Appendix 5 - Compliance Verification Checklist for Class 3b and 4 Lasers

In accordance with
CAN/CSA-Z386-14 "Safe Use of Lasers in Health Care"
published by the Canadian Standards Association

Item No.	Compliance Item Description	Standard Section	Yes	No	N/A
	Risk Assessment - Hazards, Risks and Control Measures				
	The LSO shall ensure that the hazard classification and nominal ocular hazard area (NOHA) are determined for each laser in use	4.0			
	A risk assessment shall be performed before policies and procedural guidelines are developed to determine engineering and procedural control measures	5.1			
	Persons administering and assisting in the administering of the laser systems, as well as the patient, shall be protected through the implementation of appropriate control measures and other provisions described in this Standard	5.2.3			
	Ocular & Skin Control Measures				
	All protective eyewear and filters shall be selected with an optical density (OD) sufficiently high to protect against the wavelengths of the laser in use in the NOHA	5.3.1.3			
	Appropriate protective eyewear shall be made available at each point of access to the laser controlled area	5.3.1.3			
	The protective eyewear shall be permanently labelled with applicable optical densities (OD) and wavelengths	5.3.1.3			
	The protective eyewear shall be worn by all personnel in the NOHA during laser use	5.3.1.3			
	The protective eyewear and filters shall be maintained according to manufacturer's instructions	5.3.1.3			
	The eyewear shall have side guards to protect against the beam entering between the eye and the eyewear	5.3.1.3			
	The protective eyewear and filters shall be inspected prior to use for pitting, crazing, cracking, mechanical integrity, discoloration, and coating damage	5.3.1.3			
	Optical viewing equipment (such as, but not limited to, a viewing port, microscope, endoscope, bronchoscope, ophthalmoscope, magnifying glass, loupes, or binoculars) shall be used with eye protection such as protective eyewear or a protective filter	5.3.1.3			
	All windows shall be 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 shall meet the infection control requirements of the facility and shall be non-flammable	5.3.1.3 & 5.3.2.3			
	Visual indications shall be used, e.g., a sign at eye level at entry points that shows the laser's operational status	5.3.1.3 & 5.3.2.3			
	A patient eye protection method shall be selected according to the positioning of the patient, the part of the body to be treated, the level of anesthesia, and both the wavelength and delivery system of the laser to be used.	5.3.1.3			
	Matte finished or diffusive surface instruments or other LSO-approved instruments (i.e., wet gauze) shall be used close to the beam path and adjacent to the laser impact site to reduce reflection hazards	5.3.1.3 & 5.3.2.3			
	Fire and Explosion Control Measures				

	Conducting fire drills at least once a year;	5.3.3.3			
	Keeping any fire extinguishers located in the controlled area free of obstruction;	5.3.3.3			
	Ensuring that all laser personnel know how to access and operate fire extinguishers;	5.3.3.3			
	Testing the delivery system prior to each laser procedure;	5.3.3.3			
	Monitoring the laser status;	5.3.3.3			
	Monitoring the delivery system (fibre/arm/waveguide), the path of the beam, and tissue interaction	5.3.3.3			
	Providing access to open or available water/saline;	5.3.3.3			
	Keeping wet cloths/drapes on hand to protect non-targeted areas as needed;	5.3.3.3			
	Evacuating gases from the body cavity or using an appropriate barrier, for example, an incise drape;	5.3.3.3			
	Using only nonflammable instruments and instruments with minimally reflective surfaces in the path of the beam;	5.3.3.3			
	Minimizing electrical hazards through inspection for the integrity of cords and plugs prior to use;	5.3.3.3			
	Adhering to drying times of flammable preparations and solutions as indicated by the manufacturer;	5.3.3.3			
	Evacuating plume.	5.3.3.3			
	Controls for Endotracheal (ET) Tube Procedures				
	A medical protocol for management of the airway during laser surgery shall be written by the ENT surgeon and the anesthesiologist.	5.3.3.4			
	All personnel working in a room during a shared airway procedure shall be competent in airway management procedures in the event of an airway fire.	5.3.3.4			
	Laser-resistant endotracheal tubes purposely manufactured for laser airway procedures shall be used. ET tubes shall be selected based on the wavelength of laser to be used and proof of manufacturer's testing within the surgical parameters anticipated during the surgery.	5.3.3.4			
	If the ET tube is taped to the patient's tissue or materials in the surgical field, non-flammable tape shall be used.	5.3.3.4			
	All emergency equipment designated in the airway management protocol shall be present in the room prior to beginning the surgical procedure.	5.3.3.4			
	A CO2 laser shall be tested for coaxial alignment of laser beams, and proper beam mode, prior to the patient undergoing anesthesia.	5.3.3.4			
	During jet ventilation anesthesia procedures, personnel shall be aware of the need for clear communication. The laser operator shall not place the laser in the ready mode until a verbal order is given to hold ventilation.	5.3.3.4			
	Protection of the patient's face and eyes shall be 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 shall be protected by a non-flammable tooth guard covered with wet gauze or alternative methods approved by the LSO and ENT surgeon.	5.3.3.4			
	Cotton patties used to pack the inflated ET tube cuff shall be included in the nurse's surgical sponge count.	5.3.3.4			
	Plume and LGAC Control Measures				
	Plume shall be captured and evacuated in accordance with CSA Z305.13	5.3.4.3			
	Infection Control Measures				
	Biohazardous waste shall be disposed of in accordance with the policies of the	5.4.1.3			

