The University of Toledo

LASER Safety Manual

Appendix 1 to HM-08-002

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1.0 Purpose

The purpose of this manual is to provide guidance for the safe use of LASERs and LASER systems at the University of Toledo. The intent is to identify hazards, provide recommendations for proper use, and specify training requirements. To achieve these goals the University has adopted the American National Standard for the Safe Use of LASERs (ANSI Z136.1), the American National Standard for Safe Use of LASERs in Health Care (ANSI Z136.3), and the American National Standard for Safe Use of LASERs in Educational Institutions (ANSI Z136.5).

2.0 Scope

This LASER Safety Manual applies to all persons: faculty, staff, vendors, students and visitors operating with or working in close proximity to any LASER or LASER system at the University of Toledo. Specifically, Section 24.0, Research and Instructional LASER Use, of this manual covers the requirements and recommended details that are applicable to all LASERs and LASER Systems used in research and instructional laboratories, classrooms and lecture halls at the University of Toledo. In addition, Section 25.0, Clinical LASER Use, of this manual covers the requirements and recommended details that are applicable to all LASERs used in health care applications for diagnostic, cosmetic, preventive, and therapeutic applications at the University of Toledo.

3.0 Roles and Responsibilities

3.1 LASER Safety Officer (LSO)

The Department of Environmental Health and Radiation Safety of the University of Toledo will designate an individual as the LASER Safety Officer with the authority and responsibility to effect the knowledgeable evaluation and control of LASER hazards, and the implementation of appropriate control measures, as well as to monitor compliance with required standards and regulations. The LSO will

i) Conduct Lab Inspections involved in the use of LASERs in Research Areas, and Site Surveys involved in the use of LASERs in Clinical and Operating Room Areas;
ii) Provide assistance in evaluating and controlling hazards, and with determining the Maximum Permissible Exposure (MPE) in Research and Instructional LASER use areas;
iii) Update the LASER Safety Manual, maintain all records of LASERs and LASER operators, conduct or coordinate LASER safety training, and participate in accident investigations involving LASERs.

The LSO can be contacted through the Department of Environmental Health and Radiation Safety at (419) 530-3600 or the University of Toledo Environmental Health and Radiation Safety website (http://www.utoledo.edu/depts/safety/index.html).

3.2 Medical LASER Safety Task Force

A Medical LASER Safety Task Force shall be established to ensure that faculty, staff and students are provided with information and understand the hazards associated with LASERs and LASER systems with which they may work. The Task Force consists of representatives from key Medical LASER usage areas at the University of Toledo. The LASER Safety Officer (LSO) is an ex-officio member. The Medical LASER Safety Task

Force will meet whenever necessity dictates to discuss LASER safety issues, at least once annually.

3.3 Principal Investigator (PI)

Principal Investigators are responsible for:

i) Immediate supervision of LASERs in the laboratory;
ii) Implementing and enforcing the safety recommendations and requirements prescribed in this manual;
iii) Completion of a LASER Inventory Form (Attachment 5) for each LASER under his/her control or utilized for demonstration, and for forwarding a copy to the LSO in the Department of Environmental Health and Radiation Safety;
iv) Completion of a Standard Operating Procedure (Appendix 6) for each LASER under his/her control or utilized for demonstration, and for forwarding a copy to the LSO in the Department of Environmental Health and Radiation Safety;
v) Providing a copy of the LASER Safety Manual and LASER-specific SOP(s) in the LASER work area;
vi) Completing the University's LASER Safety Training, and verifying that all individuals with possible exposure to LASERs have also completed the training;
vii) Providing and documenting LASER-specific training to LASER operators;
viii) Maintaining a LASER log for recording periods of use, service, maintenance and incidents;
ix) Ensuring that each LASER under his/her control is correctly classified and labeled;
x) Updating the LASER inventory whenever a new LASER is brought into the laboratory, removed from the laboratory or decommissioned;
xi) Notifying the LSO immediately of any exposure beyond MPE to a Class 3 or Class 4 LASER;
xii) Determining, providing, and enforcing the proper protective equipment.

3.4 Operating Room Nurse Manager

The Operating Room Nurse Manager is responsible for:

i) Immediate supervision of LASERs in the OR and Clinical Areas;
ii) Implementing and enforcing the safety recommendations and requirements prescribed in this manual;
iii) Working in coordination with the LSO to complete LASER Inventory Form (Attachment 5) and a Standard Operating Procedure (Attachment 6) for each LASER under his/her control;
iv) Providing a copy of the LASER Safety Manual and LASER-specific SOP(s) for all individuals with possible exposure to LASERs;
v) Completing the University's LASER Safety Training, and verifying that all individuals with possible exposure to LASERs have also completed the training;
vi) Providing and documenting LASER-specific training to LASER operators;
vii) Maintaining a LASER log for each individual LASER recording periods of use and incidents;
viii) Updating the LASER inventory whenever a new LASER is brought into the OR, removed from the OR or decommissioned;
ix) Notifying the LSO immediately of any exposure beyond MPE a LASER;

x) Providing and enforcing the proper personal protective equipment for each OR and Clinical LASER;
xi) Maintaining a written record of Medical Staff credentials; the record must identify the type of LASER and the accessories for which privileges have been granted.

3.5 Research LASER Operators

LASER Operators are responsible for:

i) Conducting all LASER operation in accordance with all laboratory standard operating procedures;
ii) Notifying the PI fully informed of any departure from established safety protocols, to include exposure incident;
iii) Completion of the LASER activity log;
iv) Completing the University's LASER Safety Training.

3.6 LASER Nurse/Technician

The LASER Nurse/Technician is responsible for:

i) Conducting all LASER activity in accordance with corresponding SOPs;
ii) Having no other responsibilities during a LASER procedure other than operating the LASER;
iii) Posting LASER warning signage;
iv) Ensuring that all personnel in the Operating Room are utilizing appropriate PPE, to include Eye Protection;
v) Completion of the LASER activity log;
vi) Notifying the OR Nurse Manager of any departure from established safety protocols, to include exposure incident;
vii) Completing the University's LASER Safety Training.

