Texas Tech University
Health Sciences Center

Laser Safety Manual

Revised
February 1998

Purpose of Manual Revisions

The purpose of this revision of the Laser Safety Manual is to reflect the current status of the laser safety program at TTUHSC. Additionally, it has been nearly eight years since the printing and distribution of the original laser safety manual in November 1990. The major changes found in this revision are as follows:

1. The revised manual excludes references and procedures that dealt solely with the University Medical Center. UMC has it's own laser registry and laser safety program.
2. The new manual excludes the mention of the Laser safety Committee which no longer exists. The duties and responsibilities of the committee have been transferred to the Safety Services Department-Radiation Safety Division (oversight and enforcement) and the Department of Clinical Administration (faculty credentialing for laser use).

There have been no changes to Parts 60 or 70 of the Texas Regulations for the Control of Radiation since the printing of the original manual. All holders of the November 1990 version of the manual need only to replace Sections I-V of the old manual with the amended sections of this version.

Index of Abbreviations

ANSI American National Standards Institute
BRC Bureau of Radiation Control
CDRH Center for Devices and Radiological Health
CFR Code of Federal Regulations
DOH Department of Health
FDA Food and Drug Administration
HSC Health Sciences Center
JCAHO Joint Committee for Accreditation of Hospitals
LHCP Laser Health Care Personnel
LSO Laser Safety Officer
LSS Laser System Supervisor
MPE Maximum Permissible Exposure
NHZ Nominal Hazard Zone
RSS Radiation Safety Services
TRCR Texas Regulations for Control of Radiation
TTUHSC Texas Tech University Health Sciences Center

REFERENCES

Laser Safety in Surgery and Medicine: Rockwell Associates, Cincinnati, 1985.

Safe Use of Lasers, ANSI, Standard Z136.1: American National Standards Institute, New York, 1986.

Laser Safety in the Healthcare Environment, ANSI, Standard Z136.3: American National Standards Institute, New York, 1988.

Evaluation and Installation of Surgical Laser Systems: Apfleberg, D.B. Springer-Verlog, New York, 1987.

Texas Regulation for the Control of Laser Radiation Hazards: Texas State Department of Health, 1989.

Safety with Lasers and Other Optical Sources: Sliney, D. Plenum, New York, 1982.

PREFACE

All four regional campuses of the Texas Tech University Health Sciences Center (TTUHSC) utilize laser systems in medical therapy, medical diagnostics, and as a tool in medical research. It is the purpose of this manual to acquaint users of lasers and laser systems with TTUHSC regulations and recommendations related to the use of lasers and laser systems. Nothing in this manual should be construed as limiting in diagnosis and therapy or as to interfere with the professional judgment of a physician toward his patients.

It is the user's responsibility to be aware of the hazards associated with the use of lasers and laser systems and to obey all TTUHSC, State, and Federal regulations. This manual constitutes institutional policy and serves as a guide for the regulations concerning the safe handling and use of lasers and laser systems in medicine and research.

_____ _____

President Date
Texas Tech University Health Sciences Center
February 1998

SECTION I
GENERAL INFORMATION

SCOPE OF LASER SAFETY PROGRAM: This safety program provides reasonable and adequate guidance for safe use of lasers and laser systems for diagnostic, research, and therapeutic uses at all the Texas Tech University Health Sciences Center (TTUHSC) Regional Campuses.

It is intended for use by all persons associated with the installation, operation, maintenance and repair of laser and laser system instruments registered by TTUHSC according to the provisions of Texas Regulations for Control of Radiation.

TEXAS REGULATIONS FOR CONTROL OF RADIATION (TRCR): This laser safety program is operated under the auspices of the Texas Department of Health, Bureau of Radiation Control through guidelines and regulations as delineated in TRCR, Part 60 and Part 70, dated March 1987.

The Laser Safety Officer (LSO) will formulate and maintain adequate policies and procedures for the control of laser hazards and other related safety hazards as well as recommending the appropriate laser safety training programs and materials. The LSO will also establish written guidelines for laser procedures, protocols, review of accident/incident investigation, and continuing education of laser use personnel.

The LSO is to assure that these principles are being followed and to formulate or maintain policies so that laser safety is assured. In the event of noncompliance with established policy and procedures, as described within this manual, the LSO shall take action to review items of noncompliance and recommend remedial action for violations of these policies and procedures. This may result in revocation of certain individual privileges, if indeed a serious violation has occurred. Administrative action through the Office of The President (TTUHSC) also could be forthcoming in extreme cases.

LASER SAFETY OFFICER: The Laser Safety Officer will effect the knowledgeable evaluation and control of laser hazards and have the authority and responsibility to monitor and enforce the laser safety program.

LSO Specific Responsibilities include:

a) Classification - The LSO shall classify or verify classifications of lasers and laser systems used under the LSO's jurisdiction.

b) Hazard Evaluation - The LSO shall be responsible for hazard evaluation of laser work areas.

c) Control Measures - The LSO shall be responsible for assuring that the prescribed control measures are in effect, recommending or approving substitute or alternate control measures when the primary ones are not feasible or practical, and semi- annually conducting safety audits.

d) Compliance of Policies and Procedures - The LSO shall be responsible for ensuring compliance with BRC laser related regulations.

e) Protective Equipment - The LSO shall recommend and approve protective equipment, i.e. eye wear, clothing, barriers, etc., to assure personnel safety.

f) Warning Systems and Signs - The LSO shall ensure that certain adequate warning systems and properly worded area signs or labels are installed.

g) Facility and Equipment - The LSO shall provide recommendations to departments on laser installation facilities and laser equipment prior to installation and use. This also applies to modification of existing facilities or equipment.

h) Training - The LSO shall assure that adequate safety education and training is provided to laser area personnel.

i) Medical Surveillance - The LSO shall determine the personnel categories for medical surveillance. Medical surveillance refers to specific medical examinations of laser use personnel for biological monitoring of adverse effects of laser beam exposure.

