



ACCREDITATION STANDARDS

Patient Safety

LASER SAFETY

A wide variety of lasers are used in health care and their use continues to grow with advancements in health-care technology, equipment and procedures. While lasers offer several advantages such as enhanced precision, there are also risks such as eye and skin burns, fire, toxic fumes and electrical shocks. Therefore, patient safety depends on the safe and effective use of lasers by knowledgeable health-care providers.

CSA Z386-2014 *Safe use of lasers in health care* shall be referenced in addition to this document. Consideration has also been taken to ensure compliance with ANSI Z136.3-2011 *Safe use of lasers in health care*, since both the CSA Z386-2014 and the ANSI Z136.3-2011 are referenced in the WorkSafeBC Occupational Health and Safety (OHS) Regulation – Part 7 Division 3 Radiation Exposure.

The intent of this document is to ensure that critical elements of health-care laser safety are incorporated into current practice of non-hospital medical and surgical facilities as well as physician offices where lasers may be used.

While the same principles can be reasonably applied to health-care lasers used in other applications (e.g. esthetics, laser hair removal), it is important to note that the College of Physicians and Surgeons of British Columbia has no jurisdiction over laser practices in these settings.

Definitions

health-care laser	Any laser product designed, manufactured, intended or promoted for the purposes of diagnostic, surgical, aesthetic or therapeutic laser irradiation of any part of the human body.
laser safety officer (LSO)	One who is knowledgeable in the evaluation and control of laser hazards and has responsibility for oversight of the control of laser hazards.
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 radiation hazards.
maximum permissible exposure (MPE)	The level of laser radiation to which a person can be exposed without hazardous effects or adverse biological changes in the eye or skin.

nominal ocular hazard area (NOHA)	The area within which the beam irradiance or radiant exposure exceeds the appropriate corneal maximum permissible exposure (MPE), including the possibility of accidental misdirection of the laser beam.
risk assessment	A thorough analysis of potential risks and hazards (beam and non-beam) associated with the use of health-care lasers. The process of risk assessment includes: <ul style="list-style-type: none"> a. identification of physical, chemical, and biological hazards based on tissue interaction, dosimetry, delivery system, and practice setting b. analysis or evaluation of the risks associated with those hazards c. determination of appropriate control measures to eliminate or control the hazards
wavelength	nm or λ

Laser classifications

Class 1	Laser equipment emitting radiation that is not considered hazardous even for long-term exposure. These lasers do not require hazard-warning labelling. Examples include positioning and alignment lasers, low-level laser therapy and home-use lasers.
Class 1M	Laser equipment emitting radiation that is not considered hazardous for the naked eye even for long-term exposure.
Class 2	Laser equipment emitting visible radiation in the wavelength range from 400 nm to 700 nm that is considered safe for exposures of duration less than 0.25 s. Examples include alignment lasers used in aiming invisible radiation of CO ₂ and Nd:YAG lasers.
Class 2M	Laser equipment emitting visible radiation in the wavelength range from 400 nm to 700 nm that is considered safe for the naked eye for exposures of duration less than 0.25 s.
Class 3R	Laser equipment emitting radiation that can exceed the MPE when viewed directly but with low risk of permanent eye injury.
Class 3B	Laser equipment emitting radiation considered hazardous to the skin and eyes from direct exposure or a specular reflection.
Class 4	Laser equipment emitting radiation considered hazardous to the skin and eyes from direct exposure or a specular or diffuse reflection.

The medical director assumes overall responsibility for the safe use of lasers in the non-hospital facility and/or physician office

INDICATORS:

- The medical director ensures that:
 - a laser safety program is established and maintained in accordance with CSA Z386, applicable regulations and professional standards
 - a laser safety officer (LSO) is appointed
 - the LSO has successfully completed LSO training through a recognized laser safety education provider (e.g. Rockwell Laser Industries, Laser Institute of America)
 - the LSO has the authority to suspend, restrict or terminate the operation of a laser or laser system if he/she deems that laser hazard controls are inadequate or unsafe conditions are present
 - the LSO fulfills the LSO responsibilities in accordance with CSA Z386-14 *Safe use of lasers in health care*
- The medical director verifies initial and continuing credentials or approvals for all personnel responsible for working with lasers
- The medical director ensures all laser personnel have qualifications, credentials, education and training as prescribed by CSA Z386 *Safe use of lasers in health care* (see Appendix A)
- The medical director, in collaboration with the LSO, ensures that laser safety and education programs for all personnel are conducted