3.7 Physician

Any Physician who utilizes a LASER or LASER System at the University of Toledo is responsible for:

i) Becoming credentialed for LASER use in clinical applications and surgical procedures through the Medical Staff Office prior to LASER use;
ii) Using the LASER only for its intended purpose within the scope of his/her practice, training and experience;
iii) Being familiar with safe LASER practices to ensure the safety of patients, employees, and the environment.

3.8 Department of Biomedical Engineering

The Department of Biomedical Engineering is responsible for maintaining documentation of LASER service and maintenance for all Health Care LASERs and LASER Systems, regardless of who provided the service or repair; service for any LASER must be provided by the equipment manufacturer, trained technician or trained personnel from the Department of Biomedical Engineering. The Department of Biomedical Engineering is also responsible for inspecting all rental LASERs utilized in the Health Care environment in accordance with medical equipment inspection policies (ME-08-007 and ME-08-008); the vendor must provide a record of LASER maintenance and repair.

4.0 Classifications and Definitions

LASERs and LASER systems are classified according to their capacity to produce injury, and specific controls are then described for each group. LASERs manufactured after August 1, 1976 are classified and labeled by the manufacturer. LASERs are classified according to the following criteria; for more information refer to Attachment 1.

Class 1 LASER system is considered to be incapable of producing damaging radiation levels during operation, and exempt from any control measures or other forms of surveillance.

Class 1M LASER system is considered to be incapable of producing hazardous exposure conditions during normal operation unless the beam is viewed with an optical instrument such as an eye-loupe (diverging beam) or a telescope (collimated beam), and exempt from any control measures other than to prevent potentially hazardous optically aided viewing; and is exempt from other forms of surveillance.

Class 2 LASER system emits in the visible portion of the spectrum (0.4 to 0.7 μm), and eye protection is normally afforded by the aversion response.

Class 2M LASER system emits in the visible portion of the spectrum (0.4 to 0.7 μm), and eye protection is normally afforded by the aversion response for unaided viewing; however, Class 2M is potentially hazardous if viewed with certain optical aids.

Class 3 LASER system (medium-power) may be hazardous under direct and specular reflection viewing conditions, but is normally not a diffuse reflection or fire hazard; there are two subclasses.

Class 3R LASER system is potentially hazardous under some direct and specular reflection viewing condition if the eye is appropriately focused and stable, but the probability of an actual injury is small. This LASER will not pose either a fire hazard or diffuse-reflection hazard.

Class 3B LASER system may be hazardous under direct and specular reflection viewing conditions, but is normally not a diffuse reflection or fire hazard.

Class 4 LASER system (high-power) is a hazard to the eye or skin from the direct beam, may pose a diffuse reflection or fire hazard, and ay also produce LASER generated air contaminations (LGAC) and hazardous plasma radiation.

Terminology commonly used in conjunction with the use of LASERs is contained in the following section; definitions are taken from ANSI Z136.1.

Absorption: Transformation of energy to a different form of energy by interaction with matter. Aperture: An opening, window or lens through which radiation can pass.

Attenuation: The decrease in the radiant flux as it passes through an absorbing or scattering medium.

Average power: The total energy in an exposure or emission divided by the duration of exposure or emission.

Aversion response: Closure of the eyelid, eye movement, papillary constriction or movement of the head to avoid an exposure to a noxious or bright light stimulant. The aversion response to an exposure from a bright, visible, laser source is assumed to occur within 0.25 seconds, including the blink reflex time.

Beam: A collection of light/photonic rays characterized by direction, diameter (or dimensions) and divergence (or convergence).

Beam diameter: The distance between diametrically opposed points in that cross-section of a beam where the power per unit area is l/e (0.368) times that of the peak power per unit area.
Beam divergence: The tendency of a laser beam to expand in diameter as it moves away from the source, measured in milliradians (mrad) at specified points.
Blink reflex: The involuntary closure of the eyes as a result of stimulation by an external event such as irritation of the cornea or conjunctiva, a bright flash, the rapid approach of an object, an auditory stimulus or with facial movements. The ocular aversion response for a bright flash of light is assumed to limit the exposure of a specific retina to 0.25 s or less.
Coherent: A beam of light characterized by a fixed phase relation (spatial coherence) or single wavelength, i.e., monochromatic (temporal coherence).
Collimated beam: Effectively, a "parallel" beam of light with very low divergence or convergence.
Continuous wave (CW): The output of a laser, which is operated in a continuous rather than a pulsed mode. A laser operating with a continuous output for a period > 0.25 sec. is regarded as a CW laser.
Controlled area: An area where the occupancy and activity of those within is subject to control and supervision for the purpose of protection from laser radiation hazards.
Cornea: The transparent outer layer of the human eye, which covers the iris and the crystalline lens. The cornea is the main refracting element of the eye.
Diffuse reflection: Change of the spatial distribution of a beam of radiation when it is reflected in many directions by a surface or by a medium.
Divergence: The increase in the diameter of the laser beam with distance from the exit aperture, based on the full angle at the point where the irradiance (or radiant exposure for pulsed lasers) is1/e times the maximum value. Symbol: Φ
Electromagnetic radiation: The flow of energy consisting of orthogonally vibrating electric and magnetic fields lying transverse to the direction of propagation. X-ray, ultraviolet, visible, Infrared and radio waves occupy various portions of the electromagnetic spectrum and differ only in frequency, wavelength, or photon energy.
Embedded laser: An enclosed laser that has a higher classification than the laser system in which it is incorporated, where the system's lower classification is appropriate due to the engineering features limiting accessible emission.
Energy: The capacity for doing work. Energy content is commonly used to characterize the output from pulsed lasers, and is generally expressed in joules (J).
Eye-safe laser: A Class 1 laser product. The use of term Eye-safe laser is discouraged.
Hertz (Hz): A unit expressing the frequency of a periodic oscillation in cycles per second
Infrared (IR) radiation: Invisible electromagnetic radiation with wavelengths that lie within the range of 0.70 to 1000 micrometers. This region is often broken up into IR-A, IR-B, and IR-C.
Intrabeam viewing: The viewing condition whereby the eye is exposed to all or part of a direct laser beam or a specular reflection.
Irradiance(E): Radiant power incident per unit area upon a surface. Unit: W/cm2.
Joule (J): A unit of energy. 1 Joule = 1 Watt/second.
LASER: A device that produces radiant energy predominantly by stimulated emission; an acronym for Light Amplification by Stimulated Emission of Radiation.

