Laser Hair Removal

Safety Guidelines for Facility Owners & Operators

Prepared by

The Joint Documents Working Group
of
The Federal Provincial Territorial Radiation Protection Committee

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- Safety Guidelines for Facility Owners & Operators -

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Foreword

Brief, inadvertent exposure to high-power laser radiation can cause permanent eye injury and/or skin burns. When a person chooses to work in a laser hair removal clinic, it is important for that person to be aware of the hazards involved and the safeguards to protect their clients, themselves and others. This booklet is designed to give owners and operating staff of laser hair removal devices essential information for laser safety.

However, simply following the guidelines listed in this document does not relieve the owner or operator from the obligation to take any additional measures necessary to prevent health hazards from occurring in the establishment. Operators should refer to the user information supplied by the manufacturer or distributor of their equipment, as well as any training resource materials and related guidance documents. Owners are also responsible for ensuring that they carry on business in compliance with municipal and provincial regulatory requirements, and for obtaining business licences and/or operating permits from the appropriate licensing authorities. In addition, owners and operators should be aware that use of these lasers is regulated differently in each province or territory (see Appendix A).

It is expected that these guidelines will be periodically revised as new information and experience in the use of laser are gained – use of the most current standards and regulations is highly recommended.

Introduction

In 1995 the United States (US) Food and Drug Administration (FDA) approved the use of lasers in the US as a medical device for hair removal. In 1999, the FDA gave lasers and flash lamp systems clearance for use in "permanent hair reduction". Commercially-produced lasers and laser devices are designated in the US using a numerical hazard classification system (Classes 1 through 4) and identified by attached warning labels. These labels indicate the degree of hazard that is associated with the laser radiation to which human access is possible during laser operation. The required content of laser labels is shown on page 15. Labels must indicate the laser class, the type of laser or the emitted wavelength, pulse duration (if appropriate) and maximum output. In general, class number increases with the level of potential laser hazards.

Canada has not yet adopted a specific laser hazard classification system. However, manufacturers who wish to sell, import or lease laser systems in Canada have been referred to the labelling requirements outlined in Europe[1] and the US[2]. While compliance with the requirements as stated in this document is voluntary, there are regulatory requirements governing the use of lasers in each province and territory (see Appendix A).

Based on these standards, all lasers currently used for hair removal in Canada operate with high emission levels and are therefore designated in the highest hazard classes (Class 3B & Class 4). These classifications indicate that direct exposure to the laser radiation emitted from these devices is a hazard to unprotected eyes or skin. In addition, the direct beam may be a fire hazard if it strikes combustible materials or even release toxic gases, vapours and viruses. In some cases, exposure to the reflected or scattered beam can also be hazardous. Laser safety features and specific operator training are essential for the safe use of Class 3B and 4 laser hair removal devices.

Laser safety inspections and interviews conducted with operating personnel led to the development of this booklet to provide owners and operators in laser hair removal facilities with important information on laser safety. These guidelines provide a general overview of laser hair removal and discuss the risks associated with the use of lasers. It also provides advice to owners and operators to help reduce health risks to both clients and personnel at the facility[3].

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[1] IEC 60825-1 Ed. 2.0 (2007) "Safety of laser products - Part 1: Equipment classification and requirements" (available for purchase at http://webstore.iec.ch/webstore/webstore.nsf/Standards/IEC%2060825-1?openDocument)

[2] FDA 21CFR1040.10 (2007) "Performance Standards for laser products" and "Laser Notice No. 50" (accessible at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=1040.10 and http://www.fda.gov/cdrh/ocer/guidance/1346.html)

[3] These recommendations are based on the ANSI Z136.1-2007 American National Standard for Safe Use of Lasers (available from the Laser Institute of America at http://www.laserinstitute.org/).

Glossary

ANSI: the American National Standards Institute - a private, non-profit organization that administers the US voluntary standardization and conformity assessment system.

Authorized personnel: Individuals approved by management (business owner) to operate, maintain, service or install laser equipment.

Baseline eye examination: an eye examination that used to establish a basis for comparison in the event of an accidental laser injury.

Beam: the pulsed or continuous output from a laser.

Cataract: clouding of the lens of the eye.

Coherent: a beam of light characterized by a fixed phase relationship or single wavelength (i.e. monochromatic).

Danger: indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury e.g. retinal burn from direct exposure to the laser beam

Diffuse reflection: change of the spatial distribution of a beam of radiation when it is reflected from a rough surface in many directions

Direct beam: the output beam from the laser, prior to any reflection or absorption.

Electromagnetic radiation: the flow of energy at the speed of light in the form of electric and magnetic fields. Gamma rays, X-ray, ultraviolet, visible, infrared, and radio waves occupy various portions of the electromagnetic spectrum and differ only in frequency, wavelength and photon energy.

Incidental personnel: those whose work makes it possible (but unlikely) that they will be exposed to laser energy sufficient to damage their eyes or skin (i.e. clerical or supervisory personnel who do not work directly with lasers).

Infrared radiation (IR): invisible radiation wavelengths from about 700 nm to 1,000,000 nm (1 millimetre). Hair removal lasers operate between 700 and 1400 nm.

Irradiance: the radiant power incident per unit area upon a surface, expressed in W/cm² (Symbol: E).

Joule (J): the unit used to measure the energy of a laser pulse.

kW/cm²: a kilowatt per square centimetre [see Watt].

Laser: acronym for **L**ight **A**mplification by **S**timulated **E**mission of **R**adiation.

Laser controlled area: an area that is appropriately enclosed so that no laser radiation above the maximum permissible exposure inadvertently escapes to injure unsuspecting persons. This area is subject to the control and supervision of the laser safety officer and must contain the nominal hazard zone (NHZ) unless special safety features are incorporated into the room.

Laser personnel: those who work routinely in the laser environment and are normally fully protected by engineering controls and/or administrative procedures (i.e. operators or service providers).

Laser safety officer (LSO): a person who is authorized by management (business owner) to be responsible for the laser safety program in the facility. The LSO is responsible for monitoring and overseeing the control of laser hazards.

Light: electromagnetic radiation having wavelengths between approximately 400 to 700 nm and which are perceptible to human vision (aka "visible light").

Melanin: a group of naturally occurring dark pigments found in skin and hair which absorb infrared laser radiation.

Maximum Permissible Exposure (MPE): the level of laser radiation to which an unprotected person may be exposed without adverse biological changes in the eye or skin i.e. injury

Nanometers (nm): a unit of length equal to one thousand millionth of a meter (10^{-9} m) and used in the measure of wavelengths of optical radiation i.e. ultraviolet, visible and infrared radiation.