	facility and/or jurisdiction.				
	All laser delivery components shall be processed according to the manufacturer's instructions.	5.4.1.3			
	Standard precautions or universal precautions shall be used when caring for patients. If materials are contaminated by blood-borne pathogens, staff shall adhere to the requirements for precaution in accordance with the PHAC's *Infection Control Guidelines for Preventing the Transmission of Bloodborne Pathogens in Health Care and Public Service Settings.* Note: Jurisdictional regulations should be followed as they apply.	5.4.1.3			
	Personnel shall follow facility procedures for draping of delivery systems, pre- and post-procedure cleaning of equipment, decontamination, and disposal of biohazardous waste or materials.	5.4.1.3			
	Gases, Dyes, and Liquid Coolants Control Measures				
	The manufacturer/distributor using gases, dyes, and liquid coolants in its lasers shall provide the health care facility with the material safety data sheets (MSDS) for gases, dyes, and coolants in accordance with the Workplace Hazardous Material Information System (WHMIS).	5.4.2.3			
	The health care facility shall have a policy on prevention and management of possible exposure to gases, dyes, and coolants that includes: i) educating all personnel in proper handling of gases, dyes, and coolants; ii) developing a plan to contain gases, dyes, and coolants in case of a leak, which includes the evacuation of persons present; iii) establishing a response protocol in the event of a leak, which includes: 1) personnel required; 2) equipment needed; 3) automatic increase in ventilation as needed; and 4) hazardous materials disposal; and iv) generating and submitting an incident report according to facility policy.	5.4.2.3			
	Persons exposed to gases, dyes, and coolants shall be referred to a physician and the appropriate health and safety committee personnel.	5.4.2.3			
	Purge Gas Control Measures				
	Caution should be exercised when using purge gases in a body cavity in laser surgery.	5.4.3			
	Purge gases should be filtered.	5.4.3			
	Whenever possible, CO2 should be used as a purge gas instead of air or medical air.	5.4.3			
	Administrative Controls				
	- The facility administration shall ensure that a laser safety program is established and maintained in accordance with this Standard, applicable regulations, and professional guidelines. - Policies and procedures shall be reviewed yearly and revised as necessary to follow recent standards. - The development and revision/updating of laser safety procedures shall be performed by personnel directly involved in laser use and operation, in collaboration with the LSO and with final approval by the facility administration.	7.1			
	Documentation shall include: a) Laser utilization record for each laser system: This record should include: i) patient identification;	7.2			

	ii) date, treatment, and location; iii) equipment identification; iv) wavelength of laser, if a multi-wavelength laser is used; v) laser user; vi) laser operator; vii) operational procedures; viii) delivery system (e.g., objective lenses, fibre size, lot number, serial number); ix) range of treatment parameters (e.g., power (watts), energy (joules), pulse duration, pulse repetition rate, total energy delivered); x) signature of the laser operator or designate; and xi) record of laser system shutdowns. b) **Laser safety checklist:** If operational procedures are not included on the laser utilization record, a safety checklist shall be completed for each use of the laser separate from the patient record, in accordance with manufacturer's instructions and as revised by the LSO or designate. c) **Facility laser policies and procedures:** Personnel shall have access to facility policies and procedures, and access to policies and procedures specific to each laser use area. d) **Incident reports:** Incident reports shall be made for adverse events in accordance with facility requirements. The LSO shall be advised of all incidents or adverse events immediately. e) **Audit reports:** Audits shall be conducted on an annual basis, and audit reports shall be submitted to the LSO. f) **Service and maintenance reports:** The LSO shall have access to service and maintenance reports on lasers and related equipment. g) **Laser safety committee minutes:** The LSO shall have access to laser safety committee minutes, if applicable. h) **Education and training records:** The LSO shall maintain current lists of competent personnel and authorized users. Records should include date of renewal of applicable personnel training. i) **Hazard analysis and risk assessment:** The LSO shall maintain documentation of hazard analysis and risk assessment.				
	Indications for laser system shutdown - The administrator shall provide standard operating procedures (SOPs) (see Annex B) and a checklist to deal with unscheduled shutdowns of health care lasers in case of an event or equipment malfunction. In the case of an event, the SOPs shall indicate the person(s) to be notified, and in the case of equipment malfunction, the facility's protocol for health care equipment servicing shall be followed. - The manufacturer's recommendations shall be followed during an unscheduled laser system shutdown, and the following information should be recorded in the laser utilization record: a) time and date of shutdown; b) time and date of notification of problem, if any; c) nature of problem; d) person notified (to be stated in the facility's standard operating procedures (SOPs); and e) date of return to service.	7.3			