Laser diode: A laser employing a forward-based semiconductor junction as the active medium.
Laser pointer: A laser product that is usually hand held that emits a low-divergence visible beam and is intended for designating specific objects or images during discussions, lectures or presentations as well as for the aiming of firearms or other visual targeting practice. These products are normally Class 1, Class 2 or Class 3R.
Maximum permissible exposure (MPE): The level of laser radiation to which an unprotected person may be exposed without adverse biological changes in the eye or skin.
Nominal hazard zone (NHZ): The space within which the level of the direct, reflected or scattered radiation may exceeds the applicable MPE. Exposure levels beyond the boundary of the NHZ are below the applicable MPE.
Non-beam hazard: A class of hazards that result from factors other than direct human exposure to a laser beam.
Optically aided viewing: Viewing with a telescopic (binocular) or magnifying optic. Under certain circumstances, viewing with an optical aid can increase the hazard from a laser beam
Optical density: Logarithm to the base ten of the reciprocal of the transmittance: Dl = log10(1/tl), where it is transmittance at the wavelength of interest.
Photochemical effect: A biological effect produced by a chemical action brought about by the absorption of photons by molecules that alter the molecule.
Power: The rate at which energy is emitted, transferred, or received. Unit: watts (joules per second).
Protective housing: An enclosure that surrounds the laser or laser system that prevents access to laser radiation above the applicable MPE level. The aperture through which the useful beam is emitted is not part of the protective housing. The protective housing may enclose associated optics and a workstation and shall limit access to other associated radiant energy emissions and to electrical hazards associated with components and terminals, and may enclose associated optics and a workstation.
Pulse duration: The duration of a laser pulse; usually measured as the time interval between the half-power points on the leading and trailing ends of the pulse.
Pupil: The variable aperture in the iris through which light travels to the interior of the eye.
Q-switch: A device for producing very short (»10 – 250 ns), intense laser pulses by enhancing the storage and dumping of electronic energy in and out of the lasing medium, respectively.
Q- switched laser: A laser that emits short (»10 – 250 ns), high-power pulses by means of a Q- switch.
Radiant energy: Energy emitted, transferred, or received in the form of radiation. Unit: joule (J).
Reflectance: The ratio of the total reflected radiant power to the total incident power, also called “reflectivity.”
Reflection: Deviation of radiation following incidence on a reflective surface.
Retina: The sensory membrane, which receives the incident image formed by the cornea and lens of the human eye. The retina lines the inside of the eye.

Specular reflection: A mirror-like reflection. The exact definition of a specular surface is one in which the surface roughness is smaller than the wavelengths of the incident light.
Transmission: Passage of radiation through a medium.
Ultraviolet radiation: Electromagnetic radiation with wavelengths between 0.18 to 0.4 mm (shorter than those of visible radiation).
Visible radiation (light): Electromagnetic radiation, which can be detected by the human eye. This term is commonly used to describe wavelengths that lie in the range 0.4 to 0.7 mm.
Watt: The unit of power or radiant flux. 1 Watt = 1 Joule/ second.
Wavelength: The distance in the line of advance of a sinusoidal wave from anyone point to the next point of corresponding phase (e.g., the distance from one peak to the next).

5.0 LASER Hazard Analysis

Before appropriate controls can be selected and implemented, LASER radiation hazards must be identified and evaluated. Types of hazards associated with the use of LASERs and LASER Systems include:

Eye: Acute exposure of the eye to LASERs of certain wavelengths and power can cause corneal or retinal burns (or both). Chronic exposure to excessive levels may cause corneal or lenticular opacities (cataracts) or retinal injury. Exposures can also cause temporary loss of night vision. Reflective instruments (to include surgical instruments) can present as an eye hazard in a LASER use area.
Skin: Acute exposure to high levels of optical radiation may cause skin burns; while carcinogenesis may occur for ultraviolet wavelengths (290-320 nm).
Chemical: Some LASERs require hazardous or toxic substances to operate (i.e., chemical dye, Excimer LASERs). Dye LASERs normally use a lasing medium composed of a complex fluorescent organic dye dissolved in an organic solvent. These dyes vary greatly in toxicity, mutagenicity, and potential carcinogenicity. Most solvents suitable for dye solutions are flammable and toxic by inhalation and/or skin absorption.
Electric shock: Most LASER power supplies produce high voltages that can be lethal.
Fire & explosion: Various materials used in Research and in Health Care can be flammable; examples include solvents used in dye LASERs, certain surgical drapes, some anesthesia gases, multiple surgical prep solutions, few surgical instruments, rectal gases, and plastic trachea tubes. High voltage discharge or flash lamps may cause ignition. Flammable materials may be ignited by direct beams or specular reflections from high power continuous wave (CW) LASERs.
Plume: Smoke from vaporization of tissue may contain harmful bacteria, viruses or gases.

Special care should be used and any “hazardous waste” must be disposed of properly through Environmental Health and Radiation Safety.

6.0 Hazard Control Measures

All potential LASER hazards must be eliminated or controlled for the safe use of LASERs at the University of Toledo. Engineering controls (items incorporated into the LASER or LASER system or designated into the installation by the user) shall be given priority consideration in instituting a control measure program for limiting access to LASER radiation. Enclosure of the LASER equipment or beam path is the preferred method of control, since the enclosure will isolate or minimize the hazard.

When engineering controls are impractical or inadequate, administrative and procedural controls and personal protection equipment shall be used. Administrative and procedural controls are methods or instructions, which specify rules, or work practices, or both, which implement or supplement engineering controls and which may specify the use of personal protective equipment.
Engineering, administrative and procedural control measures are summarized in Attachment 3.
In addition to engineering, administrative and procedural controls, there are also general considerations, special considerations, and area warning signs and labels.

