College of Physicians & Surgeons of Alberta

Paper-Based Compliance Verification Report Form

Class 3b and 4 Lasers

*A site visit by an ARPA remains the gold standard. The paper-based compliance verification report is used for **renewals**, not new equipment. To register new lasers, please contact an Authorized Radiation Protection Agency (ARPA) and schedule an on-site inspection.

A. Instructions:

1. Complete a separate report for each laser to be renewed.
2. Complete section B using the laser manufacturer information found in the technical manual.
3. Complete section C using the detailed guidelines provided in section F.
4. Copy and paste photographic evidence of equipment in section D (manufacturer, model name, serial number, manufacturer date).
5. Owner of equipment signs and dates the report in section D.
6. Submit sections A-D with the CPSA Equipment Profile(s) to an Authorized Radiation Protection Agency (ARPA).
7. Review the report information with ARPA in real time (i.e. Teleconference, Skype, etc).
8. ARPA signs and dates in section E.

B. Equipment Specifications

Use the he technical manual provided by the laser manufacturer to complete the following:

Type of laser: gas_____ solid_____ liquid_____

manufacturer_____ manufacturer date_____

model number_____ serial number_____

Installation: stationary ☐ mobile (on wheels) ☐ portable (hand carrying) ☐

Clinical Application (e.g. dermatology, ophthamology, etc.): _____

Output Mode: continuous wave ☐ pulsed ☐ continuous wave/pulsed ☐

Output Power: _____ watts

Pulsed Lasers: a) pulse energy:_____joules b) pulse duration: _____econds

c) pulse repetition rate: _____ pps(Hz)

Beam Diameter ($1/e^2$): _____ cm **Wavelength:** _____ nm

Focal Length (focusing lens): _____ cm **Numerical Aperture (fibre optic):** _____ (unitless)

Protective eyewear wavelength: _____ nm

Protective eyewear optical density: _____ (unitless)

Beam Divergence: _____ mrad

Nominal Hazard Zone Determination: manufacturer determined: _____meters or entire room

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C. Compliance Requirements:
In accordance with CAN/CSA Z386 14, Safe Use of Lasers in Health Care

Use Section E guidelines to indicate the following: Yes:
The laser meets the compliance requirement
No: The laser does not meet the compliance requirement
N/A: If the requirement is not applicable for the make, model or application of the laser

Item-No.	Compliance Item Description	Standard	Yes	No	N/A
	Risk Assessment - Hazards, Risks and Control Measures				
1	The nominal ocular hazard area is determined for each laser in use.	4.0			
2	Policies, procedure and control measures are based on risk assessments of laser operations.	5.1			
3	Persons are protected through the implementation of appropriate control measures.	5.2.3			
	Ocular & Skin Control Measures				
4	The required optical density of protective eyewear has been determined.	5.3.1.3			
5	Protective eyewear is available at each point of access to laser treatment controlled area.	5.3.1.3			
6	Protective eyewear is labelled with the optical density and wavelength it protects against.	5.3.1.3			
7	Protective eyewear is worn by all personnel in the laser treatment controlled area.	5.3.1.3			
8	Protective eyewear is maintained according to manufacturer guidelines.	5.3.1.3			
9	Protective eyewear has side guards on it.	5.3.1.3			
10	Protective eyewear is inspected prior to each use.	5.3.1.3			
11	Optical viewing equipment is equipped with filters that protect eyes from laser light.	5.3.1.3			
12	Patients are provided with eye protection from laser light.	5.3.1.3			
	Fire and Explosion Control Measures				
13	Fire drills are conducted once a year.	5.3.3.3			
14	Fire extinguishers are located in areas free of physical obstructions.	5.3.3.3			
15	Laser personnel know how to access and operate the fire extinguishers.	5.3.3.3			

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16	Laser delivery systems are tested prior to using lasers.	5.3.3.3			
17	The laser beam and delivering system is continuously monitored during operations.	5.3.3.3			
18	Water or saline is accessible in the laser treatment controlled area.	5.3.3.3			
19	Wet cloths and drapes are on hand to protect non-targeted areas.	5.3.3.3			
20	Patient body cavity gases are evacuated.	5.3.3.3			
21	Only non-flammable / non-reflective material is used in the path of the laser beam.	5.3.3.3			
22	Electrical hazards are minimized by inspecting power cords and plugs prior to use.	5.3.3.3			
23	Laser generated air contaminates are evacuated.	5.3.3.3			
	Controls for Endotracheal (ET) Tube Procedures				
24	A medical protocol for management of the patient airway during laser surgery is available.	5.3.3.4			
25	Persons are competent in patient airway management in the event of an airway fire.	5.3.3.4			
26	Laser-resistant endotracheal tubes are used.	5.3.3.4			
27	If the endotracheal tube is taped to the patient, nonflammable tape is used.	5.3.3.4			
28	Emergency patient airway management equipment is in the room prior to the surgery.	5.3.3.4			
29	A CO_2 laser is tested prior to the patient undergoing anesthesia.	5.3.3.4			
30	Clear communication is established during jet ventilation anesthesia procedures.	5.3.3.4			
31	The laser in not placed in the ready mode until a verbal order is given to hold ventilation.	5.3.3.4			
32	The patient's face, eyes and teeth are protected from the laser beam.	5.3.3.4			
33	Cotton patties to pack the ET tube cuff are included in the nurse's surgical sponge count.	5.3.3.4			
	Infection Control Measures				
34	Standard / universal precautions are used when caring for patients.	5.4.1.3			
35	Bio-hazardous waste is properly disposed.	5.4.1.3			
36	Procedures are available for the draping of laser delivery systems.	5.4.1.3			
37	Procedures are available for cleaning and decontamination of laser equipment.	5.4.1.3			
	Gases, Dyes, and Liquid Coolants Control Measures				
38	Material Safety Data Sheets are available.	5.4.2.3			
39	A policy exists for prevention of exposure to gases, dyes, and coolants.	5.4.2.3			

