680 nm) diode laser pointer (~1 mrad divergence) will exceed the specified FAA exposure limits [based on ANSI Z136.1-2000 NOHD Eq 50].

Table C.1: Approximate Laser Pointer Hazard Distance D (neglecting atmospheric attenuation)

Exposure Limit	D (m)
MPE ($2.5 \text{ mW}/\text{cm}^2$)	~16
SFZ ($100 \mu\text{W}/\text{cm}^2$)	~80
CFZ ($5 \mu\text{W}/\text{cm}^2$)	~356
LFZ ($50 \text{ nW}/\text{cm}^2$)	~3560

Operators of any laser must ensure that the beam is not directed into navigable airspace.

APPENDIX D

Protective Eyewear for Ultrashort Pulsed Lasers

D.1 Executive Summary

Researchers (e.g. Koschinski et al, 1998) some years ago observed induced transmittance in protective filter materials upon exposure to very high irradiances from ns, ps and fs pulsed lasers. This temporary loss of filter material attenuation can negate the protective capability of eyewear and thereby place laser users at risk of injury due to excessive laser radiation exposure. In response, the European Laser Protective Eyewear Standard EN207 has established additional eyewear testing and marking protocols to address this potential hazard. This Standard adds a pulse duration rating to the previously-established “L” attenuation number (which corresponds to the OD of the eyewear) and wavelength, as follows:

- D: rated for continuous wave lasers
- I: rated for “long pulse” lasers (>100 ns)
- R: rated for Q-switched lasers (1 ns to 100 ns)
- M: rated for ps and fs lasers (< 1 ns)

M-rated eyewear recently became commercially available. In addition to meeting the wavelength and OD (“L number”) requirements specified by Duke Laser Safety, provision and use of “M-rated” eyewear should be mandated for all laboratories using unenclosed class 3b or 4 ps and fs pulsed laser systems.

D.2 Technical Basis

Koschinski et al (1998) reported dramatic decreases in the attenuation provided by some glass and polycarbonate laser protective eyewear filter materials exposed to very high irradiances, although the filter material appeared physically undamaged. Increased transmittance was observed for polycarbonate material exposed to irradiances in excess of 4×10^9 W/cm² from a 1064 nm Q-switched (~15 ns pulse duration) Nd:YAG laser. The filter material’s OD dropped by over six orders of magnitude as the irradiance was increased from 4×10^9 W/cm² to 4×10^{11} W/cm², with ablation of filter material beginning around 10^{12} W/cm². Similarly the transmittance of semiconductor doped glass filter material increased upon exposures to 800 nm 250 fs pulse Ti:Sapphire irradiances in excess of 10^{11} W/cm². The OD dropped by five orders of magnitude as the irradiance increased to 10^{12} W/cm². The authors propose an “absorption center” model that accurately predicts this increased transmittance as a function of irradiance for the materials tested.

Several other researchers have confirmed and extended these findings to other wavelengths and filter materials. For example, Schirmacher et al (2005) compared induced transmittance in 11 types of polycarbonate filter materials and three types of glass filters exposed to 50 ns and 200 fs pulses in the 70-800 nm range, finding temporary induced transmittance at irradiances below those that caused any visible damage to the eyewear. These effects are real and have serious implications for users of ultra short pulsed laser systems.

Although US laser safety standards have been slow to react, the European laser safety community has responded to this issue by specifying improved testing and marking requirements for laser protective eyewear. The European Laser Protective Eyewear Standard EN207 adds a “D”, “I”, “R” or “M” pulse duration rating to the previously-established “L” attenuation number (which corresponds to the OD of the eyewear) and wavelength, as noted in section I above.

D.3 References

Koschinski W, Schirmer A, Sutter E. Induced transmittance of eye-protective filters. *J. Laser Appl.*, 10:126-130 (1998).

Schirmacher A, Sutter E, Werhhahn O, Siegner U, Nevenjina-Sturhan A. Investigation of the irradiance-dependent spectral transmittance of laser filters in the nanosecond- and femtosecond-pulse regime in the wavelength range between 700 and 800 nm. *J. Laser Appl.*, 17:191-197 (2005).