Nd:YAG: notation for one of the lasing media in some lasers which produces the infrared radiation i.e. neodymium:yttrium-aluminum-garnet.

Nominal Hazard Zone (NHZ): the space within which the level of the direct, reflected, or scattered radiation during normal operation exceeds the applicable maximum permissible exposure. This zone is usually smaller than and within the laser controlled area.

Optical density (OD): a material's ability to absorb laser radiation, as used in protective eyewear.

OD number: a measure of the safety of protective eyewear by how much the laser radiation is reduced when it passes through the protective eyewear (see page 15)

Radiation: Emission and propagation of energy in the form of particles or waves.

Retina: The delicate multilayered light-sensitive membrane lining the inner posterior chamber of the eyeball that contains the rods and cones, and is connected by the optic nerve to the brain.

Specular reflection: change of the spatial distribution of a beam of radiation when it is reflected from a mirror-like surface in one direction

Visible light: electromagnetic radiation having wavelengths between approximately 400 and 700 nm and which are perceptible to human vision (aka "light").

Wavelength: The distance between one peak or crest of a wave of light or other electromagnetic radiation and the next corresponding peak or crest.

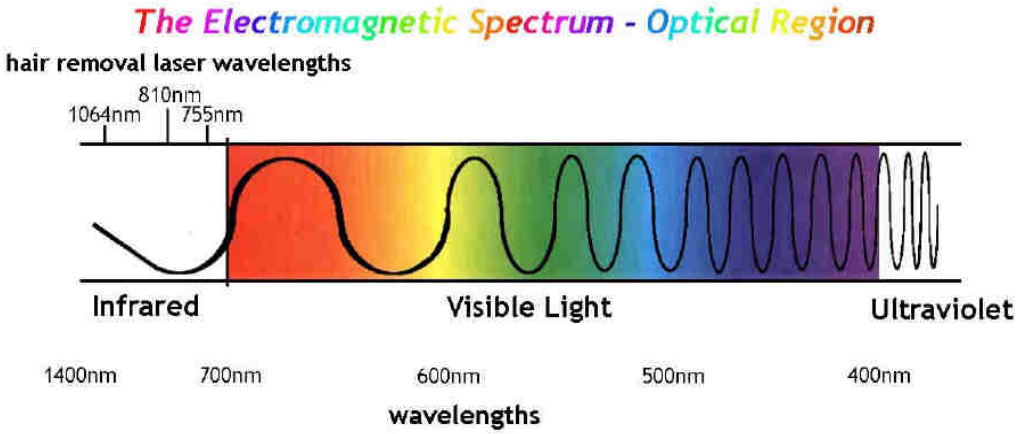
Watt/cm²: a watt per square centimetre.

Watt (W): a unit of power equal to one joule per second.

Laser Hair Removal

a) Overview of the Procedure

Laser hair removal devices operate by emitting a pulse or pulses of infrared (IR) radiation which passes through normal skin and is absorbed by melanin in the hair follicle, or root. Here it produces enough heat to destroy the hair. Typical lasers in use today are the Nd:YAG, the diode and the alexandrite[4]. Appendix D lists lasers commonly used in dermatology.



Lasers emitting IR radiation are used primarily because the energy that they produce destroys hair using a selective damage mechanism called photothermolysis. This simply means that thermal (heat) damage to pigmented tissue (i.e. hair follicle) occurs when it absorbs the laser energy. Other tissues (i.e. skin) allow most of the IR energy to pass through without absorbing and are not damaged. Melanin is the naturally occurring pigment in skin that absorbs IR radiation. However, melanin is also the pigment that makes the skin look dark brown. Skin with little melanin (i.e. light-coloured, untanned complexions) absorbs less IR radiation and is only minimally damaged by a laser when briefly exposed.

While there are no guarantees that the procedure will work for every person or on every part of a person's body, the effectiveness of laser hair removal procedures depends on the following factors:

- the training and skill of the person using the device;
- the characteristics of the laser, including wavelength, power settings, duration of each energy pulse, amount of time between pulses, and number of pulses per treatment;
- the color of the skin and hair of the person being treated; and
- the number of treatments administered and part of the body treated.

4 There are also non-laser intense pulsed light (IPL) systems using both invisible infrared radiation and visible light. These systems emit high intensity pulses of a broad range of wavelengths from 500 to 1200 nm. The longer wavelengths penetrate deeper and the shorter wavelengths shallower so that effects occur at different depths of the dermis. Filters are available for use in hair removal to reduce the unnecessary proportion of the visible wavelengths. These devices normally have a larger treatment applicator area than a laser.

For hair removal, IR must be able to penetrate into the skin with minimal absorption and arrive at the hair root to be absorbed by the melanin of the hair shaft. Consequently, fair-skinned individuals with dark hair are more easily treated; for people with naturally dark skin and/or tanned skin it is more difficult. Since hair grows in several phases, most people require repeated treatments in order to achieve good results (i.e. permanent hair reduction).

b) Side Effects

Side effects of the laser hair removal process may include:

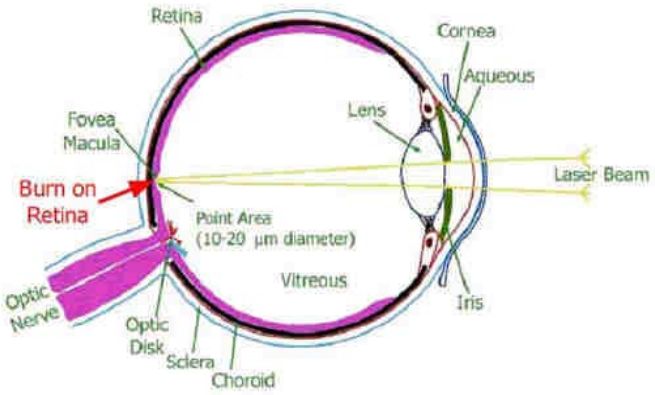
- pain
- bruising and swelling
- redness and inflammation
- blistering
- herpes simplex outbreaks and bacterial infections
- temporary skin lightening or darkening
- darkening/lightening of tattoos
- freckle loss or lightening of moles
- permanent skin pigment changes or scarring (rare)
- exacerbation of pre-existing skin conditions
- allergic reactions to anaesthetic creams

To protect the surface and upper areas of skin (i.e. the epidermis) from over heating, many lasers use cooling mechanisms. A variety of methods such as ice, gels, cold glass containers, very low temperature sprays, and cold airflow are now available to reduce side effects. The operator should also exercise caution not to overlap laser pulses during treatment.

c) Potential Laser Hazards

The primary hazard associated with laser hair removal facilities stems from inadvertent exposure to the laser emission. Exposure may occur directly from the laser to an individual or from a beam that is reflected off of any shiny surface such as a mirror, ring etc. The biological targets at greatest risk are a person's eyes and skin, as well as combustible materials causing a fire. Persons at risk are principally the client, the staff carrying out laser hair removal procedures, and service personnel. The following section describes the unique hazards presented by high power laser radiation.