j) Consulting Services - The LSO will provide consulting services on laser hazard control and on personnel training programs.

k) Authority - The LSO will have the authority, in emergency situations, to temporarily suspend or restrict the operation of a laser or laser system if it is deemed that laser hazard control measures are being violated. The LSO will inform the person(s) concerned of the violations, recommend corrective actions and monitor the progress of corrective actions. The authority to permanently suspend or restrict the operation of a laser or laser system until compliance is obtained will rest with the President of HSC.

l) Records - The LSO will ensure that the necessary records required by applicable government regulations are maintained. The LSO will insure that the appropriate records regarding medical examinations and laser safety education are maintained.

m) Surveys and Audits - The LSO will survey all areas where laser equipment is being used to ensure compliance with applicable government regulations and control measures promulgated by JCAHO. Surveys will also be conducted after any maintenance which would affect the performance characteristic of the laser system.

n) Accidents - on notification of a real or suspected incident or injury resulting from laser operation, the LSO will investigate the occurrence and initiate appropriate action. This may include the preparation of reports to applicable agencies.

o) Alternate LSO - The LSO will designate an appropriately trained individual to act as an alternate LSO during periods of extended absence. The designee will carry out the duties and responsibilities of the LSO as delineated above.

SECTION II
LASER SAFETY PROGRAM

GENERAL CONSIDERATIONS: The objectives of this laser safety program are to provide standards for the safe use of diagnostic and therapeutic lasers for health care and to ensure compliance with appropriate Federal and State Regulations. This will be accomplished by:

1. l. Determining the appropriate class of the laser system using the manufacturer's specifications, the hazards evaluation and classification description described in Sections 3 and 9 of ANSI Z-136.1-1986 or any appropriate combination.

2. Assisting in the planning and acquisition of laser systems and installations.

3. Complying with the control measures specified for that class of laser system, using the following table as a guide:

CLASS	CONTROL MEASURE	MEDICAL SURVEILLANCE
I	N/A	N/A
II	Applicable	N/A
III	Applicable	Applicable
IV	Applicable	Applicable

Control measures are considered under the headings of administrative and procedural controls, engineering controls, controlled treatment areas, personnel protective equipment, maintenance, service and procedural controls and special considerations.

Control measures shall apply when the equipment is in its intended operational mode.

The LSO shall be responsible for the establishment of surveillance of appropriate control measures and for the avoidance of needless duplication in those instances where several alternate yet equally effective control measures may limit access to laser radiation.

In medical laser research laboratories the normal use of some engineering controls by trained personnel may be inappropriate. In these instances the LSO shall establish alternate control measures which will provide adequate protection.

LASER CLASSIFICATIONS: The hazard classification system is based primarily on the ability of the optical beam to cause biological damage to the eye and hazards to other parts of the body occurring at exposure levels greater or equal to those producing eye damage.

The American National Standards Institute (ANSI) and Center for Devices and Radiological Health (CDRH) Standard divides all lasers into four major hazard categories. The following is a condensed summary of the four laser hazard classes:

Class l: Laser is considered to be incapable of producing damaging radiation levels. Class l is exempt from all control measures or any other form of surveillance during operation and maintenance.

Class 2: low-power visible laser devices which emit up to l mW power. A Class 2 laser may be viewed directly only under carefully controlled exposure conditions. Eye protection is normally afforded by light aversion response, including blink response. Helium Neon lasers used for patient alignment on various diagnostic and therapy treatments usually fall in Class 2.

Class 3: medium-power laser devices which require control measures to prevent direct intrabeam viewing or viewing with optical instruments except as a therapeutic procedure. A Class 3 laser is normally not a fire hazard. Two subgroups are specified:

1. Class 3a lasers will usually have a much larger beam diameter (expanded beam) and a very low beam density (irradiance) of 2.5 mW/cm squared or less. Lasers of this type are generally used for optical alignment applications out-of doors and are not usually found in a medical environment.

2. Class 3b lasers are continuously operating (CW) lasers with power ranges from 1 to 500 mW. They may be hazardous under direct or specular reflection viewing conditions. A diffuse reflection will not, in most cases, present any hazard to the eye. These lasers are commonly used as photocoagulators in ophthalmological or dermatological work.

Class 4: high-power laser devices which require very stringent control measures to prevent exposure of both the eye and the skin to the direct beam and specular or diffuse reflections, except as a therapeutic procedure. These lasers are commonly used as surgical lasers.

The classification of lasers or laser systems used in health care environment will, in most cases, be determined by the manufacturer. If the classification is not known, or where any class level may change because of deviations from the use intended by the manufacturer or because of addition or deletion of engineering control measures, the laser or laser system classification will be determined by the Laser Safety Officer using procedures described in Section 3 and Section 9 of ANSI Z-136.1-1986.

LASER EQUIPMENT REPORTING AND REGISTRATION:

1. The Radiation Safety Services (RSS) office or Laser Safety Officer (LSO) will be notified when any laser or laser system with a hazard classification of Class 2 or higher is installed and becomes operational. (Class l lasers are exempt from control measures and registration).

2. The intent to modify registered laser equipment, changes in operating locations or changes of intended use of laser and laser systems shall be reported to the RSS or LSO immediately.

3. The LSO will be notified prior to resuming use of any laser or laser system following repair or scheduled maintenance.

ADMINISTRATIVE AND PROCEDURAL POLICIES: Administrative and procedural policies specify rules, and/or work practices, that implement or supplement engineering controls and which may specify the use of personnel protective equipment.