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40	Persons exposed to gases/dyes/coolants are referred to a physician /laser safety committee.	5.4.2.3			
	Purge Gas Control Measures				
41	Caution is exercised when using purge gas in a body cavity during laser surgery.	5.4.3			
42	Purge gas should be filtered.	5.4.3			
43	CO_2 is used as a purge gas instead of air or medical air whenever possible.	5.4.3			
	Administrative Controls				
44	The facility administration shall ensure that a laser safety program is established.	7.1			
45	Policies and procedures shall be reviewed yearly and revised as necessary.	7.1			
46	Operations personnel are involved in the development /revision of laser safety procedures.	7.1			
47	Personnel have access to policies and procedures specific to each area of laser use.	7.2			
48	A Laser Utilization Record is kept of laser use.	7.2			
49	A laser safety checklist is used if it is not included in the Laser Utilization Record.	7.2			
50	Laser safety audits are conducted annually and reviewed by the laser safety officer.	7.2			
51	The laser safety officer has access to all reports on the lasers and related equipment.	7.2			
52	Incident reports are written for adverse laser events.	7.2			
53	The laser safety officer is immediately advised of all laser incidents or adverse laser events.	7.2			
54	The laser safety officer has access to laser safety committee minutes if applicable.	7.2			
55	The laser safety officer maintains lists and records of current authorized laser users.	7.2			
56	The laser safety officer keeps records of laser hazard analyses and risk assessments.	7.2			
57	Procedures and checklists are used to deal with the unscheduled shutdowns of lasers.	7.3			
	Laser-controlled Area				
58	The nominal ocular hazard area is restricted to the room where the laser is operated.	8.1.4			
59	Access to the room where the laser is operated is controlled.	8.2.1			
60	Power to the laser will <u>not</u> be automatically turned off by opening the entrance door(s).	8.2.1			
61	The protective eyewear required when the laser is operating will be posted at the entrance.	8.2.1			

62	Preventive measures are taken to prevent the laser beam from passing through windows.	8.2.1			
63	The area where the laser is operated is properly supervised.	8.2.1			
64	When a laser is in use only persons approved by the laser safety officer are in the room.	8.2.1			
65	The laser area is free of surfaces that could cause hazardous reflections of the laser beam.	8.2.1-2			
66	Measures are taken to prevent the laser beam from contacting combustible material.	8.2.1			
67	Lasers emitting different wavelengths are not operated simultaneously.	8.2.1			
68	When the laser is not in use the laser control panel key is kept in a secure area.	8.2.1			
69	The nominal ocular hazard area is reassessed prior to laser repair, service, or maintenance.	8.2.1			
	Heating, Ventilation, and Air Conditioning				
70	Heating, ventilation, and air conditioning (HVAC) systems comply with building codes.	8.3			
71	The air intake and outlet of the HVAC system is kept unobstructed at all times.	8.3			
72	The room is well-ventilated to help remove excess heat generated by the laser.	8.3			
	Engineering Controls (Equipment)				
73	The laser control panel provides an indication of the power output of the laser.	8.4			
74	The laser control panel has a removable key or security code.	8.4			
75	The laser has a visual warning that is activated during laser emission.	8.4			
76	The laser system is affixed with warning labels at all openings where the beam is emitted.	8.4			
77	The foot pedal controlling laser emission has a guard on it to prevent inadvertent operation.	8.4			
78	The laser operating manual is readily available to personnel.	8.4			
79	The laser delivery device operating manual is readily available to personnel.	8.5			
80	Only manufacture approved laser delivery devices are used with the laser.	8.5			
81	Laser delivery devices are assembled / tested according to the manufacturer guidelines.	8.5			
82	Laser delivery devices are maintained / serviced according to the manufacturer guidelines.	8.5			
83	Laser optical components are cleaned and inspected according to manufacturer guidelines.	8.5			
84	Only the person handling the laser delivery device may activate the laser emission switch.	8.5			

85	The laser emission footswitch is never bagged, as this can cause inadvertent firing.	8.5			
86	Instruments used in the beam path or adjacent to the treatment site have a matte finish.	8.6			
	Warning Signs				
87	Laser warning signs are posted at all points of access to the laser treatment controlled area.	8.7.2			
88	Laser warning signs indicate the wavelength and hazard class of the laser being used.	8.7.2			
89	Laser warning signs are only visible when the laser system is powered on or in standby.	8.7.2			
90	Laser warning signs indicate that protective eyewear is required to be worn.	8.7.2			
91	Laser warning signs specify the nature of the hazard and the protective measures required.	8.7.7			
92	A temporary laser area warning sign is posted whenever the laser is being serviced.	8.7.8			
	Patient Protection				
93	Patients are provided with information on risks of the laser and protective measures taken.	9.1			
94	A patient undergoing a laser procedure shall be fitted with eye protection.	9.3			
95	Patient's teeth in the operative field are protected from exposure to the laser beam.	9.2			
	Laser Acquisition				
96	The facility has a documented process for the selection and acquisition of lasers.	10.1.1			
97	The facility prepares a clear statement of objectives on the use of the laser system.	10.1.2			
98	Policies, procedures, training, and safety guidelines are in place prior to laser use.	10.1.2			
99	The appropriateness of a room is reviewed prior to laser use in the room.	10.1.2			
100	Lasers are marked with the appropriate risk classification or equipment type.	10.1.3			
101	When a laser is used on a trial basis only persons with proper credentials may use the laser.	10.1.4			
102	Safety equipment should be available at the time the laser system is acquired.	10.1.6			
103	The laser room satisfies the *Canadian Electrical Code, Part I and* manufacturer guidelines.	10.3			
	Laser Maintenance				
104	A maintenance program for the laser is in place.	10.4.2			

105	Laser inspections, tests, and maintenance require a written plan approved by the facility.	10.4.3			
106	All laser equipment malfunctions are recorded and corrected.	10.4.4			
107	Equipment service information is made available to laser users.	10.4.5			
108	Preventive maintenance is conducted to verify correct operation of the laser system.	10.4.6			
109	Inspection /maintenance shall be conducted if the laser is suspected to be damaged.	10.4.7			
110	Control measures are in place to gain access to lasers that are normally enclosed.	10.4.8			
111	Laser service personnel are properly trained.	10.4.8			
112	Laser alignment procedures are used to prevent persons from exceeding exposure limits.	10.4.10			
	Responsibilities, Education, Training and Credentials				
113	A laser safety officer has been appointed for the facility.	6.3.1.2			
114	The facility has a laser safety committee.	6.2.1.1 -			
115	The type of laser training provided has been properly evaluated.	6.2.2.4			
116	All persons involved in laser operations are trained in laser safety.	6.1			
117	A record of persons who have completed laser safety training is maintained.	6.2.2.5			
118	Only persons approved by the facility administration may use healthcare lasers.	6.3.2.2			
119	A list of personnel with laser use privileges is maintained.	6.3.1.4.2			
120	Responsibilities of persons in a laser-controlled area are clearly assigned and understood.	6.4.1.3			
121	Trainees are under the direct supervision and responsibility of authorized laser personnel.	6.4.3.1 - 3			