The laser safety officer (LSO) is responsible for directing the safe use of health-care lasers and ensuring compliance with laser hazard controls

INDICATORS:

- The LSO is responsible for:
 - the development and implementation of a laser safety program which includes quality assurance and risk management parameters
 - conducting hazard evaluations (risk assessments), including the determination of the NOHA, and implementing appropriate control measures
 - the enforcement of all laser safety policies and procedures
 - advising the medical director with respect to the safe use of lasers and compliance with protective measures
 - the investigation of all laser-related incidents and malfunctions and making recommendations for remedial and preventive action
 - conducting regular laser safety surveys to detect equipment problems or any trends toward a decrease in the level of laser safety
 - advising on the purchase of all laser equipment (systems and instrumentation)

- advising on the purchase of all laser-related personal protective equipment (PPE) to ensure appropriate PPE selection
- auditing the effectiveness of:
 - the laser safety program
 - maintenance of appropriate documentation
 - compliance with policies and procedures
 - compliance with applicable standards and regulations
- suspending, restricting, or terminating the use of a laser or laser system if laser hazard controls are inadequate or unsafe conditions are present
- the development and implementation of maintenance guidelines for the laser system
- verifying that preventive maintenance, repair, and servicing are performed and advising the user of any resulting changes or modifications to the system
- ensuring the safety education and training of all personnel involved in laser procedures
- establishing laser safety criteria for granting laser privileges to qualified physicians
- verifying and maintaining a list of laser personnel which includes their laser-specific privileges/role (e.g. physician, nurse, technician, procedure, wavelength) and documentation of their clinical competency
- the development, implementation and approval of laser documentation (e.g. logs, forms, checklists)

The surgeon (laser user) is responsible for ensuring the safety of the patient and all personnel in the laser-controlled area during laser set-up and use

INDICATORS:

- The surgeon:
 - remains in the laser room at all times during laser usage
 - ensures the environmental and procedural control measures are in place (e.g. protective eyewear, plume evacuators)
 - ensures clear communication with the laser operator (assistant)
 - handles the laser delivery device and is the only one operating the laser footswitch or hand-held device
 - selects the appropriate laser parameters for the procedure
 - activates, fires and/or deploys the laser
 - reports any unusual events and safety concerns to the LSO

Administrative control measures ensure the safe use of lasers

INDICATORS:

- Health-care lasers, used in non-hospital facilities or physician offices, are registered with the College's Non-Hospital Medical and Surgical Facilities Accreditation Program
- A risk assessment, to determine engineering and procedural controls, is performed prior to the development of laser policies and procedural guidelines; the NOHA is reassessed if it increases following repair, service or maintenance of the laser
- Laser safety program policy and procedures are in place and include:
 - equipment checks, safe-use, controls and protective measures (safety features, precautions during use)
 - education and training of personnel
 - unscheduled laser system shutdown and/or equipment malfunction
 - Prevention and management of possible exposure to gases, dyes and coolants
 - Inspections, tests, service, and maintenance
- Laser personnel qualifications, credentials, education, and training records are maintained at the facility where the laser(s) are used
- All individuals in the laser-controlled area are responsible for maintaining safe practices and have the authority to halt unsafe practice.
- Access to laser keys is restricted to only personnel authorized to operate the laser
- Laser keys are stored away from the laser when not in use
- Material safety data sheets for gases, dyes and coolants used in the lasers are current, within the last three years, and readily available
- Equipment malfunction, service and maintenance records are maintained at the facility where the laser(s) are used

Laser personnel education and training supports a safe environment of care

INDICATORS:

- All personnel within the laser-controlled area have completed training specific to his/her personnel category/role in accordance with CSA Z386 *Safe use of lasers in health care* (see Appendix A)
- Laser safety and education programs are conducted for all personnel:
 - when an existing laser system is used in a new application, undergoes a change to operational components (e.g. software upgrade, or is used with a new delivery device)
 - when a new or replacement laser system is to be placed into service
 - following a period of absence from participating in laser procedures
 - at the request of the medical director, LSO or the staff member concerned
 - at a minimum of every two years