1. Laser Safety Officer - The LSO duties and responsibilities are delineated in Section I, page 2.

2. Laser System Supervisor - Supervisors will be knowledgeable of the potential laser hazards and associated control measures, the education and training requirements for laser safety, and all procedures pertaining to laser safety at all locations under the supervisor's authority. Laser System Supervisors responsibilities will include:

a) Indoctrination - The supervisor will be responsible for the issuance of appropriate instructions and training materials on laser hazards and their control to all personnel working with lasers operated within the supervisor's jurisdiction.

b) Laser Hazard Control - The supervisor will not permit the operation of a laser unless there is adequate control of laser hazards to employees, patients, and visitors.

c) Designation of Laser Health Care Personnel - The supervisor will submit the names of individuals scheduled to work with lasers to the LSO and, in addition, will submit information as requested by the LSO for medical surveillance compliance and required training.

d) Reporting Known or Suspected Accidents - The supervisor will immediately notify the LSO or other designated authority if a real or suspected incident or injury occurs resulting from a laser operated under his or her authority.

e) Approval of Laser System Operation - The supervisor will not permit operation of a newly installed or modified laser under his or her authority without the approval of the LSO.

f) Approval of Planned Installation - The supervisor will insure that plans for laser installation or modifications are submitted to the LSO for review and approval.

g) Scheduling Service and/or Maintenance - The supervisor will be responsible for controlling the scheduling of service and maintenance of lasers and laser systems and for reporting the resumption of normal use to the LSO.

LASER SAFETY OPERATING PROCEDURES: A comprehensive list of laser dangers and precautions associated with laser surgery would be difficult to develop since each medical procedure is a different situation and can create different hazards.

Therefore, specific laser hazards and safety precautions shall be delineated in standard policies or procedures as approved by the LSO and implemented wherever laser therapy is practiced.

Laser safety procedures shall be developed for the following areas of concern.

A. Definition of the laser controlled area and access control of that area.

1. The room in which the laser is to be used shall be designated a LASER CONTROL AREA while the laser is in use in that room.

2. Approved laser warning signs shall be displayed on the outside of all doors leading into the LASER CONTROLLED AREA.

3. Access to the LASER CONTROLLED AREA shall be limited to essential, authorized personnel.

4. Appropriate protective and safety devices shall be provided and properly utilized. (pp. II-6 through II-10)

B. Protecting Body Tissues of Laser Personnel And Patients

1. Appropriate eye protection for all personnel in the Nominal Hazard Zone for each type laser shall be utilized. (p. II-7)

2. Direct viewing into the laser light source or of scattered laser light from any reflective surface is strictly prohibited.

3. Appropriate protective clothing or shielding will be utilized to prevent damage to skin for all personnel in the Nominal Hazard Zone for each type laser.

4. Smoke plume and odor evacuation systems should be utilized, when indicated, to minimize inhalation of potentially contaminated material and contribute to the general comfort of personnel in the laser controlled area.

C. Laser Mechanical Checks

1. A pre-operative check of the laser, as recommended in the instruction manual, will be made by the surgeon or qualified laser nurse/technician.

2. Pre-operation, intra-operation and post-operation check-off lists should be developed for each type laser.

3. Intra-operation considerations should include consideration of:

    a. Nonflammable prep solutions

    b. Exclusion of combustible anesthetic gases

c. Placement of equipment and surgeon controlled footpedals.

d. Use of nonreflective surgical instruments

D. Fire protocols should be developed to minimize risk and injury to patient and staff in case of an inadvertent ignition of flammable objects or gases during laser therapy procedures.

E. Each laser therapy treatment should be documented.

Documentation assists the operating team in the development of good habits in the practice of laser safety. It is also recommended for medical/legal implications of laser use

Documentation can be in the form of general and specific check lists. A laser log can be developed for quick access to patient information. Documented information should include:

1. Patient name
2. Physician, Anesthesiologist, and staff (properly credentialed) assigned responsibility for the laser case.
3. Type of anesthesia
4. Eye protection worn by patient and staff
5. Type of laser modality
6. Check lists completed by
7. Time on, time off
8. Power settings

PERSONAL PROTECTIVE EQUIPMENT: From a safety stand point the most desirable laser hazard control measure is enclosure of the laser or laser system and the laser beam path.

When other control measures do not provide adequate means to prevent access to direct or reflected beams at levels above the maximum permissible exposure (MPE), it may be necessary to use personal protective equipment. Personal protective equipment may have serious limitations when used as the only control measure with higher power Class 3 and 4 lasers or laser system; the protective equipment may not adequately reduce or eliminate the hazard. The pitfall in the use of protective equipment is that it requires knowledge to use it properly and discipline to wear it.

Personal protective equipment for laser safety generally means eye protection in the form of goggles, glasses or special prescription eyewear using special high-optical- density filter materials to reduce the potential ocular exposure below MPE limits. Some applications may

dictate use of a skin cover if chronic (repeated) exposures are anticipated at exposure levels at or near MPE limits.

Eye Protection Devices - Eye protection provides the simplest solution to the laser safety problem for constantly changing medical or research arrangements.

1. The following criteria will be used to afford additional protection whenever operational condition may result in a potential eye hazard.

    a. No person shall permit individuals to look directly into a laser beam, directly at specular reflections or align a laser by eye while looking along the axis of the laser beam when the intensities of such laser beams or reflections are greater than the MPE, unless such individuals are wearing appropriate eye protection devices for the type, class and power of the laser or laser system involved.

    b. Appropriate eye protection devices shall be used by all individuals who may be exposed to laser radiation in excess of the MPE.

    c. The following factors shall be considered in determining the appropriate protective eyewear to be used.

        1) Wave length of laser output
        2) Potential for multiwave length exposure
        3) Radiant exposure or irradiance
        4) MPE (Section 8 ANSI Z136.1-1986)
        5) Optical density of eyewear at laser output wave length
        6) Visible light transmission requirement
        7) Peripheral vision requirement
        8) Need for prescription glasses
        9) Comfort and fit
        10) Strength of materials (resistance to shock)

    d. Eye wear shall be clearly labeled with optical density and wave length for which protection is afforded.

    e. Eyewear shall be distinctively marked and associated with the laser or laser system of intended use.

    f. Side shields shall be required to be worn when regular prescription glasses are worn in lieu of clear goggles appropriate for wear with C0-2 lasers.

    g. Contact lenses, by themselves, are not considered appropriate protection from hazardous laser radiation.

    h. Protective eye wear shall be inspected at least semi- annually to assure the reliability of the protective filters and the integrity of the filter frames.