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D. Photographic evidence of laser equipment – manufacturer/model name/serial number/manufacturer date (as identified on equipment)

I have reviewed all the information contained in this form live time with an Authorized Radiation Protection Agency (ARPA). The facility in which this piece of equipment is used complies with the Alberta *Radiation Protection Act* and Regulations.

Owner Name _____ Date _____

Owner Signature _____

Your privacy is important to us!

We collect, use and/or disclose your personal information with your consent unless otherwise authorized or required by legislation. As per our CPSA Privacy Statement, we collect and use your personal information to do our College work, which is to protect the public and to guide and regulate Alberta physicians.

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THIS SECTION IS COMPLETED BY THE AUTHORIZED RADIATION PROTECTION AGENCY

E. Compliance Summary

Item no.	Corrective Action / Comments

☐ Equipment and facility are in full compliance with all applicable standards.

☐ Items of non-compliance were found and corrected as per comments provided above.

Authorized Radiation Protection Agency

Inspector Name: _____ Date: _____

Inspector Signature: _____

Agency Name: _____

Agency Address: _____

_____

_____

Please complete and return to the
College of Physicians & Surgeons of Alberta by fax: 780-428-2712 or by mail:
2700 - 10020 100 ST NW, Edmonton AB T5J 0N3
or email leeanne.lawrence@cpsa.ab.ca.

F. Detailed Guidelines

Item 1: The laser safety officer shall ensure that the hazard classification and nominal ocular hazard area are determined for each laser in use.

Verification Method: Record review.

Item 2: A risk assessment shall be performed before policies and procedural guidelines are developed to determine the engineering and procedural control measures that are required.

Verification Method: Record review

Item 3: 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 *CSA-Z386-14, Safe Use of Lasers in Health Care*.

Verification Method: Record review and site inspection

Item 4: All protective eyewear and filters shall be selected with an optical density (L-value) sufficiently high to protect against the wavelengths of the laser in use in the nominal ocular hazard area. Exposure to laser radiation from the direct beam and reflections must not exceed the maximum permissible exposure level for the eye specified in *CSA-Z386-14, Safe Use of Lasers in Health Care*. Within certain portions of the laser treatment controlled area there is the potential for ocular exposures to exceed the maximum permissible exposure level therefore laser protective eyewear is required. Lasers designed for corneal refractive surgery have a very limited nominal hazard area that extends vertically from the laser aperture to the target tissue of the patient. Therefore, protective eyewear may not be required for this particular application under normal operating conditions.

The protective eyewear must be designed specifically to protect against the wavelength of the laser in use and have a large enough optical density to attenuate laser radiation below the maximum permissible exposure level. The optical density (L- value) is defined as follows:

*Optical density = Log (exposure level **/** maximum permissible exposure level)*

The exposure level and maximum permissible exposure level are in the same units (J /cm^2 or W/cm^2). Determination of the required optical density can be complex and should be undertaken by a person trained in laser physics.

Verification Method: Check that the protective eyewear has a stamp or label on it indicating the wavelength(s) and associated optical density (L) for which it provides protection. Compare this to the required optical density for the type of laser and conditions of use.

Item 5: Appropriate protective eyewear shall be made available at each point of access to the laser treatment controlled area.

Verification Method: Perform a site inspection.

Item 6: The protective eyewear shall be permanently labelled with applicable optical densities (L) and wavelengths.

Verification Method: Inspect the protective eyewear.

Item 7: The protective eyewear shall be worn by all personnel in the nominal ocular hazard area during laser use.

Verification Method: Inspect the laser work area and interview the staff. The number of pairs of protective eyewear must be sufficient to provide protection for all persons in the treatment room including the patient.

Item 8: The protective eyewear shall be maintained according to the manufacturer's instructions. Visually check the physical condition of the protective eyewear for cracks, pitting or other evidence of damage which require replacement of the eyewear.

Verification Method: Inspect the condition of the protective eyewear and the storage method and location.

Item 9: The eyewear shall have side guards to prevent the laser beam from entering the area between the eye and the eyewear.

Verification Method: Inspect the protective eyewear.

Item 10: The protective eyewear shall be inspected prior to use for pitting, crazing, cracking, mechanical integrity, discoloration, and coating damage.

Verification Method: Inspect the protective eyewear.

Item 11: Optical viewing equipment (e.g. viewing port, microscope, endoscope, bronchoscope, ophthalmoscope, magnifying glass, loupes, or binoculars) shall be used with protective eyewear or a protective filter installed in the equipment. For example, some laser systems are designed to allow the operator to visualize the target tissue area through an optical system such as a scope lens while at the same time operating the laser. To prevent exposure to the operator from reflected and scattered laser light above the maximum permissible exposure level there should be a shutter or filter that is automatically inserted into the field of view when the laser light enters the field of view.

Verification Method: Review the optical viewing equipment description in its operating manual to verify it has installed filters. In lieu of this, protective goggles must be provided to laser users.

Item 12: 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.

Verification Method: Inspect the laser treatment room to ensure that patient eye protection is available.

Item 13: Conduct fire drills at least once a year.

Verification Method: Review the records of past fire drills to verify that they are conducted at the required frequency.

Item 14: Keep any fire extinguishers located in the controlled area free of obstruction.

Verification Method: Perform a site inspection.

Item 15: Ensure that all laser personnel know how to access and operate the fire extinguishers.

Verification Method: Review the training records.

Item 16: Test the laser delivery system prior to each laser procedure.