	Note: The laser might need to be shut down under any of the following conditions: a) shutter failure (i.e., shutter for the aiming lamp and/or laser lamp remains open); b) beam delivery system is not connected to the laser aperture securely; c) unexplained or uncontrolled operation occurs (i.e., inconsistent pulse power, power outage); d) if a fire occurred in the room; and e) other equipment malfunctions affecting the safety of the patient and attending personnel.				
	Nominal Ocular Hazard Area (NOHA)				
	If entrances to the laser-controlled area fall within the boundaries of the NOHA, administrative, engineering, or architectural design controls shall be initiated to prevent the NOHA from extending beyond the entrances. Note: *Examples of suitable controls include* a) *repositioning the patient or laser within the laser-controlled area;* b) *placing barriers in front of the entrances; and* c) *sealing cracks between doors and their frames.*	8.1.4			
	Laser-controlled Area				
	The administrator shall ensure that the area in which the health care laser is used provides a safe work environment. The following procedures shall be followed in the laser-controlled area: a) Access by staff shall be ensured at all times by controlling the entrances (in accordance with local rules for fire safety). Doors providing access to the laser-controlled area shall not be interlocked to the firing mechanism of the health care laser, i.e., the opening of a door to the laser-controlled area shall not switch off the laser. b) Signage shall comply with Figure 1 and 2, be posted at every door at eye level, and be visible only when the laser is in use and then be removed or covered. c) Personal protective equipment (PPE) intended for use with the laser in the controlled area shall be posted with each door warning sign. d) Windows and openings permitting viewing access to the laser-controlled area shall be covered or rendered in such a way as to restrict the passage of the laser beam through them. Window barriers shall be used for wavelengths shorter than 4000 nm and in between 180 nm to 300 nm, tested and approved to attenuate transmission of the laser beam to below the MPE, in accordance with the following: i) barriers shall be labelled in accordance with IEC 60825-1 (2007); ii) protection shall meet infection control requirements; iii) barriers shall be controllable from inside the laser room; and iv) barriers shall not allow any light leakage at the perimeters of the barriers. If the MPE is exceeded at the entryway, a curtain or barrier is also needed. ***Note:*** *The beam of a CO2 laser does not pass through glass. Therefore, windows and other openings might not require covering when this type of laser is in use.* e) The area shall be supervised by credentialed personnel trained in laser safety and approved by the LSO. f) The area shall be occupied by personnel approved by the LSO. g) The environment shall be free of highly reflective surfaces that could interfere with the beam path or might be present within the NOHA.	8.2.1			

	h) The environment shall be free of flammable surfaces or materials that could interfere with the beam path. i) Keys shall be removed from the control panel and stored with access only by personnel approved by the LSO. j) When more than one wavelength is present in the NOHA, only one may be activated at a time, and only one set of corresponding protective eyewear shall be out and available. k) The NOHA shall be reassessed if it increases during repair, service, or maintenance.				
	The presence of highly reflective surfaces in laser-controlled areas for Classes 3R, 3B, and 4 lasers should be minimized. Sources of reflections can include mirrors, highly polished glass, and surgical instruments.	8.2.2			
	Heating, Ventilation, and Air Conditioning				
	- Heating, ventilation, and air conditioning (HVAC) systems shall comply with appropriate national or provincial building codes and shall comply with CAN/CSA-Z317.2 or ANSI/ASHRAE 170 (ventilation standards for air quality, air changes per hour, etc.). - For the purpose of HVAC requirements, a laser-controlled area where a laser plume is generated should be considered similar to an operating room. - HVAC upgrades shall be considered for laser-controlled areas where a) the existing HVAC system does not meet the minimum air exchange rates described in Clause 8.3.2; and b) large volumes of laser plume are produced. - Augmentations to the existing HVAC system could include a) using a dedicated high-volume scavenging system, linked or vented into a permanently installed ventilation system and separate from the HVAC system, that can be localized close to the operative site; b) exhausting return air to the outdoors; or c) increasing the number of air changes per hour. - New health care facilities or those undergoing renovation should consider provisions for venting scavenged air to the outdoors so that it need not be recirculated within the laser-controlled area. - Laser equipment shall be used in a well-ventilated area to help remove excess heat generated by the laser. The air intake and outlet shall be kept unobstructed at all times.	8.3			
	Engineering Controls (Equipment)				
	The health care laser shall, as a minimum, include the following features: a) 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; *Note: In the case of pulsed lasers, the energy meter should indicate the average power of the laser, or the number of pulses per second, or both, as well as the pulse energy (per pulse).* b) 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; c) a visual warning activated during laser emission (in some circumstances, an audible warning may also be present);	8.4			