2. Protective Clothing - Personnel may be exposed to levels of radiation that clearly exceed the applicable MPE for skin.

3. In such cases clothing, gloves, and other suitable skin protection devices will be required. Consideration should also be given to the use of fire-resistant material for clothing, drapes, etc. when using Class 4 lasers.

4. Personal protective equipment will be approved and periodically inspected by the LSO.

ENGINEERING CONTROLS: The most reliable protection system against laser radiation injury are those protective features that are engineered into the laser system itself or added to the installation and laser use area. If these measures are impracticable or inadequate then protective equipment, administrative and procedural controls and training should be used.

In medical research laboratories, the normal use of some of the following engineering controls by trained personnel may be inappropriate. In these instances the LSO shall establish alternate control measures which will provide adequate protection.

Unless otherwise specified the following engineering controls apply only to Class 3 and Class 4 lasers or laser systems.

1. Protective Housing - A protective housing shall be provided for all lasers or laser systems which prevents access to radiant power or energy at levels higher than the intended classification. An interlock must be provided on the protective housing of all Class 3b and Class 4 lasers which activate on the removal (or displacement) of the protective housing so as to prevent exposure to levels above the appropriate MPE limits. In some cases, a properly interlocked room (door interlocks, ...etc.) can be considered as the protective housing for an "open beam laser" provided that other engineering and/or procedural controls preclude operation at levels above those of the intended laser classification.

2. Key-Switch Master Interlocks - All Class 3b and Class 4 lasers or laser systems shall have an operative keyed switch master interlock. The key shall be removable and the laser shall not be capable of operation when the key is removed. Only authorized system operators shall have access to the key.

3. Optical System; Interlocks/Filters - Interlock systems are required to be incorporated in conjunction with beam shutters or filters when optical viewing systems such as lenses, telescopes, microscopes, etc., are used to view the beam or beam reflection area.

4. Beam Stop or Attenuator - Lasers or laser systems should be provided with a permanently attached beam stop or attenuator which reduces the output emission to a level at or below the appropriate MPE level when the laser system is on "stand-by".

5. Viewing Optics and Windows - All viewing portals, optics, windows or display screens included as an integral part of an enclosed laser or laser system shall incorporate suitable means to attenuate the laser radiation transmitted through them to levels below the appropriate MOE. This would include, for example, a "viewing window" into a clinic or operating room which serves as the system enclosure.

6. Interlocks - Adjustments or procedures during service on the laser or laser system containing interlocks shall not cause the safety interlocks to become inoperative or the radiation levels outside of the protective housing to exceed the MPE limits, unless performed in a temporary laser controlled area. For pulsed lasers or laser systems, interlocks shall be designed to prevent firing of the laser, for example, by dumping the stored energy into a dummy load. The interlocks shall turn off the power supply or interrupt the beam for example, by means of shutters. Interlocks shall not allow automatic re-energizing of the power supply when the interlock is closed.

7. Emergency Beam-Off Switch - An emergency beam-off (panic) switch shall be available for terminating laser operation, either on the laser console, the remote control switch, or at a point of ready access.

8. Remote Controls - When a remote control such as a foot switch is used, it should be the only foot switch used by the physician operating the laser. The remote switch should be shrouded to prevent accidental activation of the laser. The remote switch must be of the "dead-man" type, i.e. a continuous, positive pressure is required to activate the beam.

9. Equipment labels - All lasers, except Class 1, shall have warning labels with the design and appropriate cautionary statement (See TRCR 60.7(c)) affixed to a conspicuous place on the laser housing.

10. Warning Signs - Each laser installation shall be conspicuously posted with a sign or signs prescribed in TRCR 60.7(c), so as to be readily visible to individuals entering the installation and to individuals in the installation.

1. Signs shall be positioned so as to preclude, during reading, human access to laser or collateral radiation in excess of MPE.

11. Warning System - An audible alarm, a warning light visible through protective eyewear or (for research only) a verbal countdown command should be used on a laser or laser system activation or start-up.

12. Laser Control Area - When the entire beam is not sufficiently enclosed and/or baffled such that access to radiation above the appropriate MPE is possible, a "laser- controlled-area" shall be established. The requirements for such an area are:

    a. A qualified supervisor shall be present during laser equipment operation.

b. The supervisor must approve personnel entry into the area if hazard warnings are not posted at all entry points into the area.

c. Appropriate eye protection must be worn by all personnel.

d. Low reflectance (diffuse surface) instruments and materials should be used near the beam to reduce laser reflections.

e. The laser or laser system will be secured so that the beam path is above or below eye level of a person in any standing or seated position, except as required for medical use.

f. Appropriate safety interlocks or barriers shall be incorporated at the doorways. Such latches/barriers shall, at all times, allow egress by those in the laser controlled area.

g. The area will be posted with appropriate warning signs.

h. From the entryway there shall be a visible or audible signal indicating that the laser is energized and operating at Class 4 levels. A lighted laser warning sign or flashing light are two appropriate methods to accomplish this requirement.

i. All windows, doorways, open portals, etc. from an indoor facility shall be either covered or restricted in such a manner as to reduce the transmitted laser radiation to levels at or below the appropriate MPE.

SPECIAL CONSIDERATIONS: The wide variety of equipment used in conjunction with lasers often have associated safety problems. Occasionally, special types of lasers pose some special type of health hazards. The following non-optical radiation hazards are considered separately.

1. Electrical Hazards - The safety standards for electrical safety should be followed. Serious electrical shock hazards exist with the higher powered lasers. The importance of adequate training and the "buddy system" when working around high voltage power supplies cannot be over-stressed. Only trained and qualified personnel should perform maintenance or repair work.

    a. Components in electrical circuits shall be evaluated with respect to electrical fire hazards. Power supplies and power supply circuits shall be enclosed in non-combustible material.

    b. Gas laser tubes and flash lamps shall be supported to minimize electrical shock or fire hazards in the event of a tube or lamp failure (explosion).

    c. The frames, enclosures and other accessible non-current carrying metallic parts of laser equipment shall be grounded.

d. Each laser will be permanently marked with its primary electrical rating in volts, frequency and watts or amperes.