Verification Method: Review the Laser Utilization Records or laser safety checklists

Item 17: Monitor the laser status, the delivery system (fibre / arm / waveguide), the path of the beam, and tissue interaction.

Verification Method: Review the policies and procedure manual to ensure this item is addressed and interview staff members.

Item 18: Ensure there is ready access to water or saline during laser treatment of the patient.

Verification Method: Inspect the treatment room to ensure a source of water or saline is available.

Item 19: Keep wet cloths/drapes on hand to protect combustible non-targeted areas as needed.

Verification Method: Review the policies and procedure manual to ensure this item is addressed and interview staff members.

Item 20: Bowel gas is flammable and the anus should be protected by covering the area with wet towels, or a wet section of an under-buttocks type of drape. Gases from the body cavity can also be removed by various evacuation techniques.

Verification Method: Review the policies and procedures manual and ensure that proper procedures are in place and that evacuation equipment is available in the treatment room.

Item 21: The most common cause of laser related fires is ignition of combustible material from accidental exposure to laser radiation. Dry, disposable materials used in the operating room such as cotton, gauze, tongue depressors, drapes, lap sponges, and towels can ignite upon exposure to a high powered surgical laser beam.

Any compound or solution containing alcohol (e.g. Hibiclens®, Hibitane®, tape removers, degreasers, benzoin, etc.) can ignite from the heat of most surgical laser tissue interactions. Flash fires can also occur if iodoforms in pooled or aerosolized Betadine are heated by a focused laser beam.

Whenever external areas of tissue are being vaporized with a CO_2 laser a layer of carbon can build up and a very high temperature generated in the carbon which can cause a fire or skin burns.

Verification Method: Verify that there are surgical procedures in place to prevent fires such as the use of wetted or fire retardant material in the operative field, removal of excess draping from the target site and that fire suppression equipment is available in the operatory (fire extinguisher, open basin of water, etc.) to deal with fires should they occur.

Item 22: High voltages associated with the laser power supply require strict attention to electrical safety in the healthcare operatory. Electrical hazards include the possibility of fluid spills entering the laser electronics, improper use of extension cords, degradation of electrical cords, footswitches and circuit breakers, and unqualified individuals performing maintenance on the laser electrical system.

Verification Method: Perform a visual check to ensure that intravenous solutions and fluid containers are not placed on or near the laser and that extensions cords are not used to supply power to the laser. Visually check that all electrical

cords, connections and switches are in good condition and do not present a tripping hazard. Check records to ensure that the maintenance on electrical systems has only been performed by properly trained and approved technicians.

Item 23: The smoke plume produced when a laser vaporizes tissue can contain a variety of contaminants including toxic compounds, bio-aerosols, dead and viable cellular material and viruses which can cause airway and eye irritation, bronchial and pulmonary congestion and the possibility of infection.

To minimize exposure to laser generated air contaminates, smoke evacuators are recommended for all plume producing procedures. Suction nozzles should be held as close as possible to the surgical site, preferably no further than 2 cm away. In- line filters with the ability to remove particles of less than 0.1 micron should be used between the suction source and the aspiration port at the surgical suite. The filter packs should be handled according to infection control procedures in the operating room.

Verification Method: Check that there is a filtered, smoke evacuation system available and that it is used and maintained in accordance with the manufacturer's recommendations by interviewing staff members and / or reviewing maintenance records.

Item 24: A medical protocol for management of the airway during laser surgery shall be written by the ENT surgeon and the anesthesiologist.

Verification Method: Review policies and procedures manual.

Item 25: 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.

Verification Method: Review training records and interview staff

Item 26: Endotracheal tubes need to have protection or special design to avoid the potential for fire when performing airway laser surgery. Therefore, 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.

Verification Method: Review equipment product description to verify it is designed to be laser-resistant at the wavelength used.

Item 27: If the ET tube is taped to the patient's tissue or materials in the surgical field, non-flammable tape shall be used.

Verification Method: Review product description to verify the product is non-flammable.

Item 28: All emergency equipment designated in the airway management protocol shall be available in the room prior to beginning the surgical procedure.

Verification Method: Check the treatment room to ensure the equipment is available.

Item 29: A CO_2 laser shall be tested for coaxial alignment of the laser beam and proper beam mode, prior to the patient undergoing anesthesia.

Verification Method: Review the Laser Utilization Records or the laser safety checklists

Item 30: During jet ventilation anesthesia procedures, personnel shall be aware of the need for clear communication.

Verification Method: Review the policies and procedures manual and interview staff members.

Item 31: The laser operator shall not place the laser in the ready mode until a verbal order is given to hold ventilation.

Verification Method: Review the policies and procedures manual and interview staff.

Item 32: 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 laser safety officer and ENT surgeon.

Verification Method: Review the policies and procedures manual, interview staff members and check to ensure that the protective equipment is available in the treatment room.

Item 33: Cotton patties used to pack an inflated ET tube cuff shall be included in the nurse's surgical sponge count.

Verification Method: Review the policies and procedures manual and interview staff members.

Item 34: Standard / universal precautions shall be used when caring for patients. If materials are contaminated by blood- borne pathogens, staff members 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.* Jurisdictional regulations should be followed as they apply.

Verification Method: Review the policies and procedures manual and interview staff members.

Item 35: Bio-hazardous waste shall be disposed of in accordance with the policies of the facility and / or jurisdiction.

Verification Method: Review the bio-hazard waste disposal records.

Item 36: Personnel shall follow the facility procedures for draping the laser delivery systems.

Verification Method: Review the policies and procedures manual and interview staff members.

Item 37: Personnel shall follow facility protocols for pre-procedure and post-procedure cleaning of equipment, decontamination, and disposal of bio-hazardous waste or materials.

Verification Method: Review the policies and procedures manual and interview staff members.

Item 38: Material Safety Data Sheets (MSDS) are required whenever hazardous products are stored or used at a worksite. For lasers operations this might include gases or laser cavity dye solutions. The MSDS provides information on the hazardous properties of the material, clinical symptoms of exposure, first-aid, etc. and are required to be available at the worksite as part of the *Workplace Hazardous Material Information System* (WHMIS) mandated under the *Alberta Chemical Hazards Regulation*. Manufacturers that use gases, dyes or liquid coolants in their lasers must provide the health care facility with the MSDS for the gases, dyes, and coolants in accordance with the WHMIS regulation.