Eyes - The human eye is designed to operate well under low lighting and bright lighting conditions. It does this by varying the size of its opening, the pupil. In low light, the pupil opens wider, letting more light into the eye. In bright light, the pupil closes down. When light passes through the cornea, pupil, and lens of the eye, it is focused onto a small area of the retina called the fovea. The fovea is the center of the retina and provides our sharpest eyesight. This normal act of focusing laser light by the eye causes an increase in the



amount of energy and/or power that is absorbed in retina. Even though we cannot see it, near IR radiation from hair removal lasers passes easily through the cornea and lens of the eye and is focused on the retina causing a very large amount of energy to be absorbed by a very small area of the retina The energy or power per unit of area on the retina can be increased by 10,000 to 100,000 times, thereby instantaneously burning the retina and other tissues around the impact area. Injury can occur even from laser radiation reflected from a mirror-like or rough surface. Excessive IR exposure at greater than 1200nm wavelengths can also cause heating of the lens, thereby producing a loss of transparency (cataract formation) or surface irregularity.

People can receive an eye injury when they are not using eye protection. Lasers may interfere with vision either temporarily or permanently in one or both eyes. Sometimes those who have received a laser eye injury have reported hearing a popping sound caused by a laser-induced explosion on the retina. Other times the symptoms of a laser burn in the eye will be a very sore eye or a headache shortly after exposure, or excessive watering of the eyes, and the sudden appearance of “floaters” (spots before the eyes) in one’s vision. Some individuals receiving laser eye injuries have reported seeing a black spot present in their field of view. Consequently, it is extremely important that all authorized personnel entering the area of the laser (the designated laser controlled area) be provided with and wear protective eyewear.

Skin and Fires - Intense laser radiation from Class 3B and 4 lasers can also burn the skin. If irradiance exceeds 10 W/cm² or beam power exceeds 0.5 W, the laser can ignite combustible materials. Operators of Class 4 lasers should be aware that unprotected wire insulation and plastic tubing may catch on fire from intense reflected or scattered beams. In addition, there have been reports of explosions caused by the ignition of dust that has collected in ventilation systems serving laser processes.

Toxic gases, vapours & viruses - Studies have shown that when high-power, focused Class 3B lasers and Class 4 lasers are utilized for treating human tissues, toxic gases, vapours & even viruses may be released into the air. High temperatures are generated in the area near the contact laser beam impact point. These high temperatures create expanding gases and particulates in areas of the impact point, which pick up tiny particles and droplets and conduct them very rapidly away from the laser beam impact point. In order to prevent contact or inhalation of these gases and toxic particles appropriate air evacuation systems must be used (see Ventilation – page 18).

Other - Other types of hazards may also exist, including electrical shock, liquid coolants, ergonomics (workstation layout, worker-machine interface), work patterns (alertness, work hours), hygiene, and room design/layout (presence of wires or cables on the floor, illumination conditions).

Safety Guidelines for Laser Hair Removal Facilities

A laser safety program is essential for all laser hair removal facilities. It must include provisions for the delegation of authority and responsibility, describe the laser classification and hazard evaluation process, and address training requirements. It must also provide direction on the designation of laser controlled areas, signage, engineering controls, protective equipment, and administrative/procedural controls. Lastly, in order to be complete a laser safety program must include regular surveillance and adequate record keeping. The remaining section provides guidelines for establishing an appropriate laser safety program at a laser hair removal facility.

a) Responsibility and Authority

Overall safety associated with the installation and use of lasers remains the responsibility of the owner and is carried out through the management organization at the facility. For Class 3B and 4 laser systems, this means that management is required to:

- establish and maintain an adequate laser safety program by designating a Laser Safety Officer (LSO)*****;
- authorize the use of laser equipment by specific personnel at the facility;
- provide adequate laser safety training and emergency procedures for the LSO and laser personnel;
- ensure applicable standards and regulations are met (see appendix A); and
- maintain adequate documentation and patient records.

***** If necessary the owner can act as the LSO in smaller facilities.

LASER SAFETY OFFICER (LSO):

The LSO is an individual with the training and experience to knowledgeably administer a laser safety program. They must be authorized by management (business owner) and are responsible for monitoring and overseeing the control of laser hazards. Management must ensure the LSO receives adequate training on potential laser hazards, risk assessment, control measures, applicable standards and regulations, medical surveillance (if applicable), and any other pertinent information pertaining to laser safety.

The laser safety officer is responsible for:

- conducting hazard evaluations and establishing laser treatment controlled areas;
- approving standard operating procedures (SOPs), administrative policies, procedural controls, and the wording on area warning signs and equipment labels;
- determining the personnel categories (i.e. incidental or laser personnel) and assuring adequate safety education and training are provided;
- recommending and approving protective equipment and engineering safety features prior to use;
- assuring that the prescribed control measures are implemented and comply with applicable federal, provincial/territorial, and local regulations (see Appendix A);
- periodically auditing the functionality of control measures in use (see Appendix B) and correcting deficiencies in a timely manner.

It is the responsibility of the owner and LSO to make employees aware of the requirements for safe use of laser hair removal devices. It is then the responsibility of employees to follow the instructions they have been given. For *incidental personnel*, this means that they must be aware of the risks associated with exposure to laser hair removal equipment and comply with all safety rules and procedures. For *laser personnel*, this means that they must:

- receive authorization from the LSO to use laser hair removal devices at the facility;
- receive safety training and emergency procedures applicable to the laser they are operating;
- be knowledgeable of all applicable standards and regulations (see Appendix A) and comply with safety rules and procedures, as outlined by the LSO;
- undergo a full medical examination following a suspected laser injury;
- document injuries involving lasers and report them to the LSO; and
- maintain an accurate record of all laser operations.

b) Laser Classification & Hazard Evaluation

Hazard evaluation is a critical component of any laser safety program, as it influences the application of control measures. The following aspects of a laser's application influence the total hazard evaluation:

- The laser's capability of injuring personnel (i.e. laser classification).
- The environment in which the laser is used.
- The personnel who may use or be exposed to laser radiation.

Laser classification is based upon the laser's capability to injure personnel and falls under seven general categories: 1, 1M, 2, 2M, 3R, 3B and 4. As mentioned before, lasers used for hair removal are mainly classified as Class 3B or Class 4.