2. Optical Radiation Hazards (Excluding the Laser Beam) - Ultraviolet radiation emitted from laser discharge tubes and pumping lamps (that is not part of the primary laser beam) shall be suitably shielded.

3. Fume Control - Adequate ventilation should be provided to protect personnel from products of vaporization and hazardous materials associated with the plumes from laser operation.

1. Airborne contaminants, smoke and noxious odors associated with the plume from laser operation should be captured near the point of evolution and evacuated from the laser use area.

4. Fire Hazards - The laser shall not be used in the presence of flammable or combustible chemicals such as anesthetics, preparation solutions, drying agents, ointments, methyl-methacrylate or other plastic resin. Wet cloth towels, or non-flammable drapes should be used to drape the treatment area instead of paper or plastic drapes.

5. Endotrachael Tubes - During surgery in the aerodigestive tract (oral nasopharengeal, laryngotracheal, or endobronchial) the endotracheal tube, where used, must be protected. Anesthesia personnel shall use non-flammable endotracheal tubes or specially wrapped red rubber or 100% silicon tubes. Other plastics, portex, anode (wired on armored) tubes (even if wrapped) shall not be used. The inflated cuff must be protected (example: wet cotton towelettes).

6. Oxygen and Flammable Gases - Inasmuch as combustion may be initiated in the aerodigestive tract at high oxygen saturation or in the presence of methane, the lowest possible mixture of oxygen should be used in laryngotracheal procedures. Adequate preparation should be provided (moistened packing in the rectal lumen and/or evacuation of methane from the colon) for colonic procedures. Tanks of gas shall be appropriately secured.

7. Endoscopes - Care should be taken to avoid impact of lasers on sheaths of flexible fiberoptic endoscopes inasmuch as most of the sheaths are flammable in the presence of a high oxygen environment.

8. Jewelry - When laser procedures are done in an office or outpatient clinic environment it is recommended that the operator not wear personal jewelry, metal rings or rings with reflective stones, since these may create potent reflection hazards.

MEDICAL SURVEILLANCE: The reason for performing medical surveillance on personnel working with lasers is to detect possible biologic damage from exposure to laser radiation. A medical surveillance exam will be performed by Occupational Medicine in the event of a possible exposure to laser radiation. Records of all medical examinations, including specific test results, completed under the direction of the Laser Safety program will be maintained by the LSO for a period of 30 years. The results of examinations should be discussed with the employee by the attending physician. All non- personally identifiable records of the examinations shall be made available on written request to authorized physicians and medical consultants.

INCIDENT INVESTIGATION AND REPORTING: Management of accidents, including reporting of alleged accidents, incident investigation and preparation of action plans for future prevention of accidents is a vital part of the laser safety program. This may be accomplished through the use of internal incident control reports and/or Texas Bureau of Radiation Control reporting as applicable.

1. Responsibilities of primary laser operators, technical, support and facility personnel.

    a. When any person knows or suspects that an incident or injury has occurred, involving a laser operated by him or other personnel, that person is to immediately inform his supervisor, the LSO or other designated responsible individual.

    b. Arrangements are to be made for immediate medical examination and treatment as necessary.

2. Responsibilities of the Laser Safety Officer

    a. Upon notification of a real or suspected incident or injury resulting from laser operations, the LSO will investigate the incident and initiate appropriate action.

    b. The investigation by the LSO shall include the following information:

        l) The nature of the laser radiation incident.

        2) The location at which the laser radiation incident occurred.

        3) The manufacturer, type, and model number of the laser or laser system involved.

        4) The circumstances surrounding the laser radiation incident, including causes.

        5) The number and names of persons involved, adversely affected, or exposed during the laser radiation incident, the nature and magnitude of their exposures or injuries and treatment involved.

6) The action, if any, which may have been taken by the LSO to control, correct, or eliminate the causes and to prevent reoccurrence.

c. If it is readily apparent to the LSO that an individual has sustained serious injury, the LSO shall immediately notify the medical school or hospital administration and the Agency of the incident.

d. When it is known or suspected that an individual has received an exposure in excess of the MPE limits for that involved laser system, the LSO shall notify the medical school or hospital administration and the Chairman of the of the incident. The LSO also shall report to the Agency writing, within ten (10) days of the discovery, all the available information relevant to the incident.

SERVICE AND MAINTENANCE: There is an important distinction between servicing and maintenance. Servicing refers to the performance of those procedures, adjustments or repairs described in the manufacturer's service instruction which would normally be performed by a serviceman representing the manufacturer or another approved electronics servicing specialist. Maintenance refers to the performance of those adjustments or procedures specified in user information as corrective operations performed by the user.

Overall servicing and maintenance should be covered by a warranty or through a service contract.

1. Any maintenance requiring removal of either the cabinet cover or the laser head cover or adjustment of the optical system should be done only by a qualified technician/engineer.

2. Preventive maintenance and trouble shooting by bio- medical or technical personnel should be limited to the following procedures:

Replacement of gas cylinders
Routine checks of the cooling system
Routine inspection and cleaning of lens
Routine inspection of the aiming system
Routine inspection and replacement of air filters
Replacement of blown fuses.

3. Unless specific training on the laser or laser system has been completed by a bio-medical technician, the company service representative must be called when the laser has malfunctioned.

4. Following any service or repair which may affect the output power or operating characteristics of a laser or laser system, the LSO shall perform necessary equipment performance inspections to confirm the continuity of laser output and control measures specified for that laser or laser system.

EQUIPMENT INSPECTIONS AND SAFETY AUDITS: The Laser Safety Officer shall be responsible for the safety inspections and audits of laser equipment. The LSO will survey by inspection, as considered necessary, all areas where laser equipment is used. The LSO will also accompany regulatory agency laser equipment inspectors and document any discrepancies noted. The LSO will ensure that corrective action is taken where required.