6.1 General Considerations

Control measures shall be devised to reduce the possibility of exposure of the eye and skin to hazardous levels of LASER radiation and other hazards associated with LASER devices during operation and maintenance. For all uses of LASERs and LASER systems, it is recommended that the minimum LASER radiation required for the application be used. LASERs are capable of causing eye injuries, burning exposed skin, igniting flammable materials, and activating toxic chemicals that release hazardous vapors, gases, debris and radiation. The beam height should be maintained at a level other than the normal position of the eye of a person in the standing or seated positions. Securely mount the LASER system on a stable platform to maintain the beam in a fixed position during operation and limit beam traverse during adjustments. Do not intentionally look directly into the LASER beam or at a specular reflection, regardless of its power. Terminate the beam at the end of its useful path. Orient the LASER so that the beam is not directed toward entry doors, windows or aisles. Clearly identify beam paths and ensure that they do not cross into populated areas or traffic paths. When the beam path is not totally enclosed, locate the LASER system so that the beam will be outside the normal eye-level range, which is between 1.2 to 2 meters from the floor. A beam path that exits from a controlled area must be enclosed wherever the beam irradiance exceeds the MPE. Minimize specular reflections. Use non-reflective tools. Remember that some tools that seem to be non- reflective for visible light may be very reflective for the non-visible spectrum. Do not wear reflective jewelry when working with LASERs. Metallic jewelry also increases shock hazards.
Review of reported incidents has demonstrated that accidental eye and skin exposures to LASER radiation, and accidents related to non-beam hazards of a LASER or LASER system, are most often associated with the following conditions:

i) Unanticipated eye exposure during alignment
ii) Misaligned optics and upwardly directed beams
iii) Available eye protection not used
iv) Equipment malfunction
v) Improper methods of handling high voltage
vi) Intentional exposure of unprotected personnel
vii) Operators unfamiliar with LASER equipment
viii) Lack of protection for non-beam hazards
ix) Improper restoration of equipment following service
x) Eyewear worn not appropriate for LASER in use
xi) Unanticipated eye/skin exposure during LASER usage

xii) Inhalation of LASER generated air contaminants and/or viewing LASER generated plasmas
xiii) Fires resulting from the ignition of materials
xiv) Eye or skin injury of photochemical origin
xv) Failure to follow standard operating procedures (SOPs)

6.2 Engineering Controls

i) Protective Housings (All Classes). A protective housing shall be required for all classes of LASERs.
ii) Operating a LASER without Protective Housing (Class 3B or 4). Procedures involving operation where the protective housing is removed must be approved by the LSO to ensure that adequate control measures are instituted.
iii) Interlocks on Removable Protective Housings (All Classes with Embedded Class 3B or 4 LASERs). Protective housings, which enclose Class 3B or 4 LASERs or LASER systems, shall be provided with an interlock system that deactivates the LASER when opened or removed.
iv) Key Control (Class 3B or 4). A Class 3B or 4 LASER or LASER system should be equipped with a key switch or master switch which shall effect beam termination and/or system shutoff. Key should never be left in the LASER or LASER system when not in use (OSHA).
v) Collecting Optics (All Classes). All collecting optics (such as lenses, telescopes, microscopes, endoscopes, eye-loupes, etc.) that integrate the use of a LASER or LASER system shall incorporate suitable means (such as interlocks, filters, attenuators) to reduce or eliminate LASER radiation to levels at or below MPE.
vi) Open Beam Path Control (Class 3B or 4). Where a beam path is unenclosed, a LASER hazard evaluation shall be effected by the LSO.
vii) Remote Interlock Connector (Class 3B or 4). A remote interlock connector should be provided for all class 3B LASER systems and shall be provided for all Class 4 LASER systems.
viii) Beam Stop or Attenuator (Class 3B or 4). A class 3B LASER or LASER system should and a Class 4 LASER or LASER system shall be provided with a permanently attached beam stop or attenuator.
ix) Reflection Control. Materials that diffusely reflect LASER radiation must be used in place of specularly reflective surfaces wherever possible. To minimize personnel exposure, specularly reflecting surfaces that are needed for beam-path control should be enclosed or shielded.

6.3 Administrative and Procedural Controls

i) Standard Operating Procedures. Written standard operating, alignment, maintenance and service procedures are required and must be approved by the LSO. This applies to all Class 3B, Class 4, and all Health Care LASERs. Refer to Attachment 6 for a template.
ii) Education and Training (All Classes except Class 1). Education and training shall be provided for operators, maintenance and service personnel. In addition, medical staff must be credentialed.

iii) Authorized Personnel (Class 3B or 4 or Embedded Class 3B or 4). Class 3B or 4 LASER systems or LASER systems with enclosed Class 3B or 4 LASERs shall be operated, maintained or serviced only by authorized personnel.

iv) Alignment Procedures (Class 3B or 4 or Embedded Class 3B or 4). There shall be written standard operating procedures (SOPs) outlining alignment methods for all Class 3B or 4 or Embedded Class 3B or 4 LASER systems. The following are suggested guidelines:

- Exclude unnecessary personnel from the LASER area during alignment.
- Whenever possible, use low-power visible LASERs for path simulation of higher-power visible or invisible LASERs.
- Wear protective eyewear and clothing to the extent possible.
- When aligning invisible (and in some cases visible) LASER beams, use beam display devices such as image converter viewers or phosphor cards to locate beams.
- Perform alignment tasks that use high-power LASERs, at the lowest possible power level.
- Use beam blocks and/or LASER protective barriers in conditions where alignment beams could stray into areas with uninvolved personnel.
- Be sure all beams and reflections are properly terminated before high-power operation.
- Post appropriate area-warning signs during alignment procedures where LASERs are normally Class 1 (enclosed).

v) Controlled Entry. All doors shall be kept closed during LASER procedures. LASER "in use" warning signs shall be posted outside all entryways.

vi) Maintenance Documentation. The Department of Biomedical Engineering is responsible for maintaining documentation of LASER service and maintenance for all Health Care LASERs and LASER Systems, regardless of who provided the service or repair.

vii) Labeling. Each LASER must be properly labeled. Information on the label must include class, the maximum output power, the pulsed duration (if pulsed), and the LASER medium or emitted wavelengths.

viii) Fire Prevention and Protection. Fire extinguishers designed for electrical fires shall be available and used with LASER systems. Flame retardant materials shall be used wherever applicable.