Class 3B hair removal devices are medium-powered lasers that can emit sufficient infrared radiation to be hazardous to unprotected eyes, both by direct or reflected viewing. Skin will not be injured by unfocused or unmagnified Class 3B laser beams.

Class 4 hair removal devices are high-powered lasers that emit sufficient infrared radiation to be hazardous to unprotected eyes, both by direct or reflected viewing. In some cases, diffusely reflected beams off matt surfaces can also be hazardous to the eyes. Skin can be injured by the direct beam and fires can be started if flammable or combustible materials in the immediate area are exposed.

The first step in a hazard evaluation is to determine the laser classification. The LSO can normally rely on manufacturer information and need not perform any measurements. The "class number" can be read off of the laser classification warning sign (i.e. 3B or 4). The LSO can then comply with all requirements of that laser class, including training (see Part c).

Then the LSO must consider the probability that unprotected personnel will be exposed to hazardous laser radiation (including operators, clients, service personnel, staff, and visitors). If exposure to the direct or specularly reflected beam is possible, the LSO must specify a laser controlled area (see Part d) and take appropriate actions to reduce the risk of overexposure (see Part e).

Lastly, the LSO must determine whether the laser could initiate a fire in an appropriate combustible material. Laser beams represent a potential fire hazard if flammable or combustible materials are exposed to irradiances exceeding 10 W/cm² or beam powers exceeding 0.5 W. Since hair removal

lasers are pulsed lasers, they usually provide beam energy information in joules (J) per laser pulse, along with the length of time of the pulse. To use this information to determine whether a laser could pose a fire hazard, simply convert the J per second of one pulse into watts (W) using the conversion 1 J/s = 1 W. Then compare this number to 10 W/cm². Example: If a laser delivers 2 J in 100 ms to a 1 cm² area, it is equivalent to 2/0.1 J/s per cm² or 20 W/cm². As this could initiate a fire in an appropriate combustible material, the LSO must apply certain fire control measures (see Part e).

c) Education & Training

The level of training is in proportion with the degree of potential laser hazards. Those using or working in the vicinity of Class 3B or 4 lasers must have laser safety training with the following topics covered:

- Fundamentals of laser operation
- Overall responsibility for laser safety
- Laser classification
- Potential laser hazards associated with operating a laser, including the significance of reflections
- Control measures
- Cleaning and maintenance of protective equipment
- Medical surveillance
- Patient care (pre- and post-treatment)
- Emergency procedures (i.e. how to use fire equipment, resuscitative procedures, etc.)

All training activities must be documented by the owner and retained on file.

d) Laser Treatment Controlled Areas, Warning Signs, & Engineering Controls

To ensure that individuals are not exposed to direct, reflected or scattered laser radiation without appropriate protection, it is necessary to:

- create a "*laser treatment controlled area*"[5] within the facility
- install adequate engineering controls; and
- post appropriate warning signs.

[5] A laser treatment controlled area is simply an area that is appropriately enclosed so that laser radiation which is above the maximum permissible exposure (MPE) does not inadvertently escape the treatment area to injure unsuspecting persons.

Laser warning signs:

Sign dimensions, letter size and color, etc. must be in accordance with American National Standard Specification for Accident Prevention Signs, ANSI Z535 series.

For Class 3B or 4 lasers, the following is required:

The signal word “DANGER”.

Instructions or protective action*.

a) For Class 3B lasers, use “LASER RADIATION – AVOID DIRECT EXPOSURE TO BEAM”.

b) For Class 4 lasers, use “INVISIBLE LASER RADIATION - AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION”

A symbol unique to lasers (use either the ANSI Z535 design or IEC 60825-1 design):

The type of laser OR emitted wavelength, pulse duration (if appropriate) and maximum output

The laser classification number

* Other additional wording that can be used when appropriate: “Laser Protective Eyewear Required”, “Invisible Laser Radiation”, “Knock Before Entering”, “Restricted Area”, and “Do Not Enter When Light is On”.

A Class 3B laser controlled area must:

- be under the direct control of authorized laser personnel trained in laser safety and laser operation;
- be located so that access to the area by spectators is limited and requires approval by the LSO;
- have only diffusely reflecting materials in or near the beam path (i.e. reflective items such as mirrors or jewellery must be removed or covered);
- provide personnel and patients with appropriate eye protection;
- have high background illumination;
- have all accessible windows, doorways, etc. covered;
- have room walls that are rough in texture, dark and non-reflecting;
- have limited amounts of flammable compounds or substances;

- provide adequate ventilation, respirators, fire fighting equipment, etc. to control all laser hazards;
- have audible and visible activation warning systems to indicate that the laser is in operation or being tested;
- have a master switch to control patient exposure;
- require secure storage (e.g. access by computer code) or disabling (e.g. removal of a key) of the laser when not in use to prevent unauthorized operation. Laser keys must be kept in a secured location; and
- have an appropriate laser warning sign posted at the entry way to the laser controlled area (see example below).

A Class 4 laser controlled area must:

- meet all the requirements of parts 1-12 of a Class 3B laser controlled area;
- have a clearly marked "Stop" button for deactivating the laser or reducing output levels in the event of an emergency;
- have area/entry safety controls designed to allow both rapid egress and admittance to the laser controlled area under emergency conditions.
- Use a door, blocking barrier, screen, or curtains to attenuate laser radiation in the entryway.
- have an appropriate laser warning sign posted at the entry way to the laser controlled area (see example below).

e) Protective Equipment

It is *extremely important* that all authorized personnel entering the laser treatment controlled area be provided with eyewear. Fire safety equipment and ventilation must also be available to protect the operator and patient from other potential laser hazards. Protective equipment must be serviced and maintained as recommended by the manufacturer to ensure safeguards remain functional.

Eyewear

Eyewear is the single most important piece of protective equipment needed by persons within the laser treatment controlled area. Studies have shown that 70 % of laser eye accidents resulted simply because available protective eyewear was not worn, or inappropriate/damaged eyewear was worn.

Protective eyewear for both the operator and the patient needs to be able to stop laser radiation coming from all directions from striking the eye. This means the eyewear must have side and top guards and fit snugly around the nose. Laser protective eyewear for the laser operator must also allow visible light to pass through it so that the wearer can see adequately to perform their tasks safely, while at the same time preventing the wavelength emitted by the laser from passing through.