	Note: Laser users need to be aware of the status of the laser at all times. The status indicators described in Item c) should fulfill this requirement. d) warning labels at all apertures (i.e., at apertures and other locations on the laser system); e) a switch guard to prevent unintended operation of the laser system (e.g., a guarded foot pedal); and f) a laser operating manual that thoroughly addresses its use and associated hazards. *Note: The LSO needs to reassess his or her hazard analysis and procedures following software upgrades.*				
	Laser delivery devices shall be in accordance with the following: a) Only the manufacturer's laser delivery devices shall be used on the laser. b) Laser delivery devices shall be assembled and tested according to the manufacturer's instructions. Testing shall be done with the laser delivery devices that will be used for the procedure. c) Optics shall be checked for their integrity and cleaned according to the manufacturer's instructions. d) The laser user handling the laser delivery device shall be the only one operating the laser footswitch or handheld device. The footswitch shall not be bagged, as this can cause inadvertent firing. e) Laser delivery devices shall be maintained and serviced according to the manufacturer's instructions. f) A laser delivery device operating manual shall thoroughly address its use and associated hazards.	8.5			
	All instruments used in the beam path or adjacent to the treatment site shall have a matte finish or a diffusive surface to prevent specular reflections and shall be checked and reprocessed as surfaces become smooth after use.	8.6			
	Warning Signs				
	Warning signs posted in the vicinity of the laser-controlled area shall a) identify the laser-controlled area; b) establish the nature of the hazard by specifying the wavelength and class of laser being used; c) be posted on all means of access to the area; d) only be posted or illuminated when the system is powered on or in standby; and e) indicate that protective eyewear shall be worn.	8.7.2			
	Permanently mounted, non-illuminated warning signs shall be avoided, as some personnel might become used to their presence and ignore them.	8.7.3			
	Where illuminated signs are in use, they shall be illuminated only when the laser system is switched on.	8.7.4			
	The appropriate warning signs shown in Figure 3 shall be posted when health care lasers are used in laser-controlled areas. The wording of the warning signs is recommended but not mandatory. Other wording that conveys the same message may be substituted.	8.7.5			
	Adequate space shall be left on all signs to permit the inclusion of pertinent information. and shall include the following: a) at Position 1, above the tail of the sunburst, special precautionary instructions or protective actions required, such as i) for Class 3B health care lasers and laser systems, "LASER	8.7.7			

	RADIATION - AVOID DIRECT EXPOSURE TO BEAM" and ii) for Class 4 health care lasers and laser systems, "LASER RADIATION - AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION" b) at Position 1, above the tail of the sunburst, special precautionary instructions or protective action such as "LASER TREATMENT IN PROGRESS - EYE PROTECTION REQUIRED, OD ___" c) at Position 2, below the tail of the sunburst, the type of laser (ruby, helium-neon, etc.) and the emitted wavelength, pulse duration (if appropriate), and maximum output; and d) at Position 3, the class of the health care laser or laser system.				
	The warning sign shown in Figure 4 shall be posted outside of a temporary laser-controlled area, e.g., during periods of servicing. When a temporary laser-controlled area is created, the area outside the temporary area remains Class 1 while the area within is either Class 3B or 4, and the appropriate danger warning is required (see Figure 3). The wording of the warning sign is recommended but not mandatory. Other wording that conveys the same message may be substituted. Adequate space shall be left on all signs to permit the inclusion of pertinent information and shall include the following: a) at Position 1, above the tail of the sunburst, "SERVICE IN PROGRESS" b) at Position 2, "DO NOT ENTER"	8.7.8			
	Patient Protection				
	To avoid accidental exposure, teeth in the operative field shall be protected with a wrapping of material appropriate to the wavelength emitted by the laser. Note: *Laser irradiation of tooth enamel could leave permanent marks.*	9.2			
	A patient undergoing a laser procedure shall be fitted with protection, e.g., padding, eye cups, glasses, etc., appropriate to the procedure, wavelength, and power levels being used. **Notes:** 1) *In the case of visible or near-infrared wavelengths (*0.4 µm *to* 1.4 µm*), the moist eye pad should be covered with a metal eye shield and another moist pad should be placed on top.* 2) *Appropriate eye shields should be placed on top of the cornea to protect the eye during laser treatment of the eyelid. Lubricant, if used, should be water based.*	9.3			
	Prior to the procedure, patients should be provided with brochures or other illustrative materials explaining the laser procedure to be performed, the steps involved during the procedure, and pre- and post-treatment instructions. Patients shall be provided with information describing the risks associated with the laser procedure and the patient protective measures that will be taken.	9.1			