A laser safety audit shall be conducted under the supervision of the LSO at least every six months. This shall include, but not be limited to, the following areas of concern:

a. Protective eyewear inspections in accordance with Texas Regulations for the Control of Radiation 60.4(d).

b. Determination of optical integrity and clarity of optic fibers, mirrors, lenses, etc.

c. Presence of dust covers.

d. Availability of signs, goggles and safety equipment.

e. A check of water hoses, filters, coolant flow and cylinder leaks.

f. Operation of smoke evacuation equipment.

g. Proper alignment of laser beams.

h. Inspection of electrical wire breakdowns, interlocks, pump oil levels, optical fiber connectors, emergency shutoffs, foot pedal controls.

i. Availability of patient protective devices (eye shields).

j. Review the pertinent laser documentation, laser safety operating procedures and protocols for each laser system.

In addition to regularly scheduled laser inspection and safety audit, the LSO shall perform confirming laser power measurements following any service or repair on the equipment which may affect the power output or operating characteristics of the laser or laser system.

RECORDS: The LSO shall maintain and make available to authorized personnel upon request complete and accurate records as follows.

1. Semi-annual equipment performance and safety audits of each laser or laser system.

2. Records of all medical examinations (including specific test results) for all personnel included in the medical surveillance program.

3. Each purchase, transfer, receipt and disposal of a laser or laser system.

4. Each incident or injury reported to the LSO.

5. Equipment performance checks following installation, modification, service and maintenance of each laser or laser system.

6. Training records.

SECTION III
AUTHORIZATION FOR USE OF LASERS AND LASER SYSTEMS

CREDENTIALING FACULTY FOR LASER SURGERY: Laser surgery is defined as the practice of using any type of laser energy for application to the human body for purposes in incision, excision, coagulation, ablation or biopsy of any tissue for purposes of diagnosis and/or treatment. The lasers included shall consist of any device or instrument approved by the FDA for use in human patients. In the case of laser instruments that are classified by the FDA as "investigational", such instruments may be used only by those physicians formally authorized, under FDA protocol investigational license), to use such a device.

The following regulations concern faculty physicians use of lasers in medicine and surgery and do not concern resident physicians use of lasers. It is understood that resident use of lasers (as for any surgical procedure) will be under the direct supervision and responsibility of a faculty physician, credentialed for use of laser and procedure being performed.

The use of laser surgical instruments shall be restricted to the authorized areas approved by the TTUHSC LSO.

The establishment of physician privileges for the clinical use of lasers is the responsibility of the Department of Clinic Administration. Individuals requesting privileges to use lasers shall meet all of the standards of TTUHSC, with regard to board certification/eligibility, special training, ethical behavior, good judgment, indications for application.

The request for the granting of clinical privileges will be initiated by the individual desiring such privileges through their respective department chairman. All applications for physician laser privileges must be approved by Clinic Administration. In evaluating each application, Clinic Administration may consult with the respective department chairman and others in evaluating each application's merit. Decisions will be based on proper hands-on experience and successful completion of approved courses in laser use and safety.

The following process shall be followed in the credentialing of physicians for laser surgery.

1. All physicians who desire privileges in laser surgery will submit an application, in writing, to their respective departmental chairman, listing those laser surgery privileges desired, as well as written documentation of training, competence, experience, and proficiency in laser surgery for the procedures for which privileges are requested. The minimal requirements for credentialing outlined above must be met.

   Documentation may consist of:

   a. Written evidence of residency training in laser surgery involving the procedure(s) requested.

b. Evidence of satisfactory completion of a formal course(s) in laser surgery. A syllabus of the course(s) and a certificate(s) of completion of said course(s) will be provided, if requested by Clinic Administration.

c. Evidence of clinical experience in patient care, under the direct and immediate supervision of a trained laser surgeon.

d. Other written evidence that is satisfactory to Clinic Administration. This written evidence may include a letter from the physician applicant listing specific details of his/her training and experience, and his/her current and continued clinical activity on laser surgery.

2. The privileges requested should be for specific types and models of lasers to be used, as well as specific procedures.

MEDICAL DIAGNOSTIC AND RESEARCH AUTHORIZATION: TTUHSC faculty and staff engaged in medical diagnostic procedures and/or research involving the use of lasers or laser devices must have sufficient training and experience in their use so that the work is conducted in a safe manner, and must be approved by the TTUHSC LSO in order to use, or direct the use of these devices. Evidence of this training and experience, and other pertinent information required for the LSO's evaluation of the individuals abilities, must be submitted prior to any research involving the laser is conducted. If the information is in order and an inspection of the applicant's laboratory(s), by the LSO, shows that the facility meets compliance with federal, state, and local safety regulations; approval is granted by the LSO.

SECTION IV
LASER EDUCATION AND SAFETY TRAINING

The primary objective of laser education is to provide concepts, principles and facts necessary for a generalized understanding of all laser systems. Comprehensive training will aid in the assurance of optimal quality patient care, prevention of accidents, compliance with policies and procedures, and appropriate care and maintenance of equipment.

1. Initial, or orientation training will be required for all laser medical personnel. Documented previous training may be accepted as fulfillment of the initial training requirement. Initial training will be provided in the form of a video Laser Safety Course provided by Radiation Safety Services.

2. Continuing education will be provided in the form of current laser publications, lectures, seminars and in-service training program.

3. Training shall be required on the potential hazards (including bio-effects), control measures, applicable standards, medical surveillance and incident reporting.

The training program(s) shall be required for users of class 3 and 4 lasers and laser systems.

Users include physicians, nurses, and technicians working with lasers. The training shall ensure that the users are knowledgeable of the potential hazards and the control measures on laser equipment they may have occasion to use. The training program is outlined as follows.