Verification Method: Determine the types of hazardous products associated with the laser system from the technical manual provided by the manufacturer. Verify that the applicable MSDS sheets are available and that staff are aware of the existence of this information and have received WHMIS training.

Item 39: Gas cylinders, which are part of some laser systems, should be properly contained within an externally vented cabinet to prevent exposure to the gas in the event of a cylinder leak since some of the gases are toxic or corrosive (e.g. excimer laser gases). Even gases which are not toxic or corrosive (e.g. argon and CO_2) can displace air and become an asphyxiation hazard. The health care facility shall have a policy on prevention and management of possible exposure to gases, dyes, and coolants that includes:

a) Educating all personnel in proper handling of gases, dyes, and coolants

b) Developing a plan to contain gases, dyes, and coolants in case of a leak which includes the evacuation of persons present at the scene

c) 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
4) Hazardous materials disposal

d) Generating and submitting an incident report according to facility policy

Verification Method: Review policies and procedures manual, training records and interview staff members. If a gas cylinder is located outside of a supply cabinet, perform a visual check to ensure that it is securely anchored. Ensure that the room containing the gas cylinder is adequately ventilated. Check records to ensure that regular preventive maintenance has been conducted on the gas delivery system.

Item 40: Persons exposed to gases, dyes, and coolants shall be referred to a physician and the appropriate health and safety committee personnel.

Verification Method: Check the records of previous exposures and review the policies and procedures manual.

Item 41: Caution should be exercised when using purge gases in a body cavity during laser surgery.

Verification Method: Review the policies and procedures manual and interview staff members.

Item 42: Purge gas should be filtered.

Verification Method: Inspect the purge gas system to ensure filtration is provided. ***Item***

43: Whenever possible, CO_2 should be used as a purge gas instead of air or medical air.

Verification Method: Review the policies and procedures manual,

Item 44: A formal system for controlling the use, maintenance and supervision of the laser must be established to ensure the safety of staff, patients and visitors. As part of the overall laser safety program there must be written operating and

maintenance procedures which include safety precautions as well as a written policy statement that addresses the conditions and authorizations for laser use and maintenance, training of staff, security, etc..

Verification Method: Review the policies and procedures manual and the record of revisions. Ensure that the technical manual provided by the manufacturer of the laser and the accessories is available and that it adequately covers the safe use and maintenance of the laser system. Ensure that there are written policy statements available to staff members concerning the administrative control of the laser system and the training of staff members.

Item 45: Policies and procedures shall be reviewed yearly and revised as necessary to comply recent and revised standards.

Verification Method: Review the policies and procedures record of revisions.

Item 46: The development and revision of laser safety procedures shall involve personnel who use and operate laser equipment, in collaboration with the laser safety officer and with final approval by the facility administration.

Verification Method: Interview staff members to ensure they have had the opportunity to provide input on the development and revision of laser safety procedures.

Item 47: Personnel shall have access to facility policies and procedures, and access to policies and procedures specific to each laser use area.

Verification Method: Interview staff to ensure they are aware and have access to these documents.

Item 48: A Laser Utilization Record shall be kept which includes the following information:

a) Patient identification

b) Date, treatment, and location c)

Equipment identification

d) Wavelength(s) of laser

e) Laser user

f) Laser operator

g) Operational procedures

h) Delivery system (e.g., objective lenses, fibre size, lot number, serial number)

i) Range of treatment parameters (e.g., power (watts), energy (joules), pulse duration, pulse repetition rate, total energy delivered)

j) Signature of the laser operator or designate k)

Record of laser system shutdowns.

Verification Method: Review records to ensure that Laser Utilization Records have been completed for past laser usage.

Item 49: If operational procedures are not included on the Laser Utilization Record, a laser 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 laser safety officer or designate.

Verification Method: Review the records to ensure that a laser safety checklist has been completed for past laser usage if operational procedures are not included on the Laser Utilization Records.

Item 50: Laser safety audits shall be conducted on an annual basis, and audit reports shall be submitted to the laser safety officer.

Verification Method: Review records to ensure that laser safety audits have been conducted annually and reviewed by the laser safety officer. Corrective action should have been taken on all deficiencies identified.

Item 51: The laser safety officer shall have access to service and maintenance reports on lasers and related equipment.

Verification Method: Interview the laser safety officer and determine what records are regularly reviewed.

Item 52: Incident reports shall be made for adverse events in accordance with facility requirements.

Verification Method: Review records to determine if any incidents reports have been written.

Item 53: The laser safety officer shall be advised of all incidents or adverse events immediately.

Verification Method: Interview the laser safety officer and determine who writes, reviews and conducts followed up.

Item 54: The laser safety officer shall have access to laser safety committee minutes, if applicable.

Verification Method: Interview the laser safety officer and determine if these minutes, if applicable, are reviewed.

Item 55: The laser safety officer shall maintain current lists of competent personnel and authorized users. Records should include date of renewal of applicable personnel training.

Verification Method: Review the records kept by the laser safety officer to ensure that the list of authorized laser users is current.

Item 56: The laser safety officer shall maintain documentation of hazard analysis and risk assessment.

Verification Method: Review the records kept by the laser safety officer to ensure these documents exist.

Item 57: The administrator shall provide standard operating procedures 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 standard operating procedures shall indicate the persons 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)

e) Date of return to service

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

e) Other equipment malfunctions affecting the safety of the patient and attending personnel

Verification Method: Review records to ensure these documents exist and have been followed as per the procedures written.

Item 58: If entrances to the laser-controlled area fall within the boundaries of the nominal ocular hazard area, administrative, engineering, or architectural design controls shall be initiated to prevent the nominal ocular hazard area from extending beyond the entrances. Examples of suitable controls include:

a) Repositioning the patient or laser within the laser-controlled area b)

Placing barriers in front of the entrances

c) Sealing cracks between doors and their frames

Verification Method: Review the records kept by the laser safety officer with respect to hazard analysis, risk assessment and determination of nominal ocular hazard areas.

Item 59: Access by staff shall be ensured at all times by controlling the entrances (in accordance with local rules for fire safety).