- Staff have a thorough understanding of the procedures for establishing and maintaining a safe environment during laser procedures
- Personnel have been educated about the fire triangle and are trained in fire drills and the use of fire extinguishers

Procedural, environmental and engineering control measures ensure the safe use of lasers

INDICATORS:

General

- Personnel in the laser-controlled area are approved by the LSO and aware of all necessary laser safety precautions
- Appropriate protective eyewear and personal protective equipment (PPE) are worn by all personnel in the NOHA during laser use
- Operator/user manuals and facility policy and procedures are readily available in the laser-controlled area
- All laser equipment malfunctions are recorded and corrected in accordance to *CSA Z386 Safe use of lasers in health care*

Warning signs and visual indicators

- Laser warning signs specify the wavelength and class of laser being used and indicate personal protective equipment (PPE) required (e.g. protective eyewear)
- Laser warning signs are placed at all entrances to the laser room, when lasers are in use, and are removed when the laser procedure is completed

Beam-related hazards

- For Class 3R, 3B, and 4 lasers, the NOHA is determined
- Boundaries of the laser-controlled area are clearly established
- The NOHA does not extend beyond the boundaries of the laser-controlled area
- Lasers and laser systems are operated in a controlled access area
- Doors to the laser room remain closed
- All windows are covered with coverings or filters with an optical density sufficiently high to protect against all the wavelengths of the lasers in use in the NOHA
- Window barriers are labeled in accordance with IEC 60825-1, controllable from inside the laser room, do not allow light leakage at the perimeters (see Appendix B)
- Reflective surfaces (e.g. jewelry, mirrors, highly polished glass) that could interfere with the beam path are minimized

- Anodized, dull, non-reflective or matte-finished instruments are used whenever possible; reflective instruments, if used, are covered with wet sponges/towels when lasers with thermal effect are being used

Fire and electrical hazards

- Fire extinguisher(s) are located in the laser-controlled area and are free of obstruction
- The environment is free of flammable surfaces or materials that could interfere with the beam path
- Fire drills are conducted at the frequency required by the BC Fire Code

Heating, ventilation, and air conditioning

- Heating, ventilation, and air conditioning (HVAC) systems comply with CSA-Z317.2
- Laser equipment is used in a well-ventilated area to ensure excess heat generated by the laser is removed
- The air intakes and outlets are unobstructed at all times

Gases, dyes, and liquid coolants

- Policy and procedures on the prevention and management of possible exposure to gases, dyes, and coolants, used in the laser, are in place and include:
 - educating all personnel in the proper handling of gases, dyes and coolants
 - developing a plan to contain gases, dyes, and coolants in the event of a leak
 - outlining personnel, equipment, automatic ventilation/exhaust and hazardous materials disposal requirements in the event of a leak
 - establishing an evacuation plan
 - referring persons exposed to gases, dyes and coolants to a physician and the appropriate health and safety personnel
- If the laser is equipped with a purge gas system, purge gases are filtered and whenever possible, CO₂ is used as a purge gas instead of medical air

Eye protection and personal protective equipment (PPE) eliminate or control hazards associated with laser use

INDICATORS:

- Protective eyewear has side guards and is permanently labelled with the appropriate optical density (OD) and wavelength
- Protective eyewear is sufficiently high to protect against the wavelength for the laser in use
- Appropriate protective eyewear is available at each point of access to the laser-controlled area
- Protective eyewear is worn by all staff in the laser room, as appropriate

- Protective eyewear and/or a protective filter is used with optical viewing equipment (e.g. microscope, endoscope, ophthalmoscope) to protect the laser user from exposure
- Protective eyewear and filters are inspected prior to use for pitting, crazing, cracking, mechanical integrity, discoloration, and coating damage
- Protective eyewear and filters are maintained according to manufacturer's instructions
- Protective eyewear is carefully handled and stored to prevent scratches and damage (e.g. stored in individual cases or sleeves when not in use)
- Patient eye protection is selected according to the positioning of the patient, body part to be treated, level of anesthesia and laser wavelength and delivery system