LASER SAFETY TRAINING PROGRAM APPLICABLE FOR LASER OPERATORS:

I. Operational characteristics of the laser bio-effects and potential hazards of the laser.

   i. Eye and skin hazards of direct and reflected beams.

   ii. Fire hazards.

   iii. Hazards and concerns with laser produced fumes and particulates.

   iv. Other associated hazards (high pressure gas, anesthesia, etc.).

II. Requirements of laser safety standards practical controls for lasers in the medical environment.

   v. Laser eye protection: types and proper selection.

   vi. Methods to eliminate the possibility of explosion hazards.

   vii. Methods for smoke evacuation.

viii. Methods to reduce fire hazards.

ix. Reducing reflected beam hazards.

x. Standard operating procedures (SOP) for laser use.

III. Methods and procedures to assure safety.

xi. Drapes in laser surgery procedures.

xii. Techniques for safety while focusing the beam.

xiii. Proper laser system controls (foot switch, etc.).

xiv. Proper laser area warning signs.

xv. Entry-way interlocks and/or control.

xvi. Control of unauthorized personnel access.

xvii. Reports and safety audits.

xviii. Laser incident/accident reporting.

xix. Periodic safety audits.

The training in laser and laser safety practices for the medical staff group is to be differentiated from the training recommended for learning the methods and techniques of laser surgery.

TRAINING FOR HEALTH CARE FACILITY STAFF: Some members of the health care facility staff may have need to understand "administrative" responsibilities (the head nurse, chief medical technician, etc.), this group will in general not require in-depth coverage of the laser standards other than specific operating procedures applicable to the system(s) with which they are involved.

SECTION V
DEFINITIONS

Ablative Surgery - removal of tissue (for example, tumor), vaporization.

Absorption - means the transformation of radiant energy to a different form by interaction with matter.

Accessible Emission Level (AEL) - means the maximum accessible emission level permitted within a particular class as set forth in TRCR Part 70.

Agency - means the Texas State Radiation Control Agency, Texas Department of Health.

Average Power - means the total energy imparted during exposure divided by the exposure time.

Aversion Response - means the movement of the eyelid or the head to avoid an exposure to a noxious stimulant or bright light. It can occur within 0.25 seconds, including blink reflex time.

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

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

Beam - means a collection of rays which may be parallel, divergent or convergent.

Beam Diameter - means the distance between diametrically opposed points in the cross-section of a beam where the power per unit is l/e times that of the peak power per unit area.

Beam Divergence (O) - means the full angle of the beam spread between diametrically opposed l/e irradiance points; usually measured in milliradians (one milliradian is approximately 3.4 minutes of arc).

Beam Expander - means any combination of optical elements which can increase the diameter of the laser beam. Laser beam expansion is always accompanied by a proportional decrease in laser beam divergence.

Beam Splitter - means an optical device which uses controlled reflection to produce two beams from a single incident beam.

C0-2 Laser - wave-length 10.6 micrometers (for infrared, invisible).

Collimated Beam - a "parallel" beam of light with very low divergence or convergence.

Continuous Wave (cw) - means the output of a laser which is operated in a continuous rather than pulse mode for a period greater than 0.25 seconds.

Controlled Area - means an area where the occupancy and activity of those within are subject to control and supervision for the purpose of protection from radiation hazards.

Diffraction - means the deviation of a part of a radiation beam, determine by the wave nature of the radiation, and occurring when the radiation beam passes the edge of an opaque obstacle.

Diffuse Reflection - means the change of the spatial distribution of a beam of radiation when it is reflected in many directions by a surface or by a medium.

Emergent Beam Diameter (a) - means the diameter of the laser beam at the exit aperture of the laser product. Measured in centimeters (cm).

Energy (Q) - means the capacity for doing work. Energy content is commonly used to characterize the output from pulsed laser products and is generally expressed in joules (Jo).

Energy Density - means the emittance (M) or irradiance (E) of electromagnetic radiation, energy per unit area, e.g., joules meter^2 or joules/centimeter^2.

Exposure - means the product of an irradiance (E) and its duration.

Gas Laser - means a type of laser where the laser action takes place in a gaseous medium.

Helium-Neon (HeNe) Laser - red aiming beam. Wave length 632.8 nanometers.

Hertz (Hz) - means the unit which expresses the frequency of a periodic oscillation in cycles per second.

Human Access - means access at a particular point to laser or collateral radiation by any part of the human body or by an object. A laser product or installation shall be considered to permit human access if radiation in excess of an accessible emission limit is incident at a point that can be reached by a straight object 3.0 + 0.1 millimeters in diameter and lO.O + 0.1 centimeters in useful length.

Incident - means an unusual event or occurrence.

Individual - means a human being.

Infrared Radiation - means the electromagnetic radiation with wavelengths that lie in the 0.7 micrometer to l millimeter range.

Installation - means any location where one or more products are used or operated.

Intensity - means the amount of energy or energy per unit time passing through a unit area perpendicular to the line of propagation at the point in question.

Intrabeam Viewing - means the viewing condition whereby the eye is exposed to all or part of a laser radiation beam.

Irradiance (E) - means the quotient of the radiant power incident on an element of a surface by the area of what element, expressed in watts per square centimeter (W/cm^2).

Joule (J) - means a unit of energy, one J = l Watt/second.

Laser - Light Amplification by Stimulated Emission of Radiation. A device which generates or amplifies electromagnetic oscillations in the spectral region between the far infrared (submillimeter) and ultraviolet. The laser consists of an amplifying (active or Casing) medium and a regenerative of feedback device (resonant cavity). The amplifying medium can be gas, solid, or liquid. The feedback medium is generally bounded by two end mirrors. The laser light produced is of high intensity, high monochromaticity, small beam divergency (collimated), and is phase coherent.

Laser Controlled Area - means any area which contains one or more lasers and in which the activity of personnel is subject to control and supervision for the purpose of protection from laser radiation hazards.

Laser Protective Device - means any device, the intended function of which is the control of laser radiation with the intent of reducing or eliminating the exposure of personnel to such radiation.