	Laser Acquisition				
	The health care facility shall have a documented process for the selection and acquisition of health care lasers. The same type of evaluation process applied to purchased equipment shall be applied to donated, leased, and loaned equipment. This process shall include an assessment of the need and usefulness of the equipment within the facility.	10.1.1			
	The following factors shall be taken into consideration when acquiring a health care laser: a) The health care facility designee should prepare a clear statement of objectives on the use of the laser system to ensure its safe and efficient use. **Note:** *It is vital that a needs assessment and impact analysis be performed to ensure the safety of both patients and personnel.* b) The health care facility shall ensure that all policies, procedures, education, training, and safety guidelines are in place prior to the use of the laser systems with patients, even when the equipment is being evaluated on a trial basis. c) The model of the laser to be acquired should be determined by the features and capabilities of the system, the laser user's preference, and the expected results. The level of difficulty in servicing the system and operating the system, and the financial practicality of using a laser system should also be taken into consideration. **Note:** *The laser user's preference should not necessarily be the primary determination of the laser selection process. The efficiency, reliability, ease of servicing, costs of service contracts, and other costs are important factors. The laser user might leave the health care facility at some time in the future; the facility could then be left with the responsibility of maintaining a laser for which there is limited use.* d) The appropriateness of the room(s) in which the laser is to be used should be reviewed for the laser system's requirements and the hazard controls affecting both the patient and laser personnel. As a minimum, the following factors should be considered during this evaluation: i) electrical services; ii) ventilation services; iii) fenestrations; iv) physical dimensions and storage space; v) access restrictions; vi) safety needs of maintenance and service personnel; and vii) additional services required to support the procedures performed in the room(s). **Note:** *Adequate consideration of these factors can lead to an improved quality of care (i.e., favourable patient recovery and outcome, laser personnel comfort and efficiency) and could have beneficial financial implications.*	10.1.2			
	Health care laser equipment shall be marked with an appropriate risk class or equipment type in accordance with the requirements of CAN/CSA-E60825-1, as applicable. Any laser system being considered for acquisition should, if possible, be installed at the health care facility for use on a trial basis by all the laser users intending to use the laser system, in order to evaluate the appropriateness of the technology and the expected use of the equipment.	10.1.3			

	The laser system which is being used on a trial basis shall only be operated by facility credentialed personnel (see Clause 6) when used with patients. The system may be operated under the supervision of a qualified clinical and/or technical representative when used on inanimate teaching or test objects.	10.1.4			
	Safety equipment may be available at the time the laser system is acquired. The following equipment could be part of the laser accessory list: a) protective eyewear for patients and personnel; b) laser-use warning signs; c) laser-resistant endotracheal tubes; d) laser-compatible endoscopes and endoguides; e) slit lamps, indirect ophthalmoscopes, and/or fiber optic delivery systems; f) disposable filtration respirators; and g) plume-scavenging systems and their replacement filters.	10.1.6			
	Instruments to be used with the laser shall have a matte or diffusive surface finish to prevent errant specular reflections of the laser light.	10.1.7			
	Laser Installation				
	The space or room in which the laser system is installed shall meet the appropriate requirements of the *Canadian Electrical Code, Part I,* and the equipment manufacturer's instructions. Note: *Users of this Standard should refer to Sections 24 and 52 of the* Canadian Electrical Code, Part I, *and to CSA Z32.*	10.3			
	Laser Maintenance				
	The health care facility LSO or designee shall ensure that a maintenance program for health care lasers is in place and that personnel are appropriately qualified, whether in-house services or contracted services are used.	10.4.2			
	Inspections, tests, and maintenance, as described in this Standard, shall be a) made in accordance with a written plan approved by the health care facility; b) made upon failure of the equipment to operate properly (equipment function settings and parameters should be noted at the time of equipment malfunction); c) made at the intervals indicated in the description of each test or inspection (these intervals should not be less than those recommended by the manufacturer); and d) recorded in a maintenance record which forms a part of the facility's permanent records. The maintenance record shall contain a page, card, or file for each laser.	10.4.3			
	All laser equipment malfunctions shall be recorded and corrected. The dates on which each malfunction, e.g., deviation from present requirements or the manufacturer's specifications, or physical damage, was first noted and ultimately corrected shall be entered in the record.	10.4.4			
	Equipment service information, i.e., repairs, maintenance, calibration, and compliance with the preventive maintenance program, shall be made available to equipment users to ensure that they are kept informed of the status of the equipment.	10.4.5			
	Preventive maintenance assurance shall verify, but not be limited to, a) correct operation of key functions of the laser's operation in conjunction with the manufacturer's service and operator manuals; b) the power output of the laser beam; Note: *This should be verified periodically, at least every six months to a year, and checked against the output rating on the control panel. With time and use, components age, dirt accumulates, and optics can become misaligned.*	10.4.6			