6.4 Personal Protective Equipment

Personal protective equipment (PPE) such as goggles, barriers, filters, clothing and gloves may be necessary if other control measures do not provide adequate means to prevent access to direct or reflective LASER beams at levels above the MPE.

6.4.1 Protective Eyewear

Eye protection must be worn by all personnel within the NHZ (Nominal Hazard Zone) defined in the SOP (i.e. within a barrier area or the entire room if the LASER is not surrounded by a barrier), including the patient in Health Care settings.

LASER protective eyewear may include goggles, face shields, spectacles, or prescription eyewear using special filter materials to reduce the potential ocular exposure below the applicable MPE. All LASER protective eyewear must be

labeled with the optical density and wavelength(s) for which protection is afforded. When working in a multi-wavelength LASER environment the eyewear protection must cover all possible wavelengths of exposure. During all Health Care LASER operations, the Physician/Surgeon must wear protective eyewear, even during microscopic and endoscopic procedures; lens filters that fit over the eyepiece may be used.

LASER protective eyewear must be inspected periodically by the user for pitting, cracking of the attenuating material, damage or weakening of strap and for mechanical integrity and light leaks in the frame. Eye protection for Health Care patients can include moist towels, goggles or intra-ocular shields.

An SOP must be prepared and approved by the LSO for operations where the beam of a Class 3 or Class 4 LASER must be viewed directly or where it is necessary to work with optical viewers in close proximity to the LASER beam. Protective eyewear must be worn whenever personnel may be exposed the beam of the embedded LASER (i.e. during maintenance or alignment).

6.4.2 LASER Protective Barriers

A blocking barrier, screen, or curtain, which can block or filter the LASER beam must be used around the controlled area, including all windows. In Health Care settings, the entire room is considered the NHZ. In Research and Instructional Areas, if barriers are not used then the entire room will be considered within the NHZ and door interlocks that deactivate the LASER must be used. All LASER barrier material must be labeled by the manufacturer with the optical protection afforded or approved by the LSO.

6.4.3 Skin Protection

For LASERs operating in the ultraviolet region of the spectrum (0.295-0.400 μm) and/or LASER welding/cutting applications, skin cover must be employed. Skin cover can be “sun screen”, gloves and clothing, keeping in mind that flame-retardant materials should be used.

6.5 Area Warning Signs and Labels

All entrances to laboratories with a Class 3b or 4 LASERs shall have a lighted warning sign that is fail-safe interlocked with the LASER to activate when the LASER is energized.

Each entrance must be posted with a warning sign in accordance with ANSI Z136.1, Sect.4.7.

- Danger. The signal word “Danger” shall be used with all signs and labels associated with Class 3R, 3B and 4 LASERs.
- Caution. The signal word “Caution” shall be used with all signs and labels associated with Class 2 and 2M LASERs.
- Notice. The signal word “Notice” shall be used on signs posted outside a temporary LASER controlled area (i.e. during periods of service).

All signs shall be conspicuously displayed in locations where they best will serve to warn onlookers.

All LASERs shall have equipment labels that conform to the current ANSI Z136.1 standard or in accordance with previous revisions.

6.6 Substitution of Alternate Control Measures

For Class 3B and Class 4 LASERs, upon review and approval by the LSO, engineering control measures and administrative controls may be replaced by written procedural, administrative or other alternate engineering controls, which provide equivalent protection. If alternate control measures are instituted, then appropriate LASER safety and operational training shall be provided.

7.0 LASER Safety Inspections and Audits

Each LASER should be inspected prior to use in accordance with the manufacturer's guidelines. The Department of Environmental Health and Radiation Safety along with the LSO will audit the LASER use in the OR annually. Laboratories are inspected annually with specific LASER audits occurring as needed.

8.0 Training and Qualification Requirements

8.1 Initial Training

All individuals operating with, or working in close proximity to LASERs are required to attend the LASER Safety training course presented by the LASER Safety Officer or view the LASER Safety PowerPoint training and complete the online testing module (https://testbank.utoledo.edu/Public/login.aspsx). This includes, but is not limited to Principal Investigators with LASERs in their laboratory, LASER operators in Research Areas, Operating Room Nurse Manager, and LASER Nurse/Technician in Clinical Areas.

8.2 Biennial Training

All individuals operating with, or working in close proximity to LASERs are required to complete the LASER Safety PowerPoint training and complete the online testing module (https://testbank.utoledo.edu/Public/login.aspsx) every two (2) years.

8.3 Supplementary Training

LASER specific training shall be conducted by the responsible Department. This training should include but is not limited to the administrative, alignment and standard operating procedures on all operable LASERs.

8.4 Qualifications

Only a qualified and authorized person is permitted to operate a LASER. The Principal Investigator or Operating Room Nurse Manager determines the employee's operational qualification from departmental or technical training or other acceptable learning experience.

Before operating a Class 3 or Class 4 LASER or a Class l LASER system that encloses a Class 3 or Class 4 LASER a person must:

1. Review the LASER Safety Manual.
2. Receive from the Principal Investigator or Operating Room Nurse Educator a thorough review of the LASER equipment to be used and the administrative, alignment and standard operating procedures (SOP).
3. Review the operating and safety instructions furnished by the manufacturer.

9.0 LASER Exposure Incidents

If an exposure incident occurs, the LASER Safety Officer must be notified by the Principal Investigator (Research/Instructional Use), or Operating Room Nurse Manager (Health Care Use), or the person operating the LASER.

If the incident causes an injury or could potentially have caused an injury, the person or persons who have received an exposure should inform their supervisor and be seen by the current contracted medical care provider for a medical evaluation. The exposed person must also complete a University of Toledo Injury/Illness Report form. This form must be forwarded to the Department of Environmental Health and Radiation Safety and the LSO. The LASER Safety Officer will conduct an investigation, and an accident investigation report will be written.