Laser Radiation - means all electromagnetic radiation which is produced as a result of controlled stimulation emission.

Laser Safety Officer (LSO) - means any individual, qualified by training and experience in occupational and public health aspects of lasers, who is designated to evaluate the radiation hazard of and to establish, administer, and be responsible for, laser radiation protection.

Laser System - means a laser in combination with an appropriate laser energy source with or without additional incorporated components.

Lasing Medium - means a material emitting coherent radiation by virtue of stimulated electronic or molecular transitions to lower energy levels.

Limiting Aperture - means the maximum circular area over which radiance or radiant exposure can be averaged.

Maintenance - means the performance of those adjustments or procedures specified in user information provided by the manufacturer, with the laser or laser system, which are to be

performed by the user to insure the intended performance of the product. It does not include "operation" or "service" as defined in this section.

Maximum Emission Duration - means the maximum duration of repeated, or continuous operation of which the laser product is capable, whichever is greater.

Maximum Output - means that maximum magnitude of energy or power, at any time after manufacture, of total accessible laser radiation emitted by a laser product over the full range of operational capability.

Maximum Permissible Exposure (MPE) - means that integrated radiance or irradiance which is specified for accessible emission limits of class l or collateral radiation of TRCR Table 70-3. Exposure duration for MPE shall be that of actual or potential personnel exposure, and not a product of classification emission duration.

Medical Laser Products - means any laser product designed or intended for purposes of in vivo diagnostic or therapeutic laser irradiance of any part of the human body.

Neodymum.Yttrium Aluminum Garnet (Nd.YAG) Laser - wavelength (A) 1 06 nanometers.

Nominal Hazard Z _ (NHZ) - means the space within which the level of the direct, reflected, or scattered radiation during normal operation exceeds the applicable MPE. Exposure levels beyond the boundary of the NHZ are below the appropriate MPE level.

Nominal Ocular Hazard Distance (NOHD) - means the distance along the axis of the unobstructed beam from the laser to the human eye beyond which the irradiance or radiant exposure during normal operation is not expected to exceed the appropriate MPE.

Operable Laser - means a laser which can produce laser radiation.

Operation - means the performance of the laser or laser system over the full range of its intended functions (normal operation). It does not include "maintenance" or "service" as defined in this section.

Optical Density (D) - means the logarithm to the base ten of the reciprocal of the transmittance.

Output Power and Output Energy - means the laser output power used primarily to rate CW lasers since the energy delivered per unit time remains constant (output measured in watts). In contrast, pulsed lasers deliver energy in pulses and their effects can be best categorized by energy output per pulse.

Power (P) - means the time rate at which energy is emitted, transferred, or received; usually expressed in watts.

Protective Housing - means those portions of a laser product which are designed to prevent human access to laser and collateral radiation in excess of the prescribed accessible emission limit under conditions specified in TRCR Part 70.

Pulse Duration - means the time increment measured between the half-peals-power points of the leading and trailing edges of the pulse.

Pulse Repetition Frequency (PRF) - means the number of laser pulses per unit time (usually expressed in seconds).

Pulsed Laser - means a laser which delivers its energy in the form of a single pulse or a train of pulses, where the duration of a pulse is less than or equal to 0.25 seconds.

Q-switch - means a device for producing very short (approximately 30 nanoseconds), intense laser pulses by enhancing the storage and dumping of electronic energy in and out of the basing medium, respectively.

Q-switched Laser - means a laser which emits short (approximately 30 nanoseconds), high-power pulses by utilizing a Q-switch.

Radiance (L) - means radiant power per unit area of radiation surface per unit solid angle of emission, expressed in watts per square centimeter per steradian (w/cm^2/Sr).

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

Radiant Exposure (H) - means the quotient of radiant energy incident on an element of a surface by the area of that element, expressed in joules per square centimeter (J/cm^2).

Radiant Intensity (I) (of a source in a given direction) - means the quotient of the radiant flux leaving the source, propagated in an element of solid angle containing the given direction, by the element of solid angle. Expressed in watts per steradian (w/Sr).

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

Reflectance, Reflectivity (P) - means the ratio of total reflected radiant power to total incident power.

Reflection - means the deviation of radiation following incidence on a surface.

Remote Control Connector - means a two-terminal connector which permits the connection of external controls placed apart from other components of the laser product to prevent human access to all laser and collateral radiation in excess of limits specified.

Safe Eye Exposure Distance (SEED) - means the distance from an operating laser such that the energy that might infringe upon the eye is less than the MPE.

Safety Interlock - means a device associated with the protective housing or enclosure of a laser product to prevent human access to excessive radiation under conditions specified.

Service - means the performance of those procedures or adjustments described in the manufacturer's service instructions which may affect any aspect of the performance of the laser or laser system. It does not include "maintenance" or "operation" as defined in this section.

Shall - the word "shall" is understood to mean mandatory.

Should - the word "should" is understood to mean that which is advisable.

Source - means the term used to describe either a laser or laser-illuminated reflecting surface.

Specular Reflection - means a mirror-like reflection.

Transmission - means the passage of radiation through a medium.

Transmittance (T) - means the ratio of total transmitted radiant power to total incident radiant power.

Ultraviolet Radiation - means the electromagnetic radiation with wavelengths shorter than those for visible radiation (0.2 - 0.4 micrometers). This region is often broken down into three spectral bands by wavelength: VV-A (315 - 400 nanometers). UV-B (280 - 315 nanometers), and UV-C (200 - 280 nanometers).

Unrestricted Area - means any area to which access is not controlled for the purposes of protection of individuals from exposure to radiation.

Vaporization - means the conversion of a solid or liquid into vapor.

Visible Radiation (Light) - means all electromagnetic radiation which can be detected by the human eye. It is commonly used to describe wavelengths which lie in the range between 0.4 micrometers and 0.7 micrometers.

Watt (W) - means a unit of power, or radiant flux.

Wavelength - means only the propagation wavelength in air of electromagnetic radiation.