Verification Method: Inspect the laser treatment controlled area to determine how access to the room is controlled.

Item 60: Doors providing access to the laser-controlled area shall <u>not</u> 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.

A remote interlock connector is an electrical port usually found on the back of the laser assembly which allows a remote switch to be installed on an entrance door that automatically shuts off the power supply to the laser if the door is opened. Class 4 lasers are equipped with this feature but it should not be used in a healthcare setting.

Verification Method: Inspect the laser treatment controlled area to verify that the entrance doors to the laser treatment controlled area have not been interlocked with the power supply to the laser. The remote interlock connector on the back of the laser assembly, if it exists, should not be connected to any circuits involving movement of the entrance door.

Item 61: Personal protective equipment intended for use with the laser in the controlled area shall be posted with each door warning sign.

Verification Method: Perform a visual inspection of the entrances to the laser treatment controlled area to verify this information is posted.

Item 62: 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. The beam of a CO_2 laser does not pass through glass. Therefore, windows and other openings might not require covering when this type of laser is in use.

Window barriers shall be used for wavelengths shorter than 4,000 nm and in between 180 nm to 300 nm, tested and approved to attenuate transmission of the laser beam to below the maximum permissible exposure level, in accordance with the following:

a) Barriers shall be labelled in accordance with IEC 60825-1 (2007)

b) Protection shall meet infection control requirements

c) Barriers shall be controllable from inside the laser room

d) Barriers shall not allow any light leakage at the perimeters of the barriers

If the maximum permissible exposure level is exceeded at the entryway, a curtain or barrier is also needed. Also, orient the laser beam so that it is directed away from entrance doors, walkways, and windows.

Verification Method: Note the orientation of the laser delivery system relative to windows, doorways and open portals in the laser treatment controlled area. Ensure that the orientation of the laser is optimum with respect to the criteria given above and that coverings and barriers have been installed wherever necessary.

Item 63: The area shall be supervised by credentialed personnel trained in laser safety and approved by the laser safety officer.

Verification Method: Interview the laser safety officer to determine who supervises the laser treatment controlled area. Review records to determine if the individuals identified have received adequate training to act as area supervisors.

Item 64: The laser treatment controlled area shall be occupied by personnel approved by the laser safety officer.

Verification Method: Interview the laser safety officer to determine who occupies the laser treatment controlled area. Review records to determine if the individuals are on an authorized user or occupant list.

Item 65: The environment shall be free of highly reflective surfaces that could interfere with the beam path or might be present within the nominal ocular hazard area.

Verification Method: Perform a visual inspection of the laser treatment controlled area and the equipment which is used in the nominal ocular hazard area to determine if there are any reflective surfaces.

Item 66: The environment shall be free of flammable surfaces or materials that could interfere with the beam path.

Verification Method: Perform a visual inspection of the laser treatment controlled area to determine if there is any combustible material or flammable substances present.

Item 67: When more than one wavelength is present in the nominal ocular hazard area, only one may be activated at a time, and only one set of corresponding protective eyewear shall be out and available.

Verification Method: Review the Laser Utilization Records to determine if more than one laser is used at a single time and if the wavelengths are different.

Item 68: As a security measure to prevent unauthorized activation of the laser system, the key must be removed from the master key-switch on the laser control panel whenever the laser is not in use. Alternately, the laser must be stored in a secure, locked location when it is not being used.

Verification Method: Check to see if the key has been removed from the master key-switch on the laser while the laser is not in use or that the laser is stored in a locked room accessible only to personnel approved to use the laser.

Item 69: The nominal ocular hazard area shall be reassessed if it increases during repair, service, or maintenance.

Verification Method: Interview the laser safety officer to determine the procedure that is used under these circumstances.

Item 70: 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 treatment-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 of the CSA standard

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.

Verification Method: Review building architectural drawings.

Item 71: The air intake and outlet shall be kept unobstructed at all times.

Verification Method: Review building architectural drawings.

Item 72: Laser equipment shall be used in a well-ventilated area to help remove excess heat generated by the laser.

Verification Method: Perform a visual inspection of the air intake and outlet within the laser treatment controlled area.

Item 73: The laser has 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 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).

Verification Method: Perform a visual inspection of the laser to ensure it has this feature.

Item 74: The laser has 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.

Verification Method: Perform a visual inspection of the laser to ensure it has this feature.

Item 75: The laser has a visual warning activated during laser emission (in some circumstances, an audible warning may also be present). Laser users need to be aware of the status of the laser at all times. The purpose of the activation warning system is to alert operators that laser emission is occurring or about to occur and that protective measures (e.g. laser goggles) are required.

Verification Method: Perform a visual check of the laser control panel to locate this feature or verify from information in the technical manual provided by the manufacturer that this feature exists.

Item 76: There must be a label located next to the laser exit aperture (i.e. probe opening) which clearly identifies the aperture. The wording on the label should simply state "laser emission aperture". The purpose of this label is to prevent accidental exposure to laser radiation among persons not completely familiar with the design of the laser who might mistake the laser exit aperture for a viewing optic.

Verification Method: Perform a visual check to verify that this label exists at the laser aperture.

Item 77: The laser has a switch guard to prevent unintended operation of the laser system (e.g., a guarded foot pedal).

Verification Method: Perform a visual inspection of the laser to ensure it has this feature.

Item 78: There is a laser operating manual available that thoroughly addresses the laser's use and associated hazards.

Verification Method: Perform a visual inspection to ensure this document is exists and is readily available to staff.

Item 79: There is a laser delivery device operating manual that thoroughly addresses its use and associated hazards.

Verification Method: Perform a visual inspection to ensure this document is exists and is readily available to staff. ***Item 80:*** Only the manufacture approved laser delivery devices shall be used on the laser.

Verification Method: Perform a visual inspection to ensure that the laser delivery device meets the manufacturer specifications.

Item 81: 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.

Verification Method: Verify that the laser delivery device was installed according to the manufacturer's instruction given in the operating manual.

Item 82: Laser delivery devices shall be maintained and serviced according to the manufacturer's instructions.

Verification Method: Review the records associated with maintenance and service of the delivery device to ensure that it meets the minimum requirements specified in the manufacturer's service manual.