	c) the integrity of all covers and insulation designed to prevent access to live parts; and d) that leakage currents are within proper limits.				
	Inspection and maintenance shall be provided if there are indications that the health care laser system a) has been subjected to extreme mechanical stress (e.g., been bumped or struck); b) has had fluid invasion into or on the laser; c) has been subjected to extreme temperature or humidity; d) performance appears to have changed; e) has portions of the enclosure cracked, removed, or missing; f) has had any attachment plug, power supply cord, or patient connection deteriorate; or g) has smoke or odours being released.	10.4.7			
	Personnel who require access to the laser or laser system contained within a protective housing or beam enclosure shall comply with the appropriate control measures of the embedded laser or laser system. The service personnel shall have education and training commensurate with the class of the embedded laser or laser system.	10.4.8			
	Secured entry or an enclosure shall be used when laser hazards that are otherwise normally shielded are exposed (i.e., during repair and maintenance).	10.4.9			
	Alignment of laser optical systems, e.g., mirrors, lenses, and beam deflectors, shall be performed in such a manner that the primary beam, or a specular or diffuse reflection of a beam, does not expose an eye to a level above the applicable MPE.	10.4.10			
	Responsibilities, Education, Training and Credentials				
	I. Each member of the laser team shall have the authority, as well as responsibility, to halt an unsafe practice. All team members shall be equally knowledgeable and aware of activities occurring in the laser controlled area to ensure patient and staff safety at all times.	6.1			
	Health care facilities where lasers are in use should have or establish a laser safety committee (LSC). The LSC shall consist of the LSO and should include, but not be limited to, representatives from a) nursing administration; b) medical administration; c) biomedical or clinical engineering; d) risk management and quality assurance; e) laser users; f) anesthesia; g) laser operators; h) occupational health professionals; i) infection control professionals; and j) clinical education services.	6.2.1.1 & 6.2.1.2			
	The duties of the LSC should include, but not be limited to, a) development and approval of policies governing the safe use of lasers in the health care facility; b) definition and implementation of maintenance guidelines for the laser system; c) definition, monitoring, and enforcement of safety standards and policies developed for laser applications; d) definition of the LSO's duties and responsibilities (See Clause 6.3.1);	6.2.1.3			

	e) ensuring that a safety survey is conducted in all areas using laser equipment at intervals determined by the LSO; f) recommendation of laser-safety criteria for granting laser privileges to qualified physicians; g) facilitating safety training and education of all staff involved with laser surgery; h) review of all laser equipment and related health care facility modifications with respect to acquisition, with input from medical personnel when appropriate; i) review of new applications for laser equipment as they become available; **Note:** When improving or expanding laser facilities, examine existing equipment or possible upgrades (laser accessories as well as the laser system) to determine to what extent already-acquired equipment can be utilized. j) review and recommendation of data elements to be included in facility-approved records, logs, and documentation forms; and k) development of quality assurance and risk management programs.				
	Facility administration shall: 1. Verify initial and continuing credentials or approvals for all personnel responsible for working with lasers (e.g., physicians, laser operators, associated health care staff, laser users other than physicians, laser service providers, and manufacturers). 2. Ensure that laser safety and education programs for all personnel are conducted a) when an existing laser system i) is used in a new application; ii) undergoes a change to operational components (e.g., software updates); or iii) is used with a new delivery device; b) when a new or replacement laser system is to be placed into service; c) following a period of absence (as determined by the LSO) from participating in laser procedures; d) at the request of the administrator, the LSO, the LSC, or the staff member concerned; and e) at a minimum of every 2 years. 3. Require that a written program be developed and used for the education and training of personnel appropriate to their responsibilities in the laser-controlled area, as recommended by the LSC and approved by the LSO. 4. Determine the qualification of instructors. Criteria and qualifications to consider are as follows: a) minimum 2 years clinical experience with lasers in a clinical environment; b) recommendations from the LSC; c) LSO (laser safety officer) or DLSO (deputy laser safety officer); d) CMLSO (certified medical laser safety officer) or equivalent; e) perioperative educators (laser experience preferred); and f) third-party experts in laser safety education.	6.2.2.1 & 6.2.2.2 & 6.2.2.3			
	Training programs shall be evaluated by the LSO and the LSC for applicability to the facility's practice.	6.2.2.4			
	Successful completion of the program for all personnel responsible for working with lasers shall be documented.	6.2.2.5			