10.0 Standard Operation Procedures (SOPs)

The OR Nurse Manager and PIs are responsible for maintaining the SOPs for each LASER operated in their respective areas. Refer to Attachment 6 for the SOP template utilized at the University of Toledo.

11.0 Research and Instructional LASER Use

11.1 Additional Hazard Control Measures

11.1.1 Unattended LASER Operation

Only Class 1 LASERs or LASER systems shall be used for unattended operation or supervision without control measures.

Unattended operation of Class 1M, 2, 2M or 3R LASER systems shall be provided with a clearly visible equipment label, for Class 2 LASERs and LASER systems stating “LASER Radiation – Do Not Stare into Beam”, for Class 2M LASERs and LASER systems stating “LASER Radiation – Do Not Stare into Beam or View Directly with Optical Instruments”, for Class 3R LASERs and LASER systems stating “LASER Radiation – Avoid Direct Eye Exposure.”

Class 3B and 4 LASERs or LASER systems shall be operated at all times under the direct supervision or control of an experienced, trained operator who shall maintain visual surveillance of conditions for safe use. The operator shall maintain visual access to the entire LASER controlled area during all conditions of operation. Unattended use of a Class 3B or 4 LASER or LASER system shall be permitted only when appropriate SOPs and control measures have been implemented to provide adequate protection and LASER safety training to those who may enter the LASER controlled area. The LSO must approve procedures where a Class 3B or 4 LASER or LASER system is left unattended.

11.1.2 LASER System Modifications

It is the responsibility of the Principal Investigator who operates or supervises the operation of a "homemade" LASER to classify and label the LASER he/she controls. Refer to either ANSI Z136.1 or contact the LSO.

LASERs or LASER systems that have been altered need to be reclassified by the LSO before operating.

11.1.3 Maximum Permissible Exposure (MPE)

The level of LASER radiation to which a person may be exposed without hazardous effect or adverse biological changes in the eye or skin. The criteria for

MPE for the eye and skin are detailed in Section 8 of ANSI Z136.1. MPE is determined by the wavelength of the LASER light, the energy involved in the exposure, and the duration of the exposure. The MPE for desired LASER use can be calculated using MPE determination tables found in the ANSI Z136.1 Standard.

11.1.4 Electrical

The installation, operation, and maintenance of electrical equipment and systems must conform to the standards stated in the National Electric Code (NFPA 70).
The use of extension cords and powerstrips is strictly prohibited.
Circuit breakers must be identified and labeled for each LASER and LASER System.
To help prevent the risk of electrical shock, all protective enclosures that surround LASER devices and high-voltage electrical sources should also be equipped with interlocks.
Power supply cords must be inspected for exposed wires and signs of fraying prior to each use; LASERs and LASER System must be tagged as DO NOT USE until repaired.

11.1.5 Hazardous Materials

Treat all dyes as hazardous chemicals; use in accordance with the University's Chemical Hygiene Plan. Dispose of dye as "Hazardous Waste."

11.1.6 General Housekeeping and Egress

The laboratory work benches must be kept clear of equipment and chemicals except those necessary for the work currently being performed. Access to exits, walkways, hallways, emergency equipment, and utility controls shall never be blocked. Use of doorstops or other means of propping doors open is prohibited in entrances of LASER areas.

12.0 Clinical and Operating Room LASER Use

12.1 Third Party LASER Use

If a LASER is rented from and operated by a third party vendor,

ix) Credentials of the third party must be provided to the Medical Staff Office;
x) Written validation of maintenance, service, cleaning, and condition of equipment must be forwarded to Biomedical Engineering;
xi) A Biomed Technician must inspect the Rental LASER prior to use in a Health Care environment,
xii) Data and elements of documentation collected by the third party are appropriate, meet UTMC policy, and can be verified;
xiii) All Health Care Professionals in the room with the third party must have adequate training on all equipment in the absence of the third party employee, thereby ensuring safe patient care at all times

12.2 Additional Hazard Control Measures

i) Fire Protection and Prevention. The following are control measures used during surgical LASER procedures to prevent and respond to fires:
- A fire extinguisher must be available during all LASER procedures.
- A container of sterile saline or water must be available.

- A fire resistant endotracheal tube shall be used for all oral and tracheal procedures.
- For lower bowel procedures the rectum may be packed with a wet sponge.
- All gauze and drapes around the surgical area should be moistened with sterile saline.
- Non explosive anesthetic gases must be used.
- Nonflammable drapes and gowns should be utilized during LASER procedures.

ii) Plume Evacuation and Filtration. A Smoke Evacuation and Filtration System must be used during all LASER procedures where a plume may be produced, such as during use of a CO2 LASER. The smoke evacuator suction tube must be placed as near to the site of LASER ablation as possible (less than 2 centimeters).

13.0 Contact Phone Numbers

Environmental Health and Radiation Safety	419-530-3600
LASER Safety Officer	419-530-3600

Attachment 1. LASER Classification

Old Class	New Class	Hazards
1	1	Incapable of producing damaging radiation levels, exempt from control measures or surveillance
	1M	Incapable of producing hazardous exposure conditions during normal operation unless viewed with an optical instrument, such as eye-loupe or telescope, exempt from control measures other than to prevent potentially hazardous optically aided viewing; exempt from other forms of surveillance
2	2	Emits in visible portion of spectrum (0.4 to 0.7 μm), eye protection normally afforded by aversion response
	2M	Emits in visible portion of spectrum (0.4 to 0.7 μm), eye protection normally afforded by aversion response for unaided viewing, however, potentially hazardous if viewed with certain optical instruments
3a	3R	Potentially hazardous under some direct and specular reflection viewing conditions if the eye is appropriately focused and stable, not a diffuse reflection or fire hazard.
3b	3B	May be potentially hazardous under direct and specular reflection viewing conditions, not normally a diffuse reflection or fire hazard.
4	4	Hazard to the eye or skin from direct beam and may pose a diffuse reflection or fire hazard. May produce LASER generated air contaminates (LGAC) and hazardous plasma radiation

Ref: ANSI Z136.1-2007

Attachment 2. Requirements by LASER Classification

Class	Procedural & Administrative Controls	Training	Medical Surveillance	LSO
1	Not Required (1)	Not Required	Not Required	Not Required
1M	Required	Application Dependent (3)	Application Dependent (3)	Application Dependent (3)
2	Not Required (2)	Not Required (2)	Not Required	Not Required
2M	Required	Application Dependent (3)	Application Dependent (3)	Application Dependent (3)
3R	Not Required (2)	Not Required (2)	Not Required	Not Required (2)
3B	Required	Required	Suggested	Required
4	Required	Required	Suggested	Required

Ref: ANSI Z136.1-2007, pg 3.