Laser equipment is set-up and monitored for safe operation

INDICATORS:

General

- The duties of each person inside the laser-controlled area are clearly assigned
- The laser is operated by authorized personnel only
- The health care laser, at a minimum, includes the following safety features:
 - a power meter (or an energy meter in the case of a pulsed laser) capable of indicating tissue incident power for Classes 3R, 3B, and 4 lasers; in the case of pulsed lasers, the energy meter indicates the average power of the laser, or the number of pulses per second, or both, as well as the pulse energy (per pulse)
 - a removable key (i.e. the laser shall be inoperable without key) or similar device without a key (i.e. keyboard or other means for on/off mechanism) for Classes 3R, 3B, and 4 lasers
 - a visual warning activated during laser emission (in some circumstances, an audible warning may also be present)
 - a switch guard to prevent unintended operation of the laser system (e.g. a guarded foot pedal)
 - a laser operating manual that thoroughly addresses its use and associated hazards
- Only the manufacturer's laser delivery devices are used on the laser
- A laser safety checklist is completed for each procedure

Pre-operation

- All control measures are in place and functioning (e.g. warning signs posted, windows covered, personal protective equipment checked and donned)
- The laser equipment is visually inspected for potential malfunctions or damage
- The laser system, including delivery system, microscope and lens, beam alignment, fiber and waveguide, is checked, tested and calibrated in accordance with manufacturer's instructions before operation

- The laser is in “standby” or “off” mode (or shut down and key removed) when not in use (or if laser use is delayed)
- Access to water/saline is immediately available
- Wet cloths/drapes are on hand to protect non-targeted areas as needed
- Lasers are not activated until flammable agents (e.g. skin prep, tinctures etc.) are dry and vapors have dissipated
- Patient is fitted with proper protective equipment, if indicated

During laser operation

- All aspects of laser and laser-related device use are monitored at all times when the laser is in “ready” mode
- The laser user (physician) and the laser operator (assistant) are in the room at all times during laser usage
- The laser operator (assistant) remains at the control panel when the laser is in “ready” mode
- Good communication between the laser user and laser operator (e.g. regarding status of laser and parameters) is maintained
- Appropriate laser parameters for a given clinical application are selected by the laser user (physician)
- The laser user (physician) handling the laser delivery device is the only one operating the laser footswitch or hand-held device
- The footswitch is not bagged, as this can cause inadvertent firing
- Appropriate eye and skin protection is employed by all personnel, if indicated
- Plume is captured and evacuated in accordance with CSA Z305.13
- Sponges and drapes near the surgical site are kept moist when using a laser

Endotracheal (ET) tube procedures

- A medical protocol for management of the airway during laser surgery is in place
- Laser-resistant endotracheal tubes purposely manufactured for laser airway procedures are used
- ET tubes are selected based on the wavelength of laser to be used and proof of manufacturer’s testing within the surgical parameters anticipated during the surgery
- If the ET tube is taped to the patient’s tissue or materials on the surgical field, non-flammable tape is used
- The CO₂ laser is tested for coaxial alignment of laser beams, and proper beam mode, prior to the patient undergoing anesthesia
- The laser operator (assistant) does not place the laser in the ready mode until a verbal order is given to hold ventilation

- Protection of the patient's face and eyes is provided by applying wet eye pads, metal shields taped into place by non-flammable tape, and wet towels placed over the face
- The patient's teeth are protected by a non-flammable tooth guard covered with wet gauze or alternative methods approved by the LSO and the surgeon
- Cotton patties used to pack the inflated ET tube cuff are included in the surgical count

Post-operation

- The laser is turned off/shut down before it is moved outside the laser-controlled area
- All unusual events and safety concerns are reported to the LSO

Laser documentation provides an accurate account of the patient's status, the actions of the laser team and the patient's outcome

INDICATORS:

- Laser procedure documentation included in the medical record includes:
 - type of laser used (e.g. wavelength, serial or biomedical number)
 - laser settings and parameters
 - safety measures implemented during laser use
 - surgical procedure
 - on/off laser activation and deactivation time for head, neck and chest procedures
 - patient protection (e.g. eye protection)
- Laser safety checklist documentation includes:
 - performing a laser self-test check before the patient is brought into the room
 - calibrating the laser, as appropriate
 - conducting a test fire of the laser
 - posting "laser in use" signs at all entrances to the procedure room
 - providing appropriate eye protection
 - covering the windows of the procedure room, as appropriate
 - checking the availability of saline at the surgical field
 - checking the appropriate type and availability of fire extinguisher for the laser being used
- A laser utilization record for each laser system is maintained and includes:
 - patient identification
 - date, treatment and location
 - equipment identification
 - wavelength of laser
 - laser user
 - laser operator
 - operational procedures

- delivery system (e.g. objective lenses, fibre size, lot number, serial number)
- range of treatment parameters, e.g. power (watts), energy (joules), pulse duration, pulse repetition rate, total energy (delivered)
- signature of the laser operator
- record of laser system shutdowns

Appendix A: Education and training of laser personnel

Level 1 Laser Training

This is necessary for:

- non-clinical facility personnel who are involved in the management of the laser program or laser services
- observers
- trainees

The content includes, but is not limited to:

- overview of CSA Z386 *Safe use of lasers in health care*
- facility policy and procedure
- types of lasers used and general applications in the facility
- roles, authority and responsibilities of laser team members
- contact information for the LSO

Level 2 Laser Training

This is necessary for:

- laser operator (assistant)

This includes:

- level 1 laser training

The content includes, but is not limited to:

- laser physics
- laser-tissue interaction
- types of lasers and their delivery systems
- accessory equipment and instrumentation needed for specific applications
- understanding treatment parameters and dosimetry
- roles, authority, and responsibilities of laser team members
- assessment of hazards and risks

- reporting
- applicable documentation

Level 3 Laser Training

This is necessary for:

- laser safety officer (LSO)

This includes:

- level 2 laser training

The content includes, but is not limited to:

- all items in level 1 and 2 training
- regulatory requirements in the specific jurisdiction
- application of CSA Z386 *Safe use of lasers in health care*
- hazard identification and implementation of applicable control measures
- facility reporting for accidents, incidents or occurrences

Level 4 Laser Training

This is necessary for:

- laser users (physician)

The content includes, but is not limited to:

- all items in level 1 and 2 training
- clinical application and techniques for intended procedures
- treatment parameters and dosimetry for intended procedures
- patient safety
- management of complications
- competency in operating the laser and its delivery systems
- competency in use of safety equipment (e.g. protective eyewear, emergency stop switch, standby switch, plume evacuator, microscope eye safety filters, accessory instrumentation, fire extinguisher, wet drapes, etc.)

Appendix B: Signage and labels

IEC 60825-1 *Safety of laser products – Part 1: Equipment classification, requirements and user's guide* (referenced by CSA Z386-2014)

- IEC 60825-1 *Safety of laser products – Part 1: Equipment classification, requirements and user's guide* does not directly specify labelling of “laser guards” (e.g. barriers, windows)
- IEC 60825-4 *Safety of laser products – Part 4: Laser guards* addresses specifications on “laser guards” (e.g. barriers, windows)

IEC 60825-4 *Safety of laser products – Part 4: Laser guards* labeling requirements

- Full specification of a protective exposure limit (PEL) (for passive laser guard):
 - the magnitude and variation with time of irradiance or radiant exposure at the front surface of the laser guard (in units of Wm^{-2} or Jm^{-2} respectively), specifying any upper limit to the area of exposure
 - the overall duration of exposure under these conditions
 - the wavelength for which this PEL applies
 - the angle of incidence and (if relevant) the polarization of the incident laser radiation
 - any minimum dimensions to the irradiated area
- The manufacturer's name, the date and place of manufacture according to ISO 11553-1, and a statement of compliance with IEC 60825-4

ANSI Z136.7 *Testing and Labeling of Laser Protective Equipment*

Window labeling

- Permanently labelled by the final manufacturer
- Legibly marked with: manufacturer (or registered trademark)
 - model
 - optical density (or minimum OD over corresponding wavelength range)
 - wavelength (or wavelength range)

Barrier labeling

- Permanently labelled by the final manufacturer
- Legibly marked with:
 - manufacturer (or registered trademark)
 - model
 - threshold limit (TL)
 - exposure time for which the limit applies

- exposure conditions

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