	Health care facilities where lasers are in use shall appoint an LSO and should appoint a deputy laser safety officer (DLSO) as needed. Note: *The LSO may delegate any responsibilities to a designate with the appropriate qualifications or credentials.*	6.3.1.2			
	The LSO shall be responsible for the following: a) facilitating the development of the laser safety program; b) implementing and enforcing all laser safety policies and procedures approved by the facility administration; c) supporting and advising the health care administration with respect to the safe use of lasers and compliance with protective measures; d) participating in the investigation of all laser-related incidents and malfunctions and making recommendations for remedial and preventive action; e) conducting hazard evaluations of sites, including determination of the NOHA; f) advising on the purchase of all laser-related personal protective equipment (PPE) and laser systems and instrumentation; g) auditing the effectiveness of i) the laser safety program; ii) maintenance of appropriate documentation; iii) compliance with policies and procedures; and iv) compliance with applicable standards and regulations; h) recommending the suspension, restriction, or termination of the use of a laser or laser system if it is determined that the laser hazard controls are inadequate or unsafe conditions are present; i) verifying that preventive maintenance, repair, and servicing are performed and advising the user of any resulting changes or modifications to the system; j) verifying that the manufacturer/distributor is in compliance with all applicable legislation; k) ensuring the safety education and training of all personnel involved in laser procedures; l) verifying and maintaining a list of health care personnel, authorized laser operators, and assistants, as well as documentation of their clinical competency; and m) any additional services requested by facility administration.	6.3.1.3			
	The education and training for the LSO and the DLSO shall include, but not be limited to, a) principles of laser science and tissue interactions; b) risk assessment; c) evaluation and selection of PPE; d) facility policies, procedures, and applicable standards and regulations for laser safety; e) wavelength-specific applications; f) laser set-up, testing, and shutdown procedures; g) monitoring the environment and equipment during laser use; and h) emergency procedures (e.g., in case of fire).	6.3.1.4			
	A list of personnel with procedure-specific and wavelength-specific laser privileges shall be maintained by the LSO and within those departments providing laser services.	6.3.1.4.2			
	The LSO, in collaboration with the facility administration, shall ensure that laser safety and education programs for all personnel are conducted a) when an existing laser system i) is used in a new application; ii) undergoes a change to operational components (e.g., software	6.3.1.4.3			

	updates); or iii) is used with a new delivery device; b) when a new or replacement laser system is to be placed into service; c) following a period of absence (as determined by the LSO) from participating in laser procedures; d) at the request of the administrator, the LSO, the LSC, or the staff member concerned; and e) at a minimum of every 2 years.				
	The assignment of a laser user shall be approved by the facility's credentials committee and administration. Maintenance of competencies, including updates on safety education, shall be monitored by the laser safety officer (LSO) at a frequency determined by facility administration. Candidates for laser user shall meet the qualifications and credentials for a given clinical setting and application.	6.3.2.2			
	In the absence of a laser operator or assisting staff, the responsibilities of the laser user shall include, but are not limited to, the following: a) Pre-laser set-up: ensuring that laser safety procedures, including correct set-up and testing of the laser and related equipment, are followed. This includes, but is not limited to, i) checking the laser system before operation; ii) ensuring controlled access to laser operation (e.g., operation key and power switch locks are restricted to authorized personnel only); iii) ensuring that the laser is in "standby" or "off" mode when not in use; iv) checking the laser beam alignment and fibre integrity; v) visually inspecting the laser equipment for potential electrical malfunctions; a vi) ensuring that user/operator manuals and facility policies are present in the laser-controlled area. b) Laser treatment: ensuring that safe laser treatment is employed for the patient and all personnel in the treatment area. This includes, but is not limited to, i) being in the room at all times during laser usage; ii) selecting appropriate laser parameters for a given clinical application; iii) ensuring appropriate eye and skin protection is employed by all personnel in the treatment area; iv) ensuring the safe and proper use of ancillary equipment (such as plume evacuators or cooling apparatus); v) safeguarding against laser beam reflection or inadvertent transmission to unintended targets (e.g., use of beam stops and minimally reflective instruments); vi) assembly of safety equipment and ensuring that it is immediately accessible should it be needed (e.g., wet gauze); and vii) immediate identification of laser-tissue complications and subsequent management. c) Post-laser treatment: ensuring the safe conclusion of laser operation. This includes, but is not limited to, i) completing documentation as required by the facility (e.g., operating checklist, log book, patient admission forms); ii) ensuring post-procedure cleaning and storage of the laser and related equipment; iii) reporting unusual events and safety concerns to the LSO; iv) ensuring that the laser equipment, patient, and laser personnel are all in safe condition to exit the laser-controlled area; and v) post-operative instructions to the patient and arrangement of	6.3.2.3			