The most important factor in selecting operator protective eyewear is that it must protect against the wavelength emitted by the laser. Therefore, *protective eyewear must be labelled with the same wavelength that is emitted by the laser (i.e. 755 nm, 810 nm, 1064 nm, etc).* Lasers commonly used in dermatology and their wavelengths are listed in Appendix D

NOTE: Eyewear will NOT provide protection for lasers that emit radiation of a different wavelength from that which the eyewear is designed for. Simple safety goggles or glasses must NEVER be used for laser eye protection!

The second important factor to look for in a pair of laser protective eyewear is the optical density number recommended by the manufacturer. For laser hair removal devices, the OD number for the eyewear is usually 5 or greater.

Optical density (OD) is a measure of how much the laser radiation is reduced when it passes through the protective eyewear. A higher OD number provides more protection; a lower OD number provides less.

OD = 1 reduces exposure by 10 times (10^1)

OD = 2 reduces exposure by 100 times (10^2)

OD = 3 reduces exposure by 1,000 times (10^3)

OD = 4 reduces exposure by 10,000 times (10^4)

OD = 5 reduces exposure by 100,000 times (10^5)

Eyewear Do's and Don'ts

Do choose eyewear recommended by the manufacturer that is suitable for the wavelength that you are using and the required OD. If the equipment is an intense pulsed light (IPL) system, use protective eyewear appropriate for multi-wavelength emissions.

Do choose eyewear that fits snugly around the face, thus protecting against laser radiation from all directions.

Do put protective eyewear on BEFORE the laser is operated.

Do provide protective eyewear for everyone in the room, including the patient.

Do provide an extra pair of protective eyewear located just outside the entry door for use in circumstances where a person may need to enter the room urgently or in an emergency.

Do follow the manufacturer's recommendations on shelf life, storage conditions and appropriate cleaning methods.

Do inspect protective eyewear regularly.

Do keep laser eyewear in an opaque case when it is not in use, as the coating can be degraded by exposure to daylight over time

Don't use eyewear that is cracked or loose, as light can pass through tiny gaps.

Don't wear eyewear which is not designed for laser safety.

Don't look into the primary beam or its specular reflection even when wearing goggles.

Don't use abrasive or harsh chemicals to clean eyewear or anything other than hat is recommended by the manufacturer.

Remember! Nothing can be done to repair or reverse a laser retinal injury!

Wearing laser protective eyewear is much less of a discomfort than experiencing eye damage!

Fire Safety

Dealing with combustible material requires that a laser operator anticipate accidental and/or unintentional laser exposures to materials and items located within the area in which they are working. Patient towels may be kept damp to reduce flammability. It may be necessary to have flammable or combustible materials near the laser emission area. For fires occurring near or on a patient/client, a container or bucket of water nearby may be preferred to a portable fire extinguisher. Either of these could be kept in the treatment room, while having access to a fire extinguisher near the room(s) housing the laser(s). If required, barriers, curtains and screens in the laser treatment controlled area should be made of flame retardant materials.

Ventilation and Infection Control

To avoid the inhalation of airborne contaminants generated by high powered lasers, appropriate air evacuation systems must be used. The required system is determined by the laser beam power (i.e. irradiance, in W/cm²):

- For a laser emitting less than 1 kW/cm², there is the potential for slight odours. Adequate building ventilation may be satisfactory.
- For 1 - 10,000 kW/cm² powered lasers, air contaminants and laser smoke are associated with noxious odours. Required precautions may include local exhaust ventilation, respiratory protection, personal protective equipment, preventative maintenance, and training/education.

Airborne contaminants may include gaseous toxic compounds, bio-aerosols, dead and live cellular material and viruses and need to be captured as near as practical to the point of production (e.g. within 2-5 cm of treatment area) and either completely trapped or vented out of the area in an environmentally sound manner. Filters and absorbers used in portable smoke evacuators require replacing on a regular basis. Always use safe work procedures when replacing filters and absorbers as they may be a biohazard".

Also, adequate and effective means to prevent the spread of infection shall be taken utilizing standard precautions for cleaning and disinfection of equipment.

f) Administrative & Procedural Controls

Safety polices and procedures need to be established, posted, and complied with. They should include:

- authorizations for laser use
- standard operating procedures (SOP)
- protective equipment (addressing both beam and non-beam hazards)
- cleaning, maintenance, and service instructions[6]
- emergency procedures
- prior-to-use checklists, including client suitability and education (see below)

[6] Note: Many lasers are computer based and 'smart' so that they will perform a number of these steps including start-up calibration, safety checks and other parameters upon start-up, and can notify the user of equipment problems.

Client suitability and education:

Assess the clients' skin type, hair colour, thickness and location of hair, presence of a tan, previous hair removal methods, medical history (ovarian or thyroid disease, diabetes, medications, history of abnormal scarring, history of cold sore outbreaks in the treatment area, or past isotretinoin use), and presence of tattoos or moles in the treatment area.

Discuss realistic outcomes (need for multiple treatment sessions, potential need for maintenance sessions, and the possibility of variable responses to treatment)

Provide pre-treatment instructions (no tanning, plucking, waxing, electrolysis, etc.)

Assess whether there is a need for prophylactic antiviral medication.

Perform a patch test prior to full treatment.

g) Medical Surveillance & Safety Inspections

The only examination required for all personnel participating in laser work is an eye examination following suspected laser injury (usually within 48 hours of an incident). Periodic medical examinations are not required, nor are examinations at the termination of the person's responsibilities with the laser. At present, no chronic health problems have been linked to working with lasers.

However, a pre-assignment medical examination is recommended. The purpose of the pre-assignment examination is to establish a baseline against which damage (primarily ocular) can be measured in the event of an accidental injury. If the ocular history shows no problems and visual acuity is found to be 20/20 (6/6 in each eye for far and near) with corrections (whether worn or not), and Amsler Grid Test and Color Vision responses are normal, no further examination is required. Any deviations from acceptable performance will require an identification of the underlying pathology, as determined by the medical or optometric examiner. Incidental personnel need only have an eye examination for visual acuity. For further information on medical surveillance, see ANSI Z136.1-2007, Appendix E.

Periodic safety inspections of the laser treatment controlled area must also be performed by the LSO (see Appendix B). Deficiencies must be documented and corrected immediately.

h) Documentation & Records

Owners need to keep records and have them available on site, including:

- Laser operators authorized on the laser(s) found on-site
- Laser operator(s) qualifications, education, test results and safety training
- Standard operating procedures (SOP)
- Safety checklist:
- Setup of laser controlled area with signs, window barriers, etc.
- Confirmation of eyewear type and availability
- Patient protection, including removal or covering of reflective surfaces (e.g. jewellery)
- Safety equipment such as smoke evacuator, fire safety equipment, etc.

- Protective eyewear information
- Safety inspections
- Medical exam results
- Accident reports
- A record for each client showing the client's name, address, dates of treatment, type of treatment, etc.