Item 83: Laser optics shall be checked for their integrity and cleaned according to the manufacturer's instructions.

Verification Method: Review the records associated with maintenance and service of the laser optics to ensure that it meets the minimum requirements specified in the manufacturer's service manual.

Item 84: The laser user handling the laser delivery device shall be the only one operating the laser footswitch or handheld device.

Verification Method: Interview staff to ensure that they are following this requirement.

Item 85: The footswitch shall not be bagged, as this can cause inadvertent firing.

Verification Method: Perform a visual inspection to verify this and interview staff to ensure that they are following this requirement.

Item 86: 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.

Verification Method: Perform a visual inspection to verify this.

Item 87: The laser treatment controlled area is a designated room in which the laser is used and where the occupancy and activities are subject to control measures and supervision for the purpose of protection from laser radiation. Laser warning signs must posted outside all entry points to this area.

Verification Method: Perform a visual inspection to verify this.

Item 88: Laser warning signs establish the nature of the hazard by specifying the wavelength and class of laser being used.

Verification Method: Perform a visual inspection to verify this.

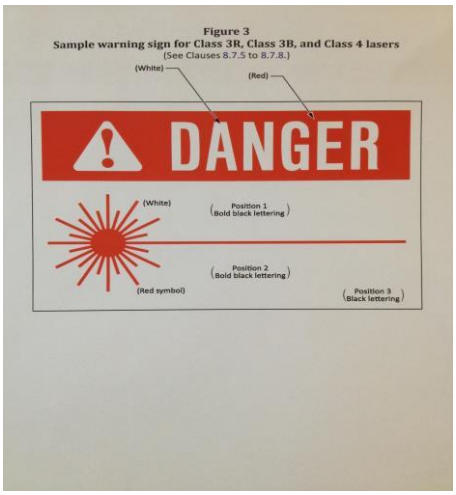
Item 89: Laser warning signs are only to be posted or illuminated when the system is powered on or in standby. Permanently mounted, non-illuminated warning signs shall be avoided, as some personnel might become used to their presence and ignore them. Where illuminated signs are in use, they shall be illuminated only when the laser system is switched on.

Verification Method: Perform a visual inspection to verify this.

Item 90: Laser warning signs indicate that protective eyewear shall be worn.

Verification Method: Perform a visual inspection to verify this.

Item 91: The appropriate warning signs shown in Figure 3 of CSA-Z386-14, *Safe Use of Lasers in Health Care,* 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.



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 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:

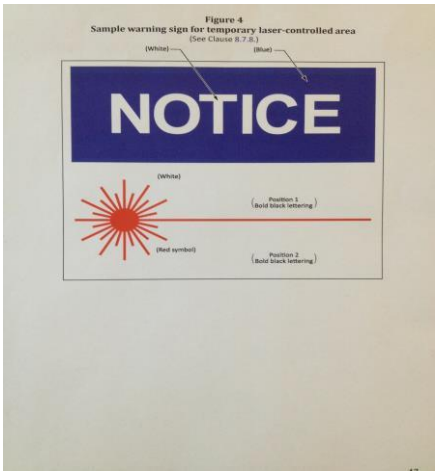
“LASER TREATMENT IN PROGRESS - EYE PROTECTION REQUIRED, OD _____”

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 (i.e. Class 3B or Class 4) of the health care laser or laser system.

Verification Method: Perform a visual inspection to verify this.

Item 92: A temporary laser treatment controlled area must be established whenever there is maintenance on the laser system that would add to or increase the nominal ocular hazard area beyond the normal boundaries of the laser treatment controlled area. Under these circumstances special control measures are required. This includes area restriction and the posting of a special laser warning sign shown in Figure 4 of CSA-Z386-14, *Safe Use of Lasers in Health Care*, outside of the area.



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”

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 of CSA-Z386-14, *Safe Use of Lasers in Health Care*). The wording of the warning sign is recommended but not mandatory. Other wording that conveys the same message may be substituted.

Verification Method: Ensure that maintenance personnel assign the entire room that houses the laser as a temporary laser treatment controlled area and that staff understand the meaning of the special warning sign and area restrictions while this work is in progress.

Item 93: Prior to the health care 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 the pre-treatment /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.

Verification Method: Perform a visual inspection to verify that this information exists and interview staff to ensure that this procedure is carried out.

Item 94: 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.

In the case of visible or near-infrared wavelengths (400 nm – 1400 nm), the moist eye pad should be covered with a metal eye shield and another moist pad should be placed on top.

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.

Verification Method: Perform a visual inspection to verify that this equipment exists and interview staff to ensure that this procedure is carried out. Also review the facility policies and procedures manual to ensure that these requirements are documented.

Item 95: 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. Laser irradiation of tooth enamel could leave permanent marks.

Verification Method: Perform a visual inspection to verify that this equipment exists and interview staff to ensure that this procedure is carried out. Also review the facility policies and procedures manual to ensure that these requirements are documented.

Item 96: 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 equipment that is purchased 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.

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented.

Item 97: 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. It is vital that a needs assessment and impact analysis be performed to ensure the safety of both patients and personnel.

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented.

Item 98: 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.

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented.

Item 99: 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:

a) Electrical services

b) Ventilation services

c) Fenestrations

d) Physical dimensions and storage space e)

Access restrictions

f) Safety needs of maintenance and service personnel

g) Additional services required to support the procedures performed in the room(s).

Adequate consideration of these factors can lead to an improved quality of care (i.e. favorable patient recovery and outcome, laser personnel comfort and efficiency) and could have beneficial financial implications.

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented.

Item 100: 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.

Verification Method: Perform a visual inspection of the laser to ensure that it is contains this marking.

Item 101: A laser system which is being used on a trial basis shall only be operated by facility credentialed personnel 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.

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented.

Item 102: Safety equipment should 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

g) Plume-scavenging systems and their replacement filters

Verification Method: Check the inventory of accessories items that were provided with the laser.

Item 103: 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. Refer to Sections 24 and 52 of the Canadian Electrical Code, Part I, and to CSA Z32.

Verification Method: Review the architectural electrical drawings for the facility.

Item 104: To ensure optimum, safe, performance of the laser system it is necessary to establish a program of regular preventive maintenance and calibration conducted by qualified maintenance personnel whether from in-house services or contracted services. All maintenance, repairs, calibrations, alignments and equipment modifications must be documented.