1) Alignment and service procedures shall require procedural or administrative controls if a Class 1 LASER system contains an embedded Class 3B or 4 LASER.

2) Not required except for conditions of intentional intrabeam exposure applications.

3) Certain uses of Class 1M or 2M LASERs or LASER systems that exceed Class 1 or Class 2

Attachment 3. Control Measures for LASER Classes

Engineering Control Measures	Classification						
	1	1M	2	2M	3R	3B	4
Protective Housing (4.3.1)	X	X	X	X	X	X	X
Without Protective Housing (4.3.1.1)	LSO shall establish Alternative Controls						
Interlocks on Removable Protective Housings (4.3.2)	∇	∇	∇	∇	∇	X	X
Service Access Panel (4.3.3)	∇	∇	∇	∇	∇	X	X
Key Control (4.3.4)	—	—	—	—	—	•	X
Viewing Windows, Displays Screens and Collecting Optics (4.3.5.1)	Assure viewing limited < MPE						
Collecting Optics (4.3.5.2)							
Fully Open Beam Path (4.3.6.1)	—	—	—	—	—	X NHZ	X NHZ
Limited Open Beam Path (4.3.6.2)	—	—	—	—	—	X NHZ	X NHZ
Enclosed Beam Path (4.3.6.3)	None is required if 4.3.1 and 4.3.2 fulfilled						
Remote Interlock Connector (4.3.7)	—	—	—	—	—	•	X
Beam Stop or Attenuator (4.3.8)	—	—	—	—	—	•	X
Activation Warning System (4.3.9.4)	—	—	—	—	—	•	X
Indoor LASER Controlled Area (4.3.10)	—	*	—	*	—	X NHZ	X NHZ
Class 3B Indoor LASER Controlled Area (4.3.10.1)	—	—	—	—	—	X	—
Class 4 LASER Controlled Area (4.3.10.2)	—	—	—	—	—	—	X
Outdoor Control Measures (4.3.11)	X	* NHZ	X NHZ	* NHZ	X NHZ	X NHZ	X NHZ
LASER in Navigable Airspace (4.3.11.2)	X	* NHZ	X NHZ	* NHZ	X NHZ	X NHZ	X NHZ
Temporary LASER Controlled Area 4.3.12)	∇ MPE	∇ MPE	∇ MPE	∇ MPE	∇ MPE	—	—
Controlled Operation (4.3.13)	—	—	—	—	—	—	•
Equipment Labels (4.3.14 and 4.7)	X	X	X	X	X	X	X
LASER Area Warning Signs and Activation Warnings (4.3.9)	—	—	—	—	•	X NHZ	X NHZ

LEGEND:
- X Shall
- • Should
- — No Requirement
- ∇ Shall if enclosed Class3B or Class 4 LASER
- MPE Shall if MPE is exceeded
- NHZ Nominal Hazard Zone analysis required
- * May apply with use of optical aids
- ( ) Reference, ANSI Z136.1-2007

Attachment 3. Control Measures for LASER Classes (cont.)

Administrative and Procedural Control Measures	Classification						
	1	1M	2	2M	3R	3B	4
Standard Operating Procedures (4.4.1)	—	—	—	—	—	•	X
Output Emission Limitations (4.4.2)	—	—	—	—	LSO Determination		
Education and Training (4.4.3)	—	•	•	•	•	X	X
Authorized Personnel (4.4.4)	—	•	—	•	—	X	X
Alignment Procedures (4.45)	∇	∇	∇	∇	∇	X	X
Protective Equipment (4.6)	—	•	—	•	—	•	X
Spectators (4.4.6)	—	•	—	•	—	•	X
Service Personnel (4.4.7)	∇	∇	∇	∇	∇	X	X
Demonstration with General Public (4.5.1)	—	•	X	•	X	X	X
LASER Optical Fiber Transmission Systems (4.5.2)	MPE	MPE	MPE	MPE	MPE	X	X
LASER Robotic Installations (4.5.3)	—	—	—	—	—	X NHZ	X NHZ
Protective Eyewear (4.6.2)	—	—	—	—	—	•	X
Window Protection (4.6.3)	—	—	—	—	—	X	X NHZ
Protective Barriers and Curtains (4.6.4)	—	—	—	—	—	•	•
Skin Protection (4.6.6)	—	—	—	—	—	X	X NHZ
Other Protective Equipment (4.6.7)	Use may be required						
Warning Signs and Labels (4.7) (Design Requirements)	—	—	•	•	•	X NHZ	X NHZ
Service Personnel (4.4.2)	LSO Determination						
LASER System Modifications (4.1.2)	LSO Determination						

LEGEND:
- X Shall
- • Should
- — No Requirement
- ∇ Shall if enclosed Class3B or Class 4 LASER
- MPE Shall if MPE is exceeded
- NHZ Nominal Hazard Zone analysis required
- * May apply with use of optical aids