All records must be typed or legibly written in ink and kept on site.

Appendices follow this page. Appendix A provides guidance regarding applicable laser hair removal standards and regulations. Appendix B is a Laser Hair Removal Devices/Facilities Inspection Form that can be used by laser owners and operators as a quick check to verify that the Safety Guidelines are in place and being followed. Appendix C is a brief introduction about how laser radiation is produced. Appendix D provides contact information for provincial government agencies.

Appendix A: Federal and Provincial/Territorial Regulations and Standards Applicable to the Sale and Use of Laser Hair Removal Devices

Canada's federal government controls the sale, lease and import of hair removal lasers, as per the *Radiation Emitting Devices Act* (available at http://laws.justice.gc.ca/en/R-1) and laser hair removal devices must meet the requirements of the *Act*. Laser therapy facilities are advised that they should only purchase laser hair removal devices that have an active Canadian medical device licence in accordance with the *Medical Devcies Regulations*. Licence status can be verified by checking www.mdall.ca.

Alberta

Radiation Protection Regulation, Alta. Reg. 182/2003

A registration certificate is required for Class 3B and 4 lasers, issued by the Director of Radiation Health.

The owner of a "health care facility" shall ensure that the installation and use of lasers complies with CAN/CSA-Z386-01, "Laser Safety in Health Care Facilities" published by the Canadian Standards Association.

The owner of a facility not designated for health care shall insure that the installation and use of lasers complies with ANSI Standard Z136.1-2000, "American National Standard for the Safe Use of Lasers" published by the American National Standards Institute.

See Schedule 2, Table 1 for Maximum Exposure Limits Laser Radiation for any Persons.

British Columbia

BC Ministry of Health Services: Guidelines for Personal Service Establishments (PSEs)

Personal Services Establishments Regulations Reg. 202/83, Filed June 17, 1983.

The *WorkSafeBC Occupational Health & Safety Regulation* (Part 7 Division 3 Radiation Exposure)

laser equipment must be installed, operated and maintained in accordance with the American National Standard Institute (ANSI) Z136.1 – 2007 Safe Use of Lasers and American National Standard Institute (ANSI) Z136.3 – 2005 Safe Use of Lasers in Healthcare Facilities (both of these standards are available from the Laser Institute of America, see http://www.laserinstitute.org/)

Manitoba

Workplace Safety and Health Regulation, Man. Reg. 217/2006, under *Workplace Safety and Health Act*, C.C.S.M. c. W210

An employer must ensure that a laser used in a workplace is installed, used and maintained in accordance with ANSI Standard Z136.1-2005, American National Standard for Safe Use of Lasers.

If laser equipment is used in a health care facility, an employer must develop and implement safe work procedures respecting the use of laser equipment and ensure that lasers are operated and maintained in accordance with CSA Standard Z386-01 (R2006), Laser Safety in Health Care Facilities.

New Brunswick

General Regulation - Occupational Health and Safety Act, N.B. Reg. 91-191

An employer shall ensure that laser beams are operated and used in accordance with ANSI standard ANSI Z136.1-1993, "American National Standard for Safe Use of Lasers".

An employer shall ensure that all sources of intense infra-red radiation are shielded as near the source as possible by heat absorbing screens, water screens or other suitable devices.

An employer shall ensure that employees are provided with and wear properly fitting goggles, face shields or other adequate eye protective equipment when entering an area where they may be subjected to infra-red radiation liable to injure or irritate the eyes.

An employee shall wear the eye protective equipment when entering an area where the employee may be subjected to infra-red radiation liable to injure or irritate the eyes.

Newfoundland and Labrador

At the time of writing these guidelines, no regulations or standards applicable to laser hair removal existed in Newfoundland and Labrador.

Northwest Territories

General Safety Regulations, R.R.N.W.T. 1990, c. S-1

Equipment capable of producing infrared radiation or laser beams must be arranged or shielded so that no person is exposed to harmful effects of radiation, or such persons shall be provided with suitable equipment to prevent injury from exposure.

Only properly qualified personnel shall be permitted to operate radiation producing machines where there is danger of radiation being injurious to a person.

Nova Scotia

At the time of writing these guidelines, no regulations or standards applicable to laser hair removal existed in Nova Scotia.

Nunavut

General Safety Regulations, R.R.N.W.T. 1990 c. S-1

Equipment capable of producing infrared radiation or laser beams must be arranged or shielded so that no person is exposed to harmful effects of radiation, or such persons shall be provided with suitable equipment to prevent injury from exposure.

Only properly qualified personnel shall be permitted to operate radiation producing machines where there is danger of radiation being injurious to a person.

Ontario

The province of Ontario under the general duty clause of the *Occupational Health and Safety Act* requires employers to take every precaution reasonable in the circumstances for the protection of a worker. To fulfill this duty, the Ministry of Labour accepts the ANSI Z136 series of standards (CSA Z386-08 for health care facilities) to protect workers from hazards associated with the use of lasers.

Prince Edward Island

Radiation Safety Regulations, P.E.I. Reg. EC547/84

When laser beams are used for medical purposes (a) the design and manufacture of such shall be in accordance with the requirements of the *Radiation Emitting Devices Act* (Canada) R.S.C. 1985, Chap. R-1; (b) the operation and use of such shall be in accordance with the requirements of the Minister; and (c) warning signs indicating "Laser Beam in Use" shall be posted in areas where laser beams are in use.

General Regulations, P.E.I. Reg. EC180/87

The employer shall ensure that when laser beams are used the operation that use is in accordance with the American National Standard for the Safe Use of Lasers endorsed standard number 21361, 19/9 ANSI (R1), and amendments thereto.

The employer shall ensure that all sources of intense infra-red radiation are shielded as near the source as possible by heat absorbing screens, water screens, or other suitable devices.

The employer shall ensure that employees are provided with and all employees shall wear properly fitting goggles, face shields, or other adequate eye protection when entering an area where they may be subjected to heat rays liable to injure or irritate the eyes.

Quebec

Occupational Health and Safety Regulation respecting, R.Q. c. S-2.1, r.19.01

All intense infra-red radiation sources shall be shielded by one of the following devices: (1) heat absorbent screens; (2) water screens; (3) any other devices to protect workers.

Saskatchewan

Radiation Health and Safety Regulations, 2005, R.R.S. c. R-1.1 Reg. 2

Owners must ensure that lasers are installed, operated, labelled and maintained in accordance with American National Standards Institute (ANSI) Z136.1-2000, Safe Use of Lasers; and if the laser or laser device is a medical laser in a health care facility, the laser must be installed, operated, and maintained in accordance with American National Standards Institute (ANSI) Z136.3-2004, Safe Use of Lasers in Health Care Facilities.