	appropriate patient follow-up over the healing period.				
	Laser users shall undergo Level 4 laser training as outlined in Annex E with review of education at a minimum of every 2 years.	6.3.2.4			
	The assignment of a laser operator shall be approved by the facility's credentials committee and administration. Maintenance of competencies, including updates on safety education, shall be monitored by the laser safety officer (LSO) at a frequency determined by facility administration. Candidates for laser operator shall meet the qualifications and credentials for a given clinical setting and application.	6.3.3.2			
	The responsibilities of the laser operator shall include, but are not limited to, the following: a) Pre-laser set-up: ensuring that laser safety procedures, including correct set-up and testing of the laser and related equipment, are followed. This includes, but is not limited to, i) establishing the laser-controlled area; ii) obtaining the laser key, and positioning the laser and all required laser-related and safety equipment in the laser-controlled area; iii) visually inspecting the laser equipment for potential malfunctions or damage; iv) performing applicable testing or calibration as indicated in the manufacturer's instructions; and v) returning the laser to the "standby" position or shutting down and removing the key if laser use is delayed. b) Laser treatment: ensuring that safe laser treatment is employed for the patient and all personnel in the treatment area. This includes, but is not limited to, i) monitoring all aspects of laser and laser-related device use at all times when the laser is in "ready" mode; ii) being in the room at all times during laser usage, and remaining at the control panel when the laser is in "ready" mode; and iii) ensuring good communication between laser user and laser operator (e.g., regarding status of laser and parameters). c) Post-laser treatment: ensuring the safe conclusion of laser operation. This includes, but is not limited to, i) completing documentation as required by the facility (e.g., operating checklist, log book, patient admission forms); ii) ensuring post-procedure cleaning and storage of the laser and related equipment; and iii) reporting unusual events and safety concerns to the LSO.	6.3.3.3			
	Laser operators shall undergo Level 2 laser training as outlined in Annex E with review of education at a minimum of every 2 years.	6.3.3.4			
	The assignment of health care personnel shall be approved by the facility's credentials committee and administration. Health care personnel shall be authorized to perform specific duties in a laser-controlled area. Candidates for health care personnel shall meet the qualifications and credentials for a given clinical setting and application.	6.4.1.2			
	Responsibilities of health care personnel in a laser-controlled area shall be clearly assigned and be understood by all respective individuals. Health care personnel should restrict their actions during laser treatment to their specific role only and not engage in activities beyond their scope.	6.4.1.3			
	Health care personnel shall undergo Level 1 laser training as outlined in Annex E with review of education at a minimum of every 2 years.	6.4.1.4			
	Responsibilities of observers in a laser-controlled area are to remain non-obstructive to the process of laser treatment and to not interfere with any aspect	6.4.2.2 &			

	of activities during the session. If an observer is feeling unwell or anticipates disruption of the laser treatment process in any way, that individual shall inform the laser user or laser operator of the situation and ask permission to leave the laser-controlled area. Observers shall comply with all facility policies and procedures. The LSO shall determine the level of education or orientation required for observers in the NOHA.	6.4.2.3			
	Trainees shall be under the direct supervision and responsibility of authorized laser personnel. Responsibilities of trainees in a laser-controlled area are to remain non-obstructive to the process of laser treatment and to not interfere with any aspect of activities during the session. Trainees shall strictly abide by instructions outlined by their laser personnel supervisor. If a trainee is feeling unwell or anticipates disruption of the laser treatment process in any way, that individual shall inform the laser user or laser operator of the situation and ask permission to leave the laser-controlled area. Trainees shall undergo Level 1 laser training as outlined in Annex E.	6.4.3.1 & 6.4.3.2 & 6.4.3.3			
	Annex E - Education and Training				
	Level 1 - This is necessary for: • non-clinical facility personnel who are involved in the management of the laser program or laser services • observers • trainees This is suggested for: • non-clinical members of the laser safety committee (LSC) • administration and management, assumed to be non- clinical personnel. Need is education on the risk management aspects - standards, audit, and compliance. The content shall include, but is not limited to, the following: • overview of this Standard • 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	E.1			
	Level 2 - This is necessary for: • Laser operator (LO) This includes: • Level 1 laser training The content shall include, but is not limited to, the following: • 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	E.2			

	Level 3 - This is necessary for: • Laser safety officer (LSO) This includes: • Level 2 laser training The content shall include, but is not limited to, the following: • all items in Level 1 and 2 training • regulatory requirements in the specific jurisdiction • application of this Standard • hazard identification and implementation of applicable control measures • facility reporting for accidents, incidents, or occurrences	E.3			
	Level 4 - This is necessary for: • Laser users (LU) The content shall include, but is not limited to, the following: • 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.)	E.4			