Verification Method: Review procedures to ensure that all maintenance, calibration, repairs or modifications to the laser system have been conducted and that only qualified personnel (vendor representatives or trained in-house staff) have performed this work. Check that maintenance has been conducted at regular intervals recommended by the manufacturer.

Item 105: Inspections, tests, and maintenance shall be made and recorded:

a) In accordance with a written plan approved by the health care facility

b) Upon failure of the equipment to operate properly (equipment function settings and parameters should be noted at the time of equipment malfunction)

c) At the intervals indicated in the description of each test or inspection (these intervals should not be less than those recommended by the manufacturer).

d) Using 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.

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented.

Item 106: 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.

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented. Review the records of equipment repair to ensure that the information complies with the requirements indicated.

Item 107: 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.

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented. Interview the staff to determine if they have been provided with this information in the past.

Item 108: Preventive maintenance assurance shall verify, but not be limited to the following:

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. 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.

c) The integrity of all covers and insulation designed to prevent access to live parts. d)

That leakage currents are within proper limits.

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented. Review the preventive maintenance records to ensure that all of the items indicated are being checked.

Item 109: Inspection and maintenance shall be provided if there are indications that the health care laser system been subjected to any of the following conditions:

a) Extreme mechanical stress (e.g., been bumped or struck)

b) Fluid invasion into or on the laser c)

Extreme temperature or humidity

d) The equipment performance appears to have changed e)

The enclosure is cracked, removed, or missing

f) Any attachment plug, power supply cord, or patient connection has deteriorated g)

Smoke or odors have been released

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented.

Item 110: 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. Secured entry or an enclosure shall be used when laser hazards that are otherwise normally shielded are exposed (i.e., during repair and maintenance).

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented.

Item 111: The service personnel shall have education and training commensurate with the class of the embedded laser or laser system.

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented. Check the training records/qualification of persons who service the equipment.

Item 112: 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 maximum permissible exposure level.

Verification Method: Review the facility policies and procedures manual to ensure that these requirements are documented. Ensure that there are written procedures which provide guidance on performing laser beam alignments. Interview staff to determine if these procedures are routinely use.

Item 113: Health care facilities where lasers are in use shall appoint a laser safety officer and should appoint a deputy laser safety officer as needed. The laser safety officer may delegate any responsibilities to a designate with the appropriate qualifications or credentials. The laser safety officer 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 nominal ocular hazard area f)

Advising on the purchase of all laser-related personal protective equipment 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

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

m) Any additional services requested by facility administration

Verification Method: Review the facility policies and procedures manual to ensure that this requirement is documented and has been carried out.

Item 114: Health care facilities where lasers are in use should have or establish a laser safety committee. The duties of the laser safety committee 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 laser safety officer's duties and responsibilities

e) Ensuring that a safety survey is conducted in all areas using laser equipment at intervals determined by the laser safety officer

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. 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

k) Development of quality assurance and risk management programs

Verification Method: Review the facility policies and procedures manual to ensure that this requirement is documented and has been carried out.

Item 115: Training programs shall be evaluated by the laser safety officer and the laser safety committee for applicability to the facility's practice.

Verification Method: Review the facility policies and procedures manual to ensure that this requirement is documented and has been carried out.

Item 116: All persons involved in laser operations are trained in laser safety. The level of laser training training required, as described in CSA-Z386-14, *Safe Use of Lasers in Health Care- Annex E,* is:

a) Level 1 Training

1. Non-clinical facility personnel who are involved in the management of the laser program or laser services
2. Observers

3. Trainees
4. Non-clinical members of the laser safety committee
5. Administration and management, assumed to be non-clinical personnel.

The content shall include, but is not limited to, the following:

1. Overview of the CSA-Z386-14 *Safe Use of Lasers in Health Care*
2. Facility policy and procedure
3. Types of lasers used and general applications in the facility
4. Roles, authority, and responsibilities of laser team members
5. Contact information for the laser safety officer

b) Level 2 Training

1. Laser operator

The content shall include, but is not limited to, the following:

1. Level 1 laser training
2. Laser physics
3. Laser–tissue interaction
4. Types of lasers and their delivery systems
5. Accessory equipment and instrumentation needed for specific applications
6. Understanding treatment parameters and dosimetry
7. Roles, authority, and responsibilities of laser team members
8. Assessment of hazards and risks
9. Reporting
10. Applicable documentation

c) Level 3 Training

1. Laser safety officer

The content shall include, but is not limited to, the following:

1. Level 2 training
2. All items in Level 1 and 2 training
3. Regulatory requirements in the specific jurisdiction
4. Application of CSA-Z386-14 *Safe Use of Lasers in Health Care*
5. Hazard identification and implementation of applicable control measures
6. Facility reporting for accidents, incidents, or occurrences

d) Level 4 Training

1. Laser users

The content shall include, but is not limited to, the following:

1. All items in Level 1 and 2 training
2. Clinical application and techniques for intended procedures
3. Treatment parameters and dosimetry for intended procedures
4. Patient safety
5. Management of complications
6. Competency in operating the laser and its delivery systems

7. 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.)

Verification Method: Review the list of persons involved in the use of lasers, their classification and training records.

Item 117: A record of persons who have completed laser safety training is maintained.

Verification Method: Review training records

Item 118: Facility administration shall 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).

Verification Method: Review authorized user list to ensure it is up-to-date.

Item 119: A list of personnel with procedure-specific and wavelength-specific laser privileges shall be maintained by the laser safety officer and within those departments providing laser services.

Verification Method: Review authorized user list to ensure it is up-to-date.

Item 120: Responsibilities of persons in a laser-controlled area are clearly assigned and understood.

Verification Method: Review the facility policies and procedures manual to ensure the responsibilities of persons are clearly identified. Interview staff to ensure they understand their assigned responsibilities within the laser-controlled area.

Item 121: 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 CSA-Z386-14 *Safe Use of Lasers in Health Care – Annex E*.

Verification Method: Review the facility policies and procedures manual to ensure the responsibilities of persons are clearly identified. Interview staff to ensure they understand their responsibilities.