An owner of a Class 3B or 4 laser must fully inform all occupational workers who may be exposed as to the hazards of this radiation under the conditions of use an owner of a laser must draw the attention of the occupational workers to the viewing restrictions that are indicated on the laser classification label.

The owner of a class 3 or class 4 must ensure that no part of the body of any person is deliberately exposed to the direct beam of the laser except under the direction of a duly qualified medical practitioner (or, in the case of a non-medical laser procedure, a person who has been formally trained to carry out the procedure for which the laser or laser device is to be used; and can demonstrate to the satisfaction of an officer his or her knowledge of the equipment, the biological effects associated with its use and the necessary safety procedures).

The owner of a class 3b or class 4 laser must ensure that each operator of the laser or laser device is a duly qualified medical practitioner (or, in the case of a non-medical laser procedure, a person who has been formally trained to carry out the procedure for which the laser or laser device is to be used; and can demonstrate to the satisfaction of an officer his or her knowledge of the equipment, the biological effects associated with its use and the necessary safety procedures).

Yukon Territories

Radiation Protection Regulations, Y.O.I.C. 1986G/164

Every person who becomes an owner of laser equipment shall complete and deliver Form A to the Director within 30 days of becoming an owner.

Owners of laser equipment shall develop a written code of practice for the safe operation of the equipment.

The code of practice shall be provided to and discussed with each employee and employers shall satisfy themselves that it is fully understood by the employees.

The code of practice shall make reference to these regulations and shall include the following items:

- a provision that all laser work shall be discussed with the person designated to ensure that the code of practice is followed;
- a provision that all persons engaged in laser work shall be medically examined before engaging in laser work and at such other times as may be considered necessary;
- a requirement that an accurate log be kept of all laser operations which shall include the names of all those engaged on the work;
- a clear definition of the laser working area;
- a requirement that access to the defined laser working area be restricted to only essential personnel;
- a requirement that the working area be screened from all other areas and that warning lights be placed so as to indicate when laser equipment or laser apparatus is in operation or is being tested;
- a requirement that all laser work shall be carried out in areas with high intensity background illumination;
- a requirement that "free field" laser operation must be restricted;
- a requirement that all laser operations must be "beam terminated" at a suitable material;
- a requirement that safety spectacles appropriate to the type of emission must be worn in the area at all times;

- an instruction to all personnel not to look into the primary beam or into its specular reflection even when wearing protective glasses;
- a requirement that precautions must be taken to prevent electric shock;
- a requirement that all personnel in laser work must be instructed in resuscitative procedures;
- a requirement that all visual disturbances, after-images, burns and skin eruptions must be reported to the person in charge of the operation;
- a requirement that any of the incidents or accidents must be recorded;
- a requirement that all personnel must be made fully aware of the hazards of the work and be instructed in emergency procedures;
- instructions to ensure compliance with section 25.

All persons who will be engaged in work with laser equipment shall be medically examined prior to being engaged in such work. The findings of the medical examination shall be recorded. The medical examination shall include a report from an ophthalmologist on visual acuity, visual fields, retinoscopy and the condition of the ocular media. The ophthalmic examination shall be repeated at six month intervals and after any accidental exposure; the report of such examinations shall be recorded. The expenses involved in obtaining these examinations shall be paid by the employer.

All persons engaged in work with laser equipment shall be instructed by the owner in the hazards relating to (a) high and low voltage supplies, (b) static electricity, (c) flash tube brilliance, (d) flash tube explosion, (e) flash tube infra-red and ultra-violet light, (f) toxic chemicals and gases, (g) liquid coolants, (h) flammable gases, (i) flammable and fusible materials in the beam path, and (j) reflective surfaces in the beam path.

The walls of any room in which work involving the use of laser equipment or laser apparatus is carried out shall be rough in texture, dark and non-reflecting.

All laser equipment shall be rendered non-reflecting.

No person shall permit the operation of any laser equipment unless the appropriate warning symbol is clearly displayed at all points of approach to, and in and around, the area of operation of the laser equipment.

All visual disturbances, after-images, burns, and skin eruptions affecting any person engaged in work involving the use of laser equipment shall be reported to the person in charge of the operation and the details shall be recorded and that person shall ensure that the Director is notified.

Appendix B: Sample Laser Hair Removal Devices/Facilities Inspection Form

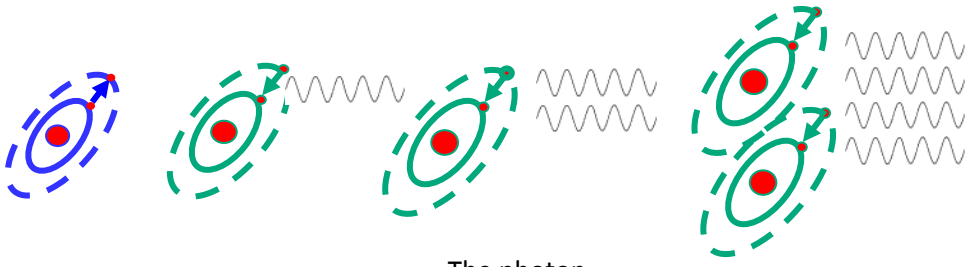
Date: Location:	
Inspector:	
Laser Class / Power:	
Manufacturer / Model / Serial #:	
Laser Treatment Controlled Area	
Is the laser located in a separate room with a closable door?	☐Yes ☐No ☐N/A
Does this room have laser warning signs posted at the entries?	☐Yes ☐No ☐N/A
Are transparent windows and other openings covered?	☐Yes ☐No ☐N/A
Are only trained & authorized persons with personal protective equipment allowed in the treatment area?	☐Yes ☐No ☐N/A
Have reflective items and jewellery been covered?	☐Yes ☐No ☐N/A
Is adequate air evacuation/filtering provided for smoke/odour removal?	☐Yes ☐No ☐N/A
Is regular maintenance conducted on the ventilation system?	☐Yes ☐No ☐N/A
Do cables, wires, etc. exist that create a fall or slip hazard?	☐Yes ☐No ☐N/A
Are electrical cords damaged?	☐Yes ☐No ☐N/A
Have adequate measures been taken to control flammable liquid or gas hazards?	☐Yes ☐No ☐N/A
Protective Equipment	
Are persons in the treatment area wearing protective eyewear when the laser is on?	☐Yes ☐No ☐N/A
Is protective eyewear designed to stop laser radiation coming from all directions?	☐Yes ☐No ☐N/A
Is protective eyewear labelled with the same wavelength that the laser operates at?	☐Yes ☐No ☐N/A
Is protective eyewear labelled with an optical density recommended by the laser manufacturer (normally 5 and higher)?	☐Yes ☐No ☐N/A