Attachment 4. Optical Densities for Protective Eyewear

LASER Type/ Power	Wavelength (nm)	OD for 0.25 seconds	OD for 10 seconds	OD for 600 seconds	OD for 30,000 seconds
XeCl 50 watts	308[a]	---	6.2	8.0	9.7
XeF 50 watts	351[a]	---	4.8	6.6	8.3
Argon 1.0 watt	514	3.0	3.4	5.2	6.4
Krypton 1.0 watt	530	3.0	3.4	5.2	6.4
Krypton 1.0 watt	568	3.0	3.4	4.9	6.1
HeNe 0.005 watt	633	0.7	1.1	1.7	2.9
Krypton 1.0 watt	647, 752	3.0	3.4	3.9	5.0
GaAs 50 mW	840	---	1.8	2.3	3.7
Nd:YAG 100 watt	1.064 μm[a]	---	4.7	5.2	5.2
Nd:YAG (Q-switch)[b]	1.064 μm[a]	---	4.5	5.0	5.4
Nd:YAG[c] 50 watts	1.33 μm[a]	---	4.4	4.9	4.9
CO_2 1000 watts	10.6 μm[a]	---	6.2	8.0	9.7

[a]Repetitively pulsed at 11 Hertz, 12 ns pulses, 20mJ/pulse

[b] OD for UV and FIR beams computed using 1 mm limiting aperture which presents a "worst case scenario. All visible/NIR computation assume 7 mm limiting aperture.

[c] Nd:YAG operating at a less common 1.33 μm wavelength.

NOTE: All OD values determined using MPE criteria of ANSI Z-136.1

<u>**Attachment 5. LASER Inventory Form**</u>

Please complete a separate form for each LASER (excluding LASER printers, pointers, bar code readers).

Principal Investigator/Physician	Office Phone	Department

Date:	

LASER Manufacturer	*Model*	*Type (Pulsed or CW)*	*Description (ie; He-Ne,ND: YAG)*	*Serial Number/Biomed #*

Sales Rep	*Company*	*Phone*	*Email*

If Pulsed, Duration:	

Is LASER operable? ☐YES ☐NO

If no, is LASER posted with a DO NOT USE SIGN and a LOCKOUT DEVICE? ☐YES ☐NO

Wavelength:	☐µm ☐nm (check one)	Max. Beam Power/Energy:	☐mW ☐mJ (check one)
Wavelength:	☐µm ☐nm (check one)	Max. Beam Power/Energy:	☐mW ☐mJ (check one)
Wavelength:	☐µm ☐nm (check one)	Max. Beam Power/Energy:	☐mW ☐mJ (check one)
Wavelength:	☐µm ☐nm (check one)	Max. Beam Power/Energy:	☐mW ☐mJ (check one)
Wavelength:	☐µm ☐nm (check one)	Max. Beam Power/Energy:	☐mW ☐mJ (check one)
Wavelength:	☐µm ☐nm (check one)	Max. Beam Power/Energy:	☐mW ☐mJ (check one)
Wavelength:	☐µm ☐nm (check one)	Max. Beam Power/Energy:	☐mW ☐mJ (check one)

Hazard class of LASER as indicated by manufacturer:	Has LASER been modified and the hazard class changed?
☐1 ☐2a ☐2 ☐3a ☐3b ☐4 ☐Unknown	☐Yes ☐No ☐Don't Know

LASER Location:	Bldg:	Room #:

Lab. Phone:	

Send or e-mail copy of completed form to: LASER Safety Officer
Environmental Health and Radiation Safety

Attachment 6. Standard Operating Procedure Form

The ANSI Z136.1 recommends written SOPs for activities involving Class 3b LASERs, and requires written SOPs for Class 4 LASERs and LASER systems. The University of Toledo's LASER Safety Manual requires SOPs for all Class 3 and Class 4 LASERs. A SOP should be a concise document that gives safety instructions specific to the LASER and associated equipment.

Maximum Permissible Exposure (MPE):_____
(Assistance provided by LASER Safety Officer)

Calculated Nominal Hazard Zone
For this LASER is: _____and the area of the NHZ has been demarcated.

Nominal Hazard Zone (NHZ)
The NHZ relates to the space within which the level of direct, reflected, or scattered radiation during normal operation exceeds the appropriate MPE. Exposure levels beyond the boundary of the NHZ are below the appropriate MPE level. No control measures are needed outside the NHZ.

All areas within the walls of rooms or laboratories that house Class 3b or Class 4 shall be considered NHZs at the University of Toledo.
The NHZ may also be calculated using the following formula:

$$NHZ = \frac{1}{\phi}\left[\left(\frac{4\Phi}{\pi * MPE}\right)^{1/2} - a\right]$$

Where ϕ is the emergent beam divergence measured in radians; Φ is the radiant power (total radiant power for continuous wave LASERs or average radiant power of a pulsed LASER) measured in watts; and *a* is the diameter of the emergent LASER beam, in centimeters.

Hazards associated with this LASER *(check all that apply)*:

- ☐ Eye
- ☐ Skin
- ☐ Electrical
- ☐ Chemical
- ☐ Fire
- ☐ Air contaminants
  Please describe:
  _____
  _____
  _____
- ☐ Other
  Please describe:
  _____
  _____
  _____

(Example: compressed gases, excimer gas LASERs), dyes, cryogenic liquids, toxic fumes and gases, ionizing radiation, and toxic materials. Consideration should also be given to the ***proper disposal*** of any hazardous materials)

Control Measures.
For each hazard listed above briefly state the control measures to be used.

Specific type of eye and/or skin protection used (include OD of eye protection)

Description of entryway controls

Reference to equipment

NHZ procedures

Shutdown procedures

Other controls in place

Alignment Procedures for this LASER (*list here or attach)*

De-energization procedures when working on exposed electrical parts
(See Lockout/Tagout Guideline for assistance)(List here or attach)

Training Requirements
All users of this LASER must first receive the following training:

- ☐ LASER Safety Training and:
- ☐ Lab Specific Training: (describe)_____

All training for this LASER is provided by the Laboratory PI or Designee (Lab Specific) and the LASER Safety Officer (General LASER Safety).

Emergency Procedures
List actions to be taken in case of emergency and personnel to be contacted.

Approved Personnel
List all individuals who are approved to operate the LASER without supervision.

Note: A hazard evaluation assisted by the LASER Safety Officer is also required by ANSI for Class 3b and 4 LASERs and associated equipment. This should be kept on file or attached to your SOP.