Laser Device	
Is an emergency shutoff switch for the laser available to the operator or assistant?	☐Yes ☐No ☐N/A
Can the laser be disabled when not in use, by removal of a key or coded access, etc?	☐Yes ☐No ☐N/A
Is the switch that controls patient exposure to laser radiation guarded or else require two simultaneous actions, such as foot pedal depression and hand trigger, in order to operate?	☐Yes ☐No ☐N/A
Procedures	
Has the operator(s) received laser safety training?	☐Yes ☐No ☐N/A
Do operators follow standard operating procedures?	☐Yes ☐No ☐N/A
Does the operator remove their hand/foot from the trigger switch placing the laser on standby, when conversing, changing position, etc?	☐Yes ☐No ☐N/A
Is the operator well versed in how to handle procedural complications / emergencies?	☐Yes ☐No ☐N/A
Eye Examinations	
Have personnel working within the laser treatment controlled area had a baseline eye examination?	☐Yes ☐No ☐N/A
Is the laser operator's eyesight compromised in any way (i.e. lens removed, taking medications)?	☐Yes ☐No ☐N/A
Patient care	
Is the client suitable for the treatment?	☐Yes ☐No ☐N/A
Do they know how the procedure works, recovery times, follow-up care, etc?	☐Yes ☐No ☐N/A
Have they avoided tanning?	☐Yes ☐No ☐N/A
Is protective eyewear provided for the patient?	☐Yes ☐No ☐N/A
Has a patch test been performed prior to full treatment?	☐Yes ☐No ☐N/A
Is care taken to not overlap laser pulses during treatment?	☐Yes ☐No ☐N/A
Laser Safety Officer:	
Qualified Operators:	

Appendix C: Introduction to Laser Light

The word laser is an acronym for **l**ight **a**mplification by **s**timulated **e**mission of **r**adiation. A laser device produces single wavelength radiation at the atomic level by stimulating atoms to emit their radiation together and in phase with one another. The term 'in phase', means radiation waves whose crests and troughs arrive at a place at the same time. Each laser emits photons with a specific frequency and wavelength only, which produces a uniform or coherent beam, so that their effects reinforce each other. Amplification of the photons inside the laser occurs because of mirrors located at each end which reflect the radiation back and forth over the atoms stimulating them to re-emit more photons again and again before releasing them.

Laser Light Production from Atoms



Electricity adds energy to a laser atom…

The laser atom spontaneously emits a photon (light)…

The photon stimulates another atom to emit a photon that is in-phase with the first photon and these photons…

…stimulate more atoms to emit light in-phase with the very first photons, etc…

The resulting output from a laser is a very strong coherent beam of energy at a single wavelength. The laser emits a very intense beam, which will travel great distances, while maintaining is size and strength as it travels, due to the very small beam divergence.

The energy in the beam emitted by most hair removal devices is a beam of pulsed energy made of wavelengths found in the near infrared (IR) region of the electromagnetic spectrum. These wavelengths are beyond the normal visual response range of the human eye and consequently are invisible. Since the emitted energy cannot be seen it is not referred to as "light" but rather more correctly by the terms "radiation" and "infrared radiation". These two terms are to be used interchangeably in these guidelines when describing laser emissions from laser hair removal devices. The use of the term "radiation" is not meant to imply that ionizing radiation such as x-rays and/or gamma rays are emitted from these lasers.

Appendix D: Lasers Commonly Used in Dermatology

Wavelength (nm)	*Laser*	*Indications*
308 (Ultraviolet)	Excimer	Psoriasis, vitiligo, leukoderma
455; 514 (blue-green)	Argon (continuous)	Telangiectases, thick port wine stains in adults; epidermal pigmented lesions
504-690 (green-yellow-red)	Argon-pumped tunable dye (continuous)	Telangiectases, thick port wine stains in adults; epidermal pigmented lesions; photodynamic therapy
510 (green)	Flashlamp-pumped dye (short-pulsed)	Epidermal pigmented lesions; red tattoos
511 (green)	Copper vapor / bromide (pseudo-continuous)	Epidermal pigmented lesions
521;531 (green)	Krypton(continuous)	Epidermal pigmented lesions
532 (green)	KTP (pseudo-continuous)	Telangiectases, thick port wine stains in adults; epidermal pigmented lesions
532 (green)	KTP (long-pulsed)	Telangiectases, thick port wine stains in adults; epidermal pigmented lesions
532 (green)	Frequency doubled Q-switched ND;YAG (pulsed)	Epidermal pigmented lesions; red tattoos
568 (yellow)	Krypton (continuous)	Telangiectases, thick port wine stains in adults
585-600 (yellow)	Flashlamp-pumped dye (long-pulsed)	Port wine stain, port wine stain in children, telangiectases, warts, hypertrophic scars, striae
694 (red)	Q-switched ruby (pulsed)	Epidermal and dermal pigmented lesions; blue, black and green tattoos
755 (infrared)	Q-switched alexandrite (pulsed)	Epidermal and dermal pigmented lesions; blue, black and green tattoos
755 (infrared)	Alexandrite (long-pulsed)	Hair removal
810 (infrared)	Diode (long pulsed)	Hair removal
980 (infrared)	Diode (continuous; pulsed)	Vascular lesions; telangiectasia
1064 (infrared)	Q-switched Nd:YAG (pulsed)	Dermal pigmented lesions; blue and black tattoos
1064 (infrared)	Nd:YAG (long-pulsed)	Hair removal
1064 (infrared)	Nd:YAG (continuous)	Deep coagulation of tissue
1320 (infrared)	Nd:YAG (pulsed)	Non-ablative skin resurfacing
2940 (infrared)	Erbium:YAG (pulsed)	Skin resurfacing
2100 (infrared)	Ho:YAG (pulsed)	Coagulation, vaporization, and cutting of tissue, epidermal pigmentation and non-pigmented lesions, multicoloured tattoos, warts
10600 (infrared)	Carbon dioxide (continuous; pulsed)	Coagulation, vaporization and cutting of tissue; skin resurfacing

(Source: ANSI Z136.3-2005, American National Standard for the Safe Use of Lasers in Health Care Facilities, Appendix C: Table C1)

Appendix E: Contacts for Further Information

Provincial Government Agencies:

Appropriate provincial department contact listings can be found at:

http://www.hc-sc.gc.ca/ewh-semt/radiation/fpt-radprotect/index-eng.php