Laser Hair Removal Devices:

Safety Guidelines for Owners/Operators

BC Centre for Disease Control
September 2005

Adopted September 2011 by:
Health Protection Branch
Population and Public Health Division
Ministry of Health

BC Centre for Disease Control
AN AGENCY OF THE PROVINCIAL HEALTH SERVICES AUTHORITY
Radiation Protection Services

Table of Contents

Foreword

A 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 required 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 their training resource materials and related guidance documents available. 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 subject to provincial legislation, for purposes of worker health and safety as well as client safety when treatment is given. When used by a member of a designated "Health Profession" as defined by the *Health Professions Act*, the professional regulatory body has been delegated the authority to govern professional practice of their members in the public interest. Operators of personal services establishments in British Columbia, as defined by the Personal Services Establishment Regulation, must comply with, maintain and operate their establishments in a way that prevents health hazards from occurring. Public Health Officials may refer to this document and to the Ministry of Health Services' *Guidelines for Personal Services Establishments*,* when assessing whether a laser hair removal facility is installed and operated in accordance with the Personal Services Establishment Regulation.

Editor's note, September 2011: The Personal Service Establishments Regulation has been repealed and is now covered under the Regulated Activities Regulation.

In addition, owners/operators should be aware of the *BC Workers' Compensation Board's Occupational Health & Safety Regulation (Part 7 Division 3 Radiation Exposure)* * which states: Equipment producing ionizing or non-ionizing radiation must be installed, operated and maintained in accordance with the applicable standard, as listed in the regulation. A Workers' Compensation Board inspector may visit a site and inspect for compliance with the Occupational Health & Safety Regulation. (Note: In this Guideline the Workers' Compensation Board will also be referred to by their preferred operational name of 'WorkSafeBC'.)

* **Note:** The Occupational Health & Safety Regulation may be viewed on the internet at http://www.worksafebc.com and the Guidelines for Personal Services Establishments at http://www.health.gov.bc.ca/protect/ehp_pse.html

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- Terry Spock, Secretary
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- Brian Phillips, Director

Introduction

In 1995 the United States Food and Drug Administration (USFDA) approved the use of lasers in the US as a medical device for hair removal. In 1999, the US 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 to 4) and identified by attached warning labels. These labels also indicate the degree of hazard that is associated with the laser radiation to which human access is possible during laser operation. Canada has not yet adopted a similar laser hazard classification system, so reliance is placed on a laser device entering Canada being labeled in conformance with US requirements. Canada's federal government controls the importation, sale and leasing of hair removal lasers by requiring the laser manufacturer to obtain a device import license. The guidance in this document applies to laser systems only (not flash lamps).

Currently, lasers used for skin resurfacing, skin lesions and hair removal in BC operate with high emission levels and are therefore designated in the highest hazard classes (Class 3b & 4). These classifications indicate that the laser radiation emitted from these devices is a hazard to unprotected eyes or skin from exposure to the direct beam. Exposure to the reflected or scattered beam may be hazardous under some conditions. The direct beam may also be a fire hazard if it strikes combustible materials. Safety features that form part of the laser devices and operator training specific to the laser type, are essential for their safe use.

Staff at the British Columbia Centre for Disease Control's (BCCDC) Radiation Protection Services (RPS) became aware of concerns regarding laser safety at laser hair removal facilities. RPS staff visited a number of sites, usually accompanied by an Environmental Health Officer (EHO). Laser safety inspections and interviews conducted with operating personnel lead to the development of these Guidelines to provide owners, operators and others in laser facilities in BC with important information on laser safety.

These Guidelines address general laser safety, roles and responsibilities, the risks associated with the use of lasers and provides advice for laser personnel to help reduce health risks to their clients, to themselves and to others.

Glossary of Terms

ANSI: the **A**merican **N**ational **S**tandards **I**nstitute - a private, non-profit organization that administers the US voluntary standardization and conformity assessment system.

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

Beam: the pulsed or continuous output from a laser.

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 the electric and magnetic fields.

Incidental personnel: those whose work makes it possible, but unlikely, that they will be exposed to laser energy sufficient to damage their skin or eyes.

Infrared: invisible radiation with wavelengths from approximately 700 nanometers (nm) to 1 millimeter. Hair removal lasers operate between 700 nm and 1400 nm.

Irradiance: the power per unit area, usually expressed in watts per square meter, used to measure or quantify the intensity of laser radiation.

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

kW/cm^2: a kilowatt per square centimeter [see *Watt*].

Laser: an acronym which stands 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.

Laser personnel: those who work routinely in the laser environment and must be fully protected.

Laser safety officer: the person with training and experience who is authorized by administration to be responsible for the laser safety program in the facility.

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

MPE: abbreviation for the **M**aximum **P**ermissible **E**xposure allowed by the laser standard before injury occurs to the skin or eyes.

Nanometer (nm): a unit of length equal to 0.000,000,001 meters and used in the measure of wavelengths of light and infrared radiation.

Nd:YAG: notation for the component in a laser which produces the infrared radiation i.e. neodymium:yttrium-aluminum-garnet.

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

NOHD: abbreviation for Nominal Ocular Hazard Distance which is the distance along the axis of the unobstructed beam from a laser to a human eye, beyond which the irradiance or radiant exposure, during installation or service, is not expected to exceed the appropriate maximum permissible exposure.

Optical Density [OD]: a material's ability to absorb laser radiation, as used in protective eyewear.

OD number: an indication of the protection of laser safety eyewear; a measure of how much the laser radiation is reduced when it passes through the protective eyewear.

Optical instruments: instruments designed to aid vision [e.g. binoculars, microscope].

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.

Visible Light: electromagnetic radiation perceptible to human vision and having wavelengths between approximately 400 nm and 700 nm.

Wavelengths: the distance between one peak or crest of a wave of light, heat, or other energy and the next corresponding peak or crest.

Watt/cm^2: a watt per square centimeter, which is a unit of irradiance.

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

Laser Terminology

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 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 can not be seen it is not referred to as "*light*" but rather more correctly by the terms "*radiation*" and "*infrared radiation"*. These two terms are used interchangeably in these guidelines when describing laser emissions from hair removal lasers. 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.

Laser Safety Responsibility

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 lasers, management shall designate a Laser Safety Officer (LSO) to be responsible for implementing a laser safety program in the facility. In environments such as a hair removal clinic where laser systems are used, the requirements for and principles of the safe use of laser systems are no less stringent than when the same systems are used in large institutional settings such as hospitals. It is the responsibility of the senior operator in these non-hospital environments to be aware of the requirements for safe use. This means that:

a) laser operators must be trained in laser safety and be knowledgeable of local regulations.

b) periodic laser safety audits of the facility and personnel safety features (e.g. eyewear, barriers, area controls, warning signs, etc.) and equipment safety features (interlocks, labels, etc) shall be conducted and documented, with any identified deficiencies being duly corrected in a timely manner.

Laser Hair Removal Process

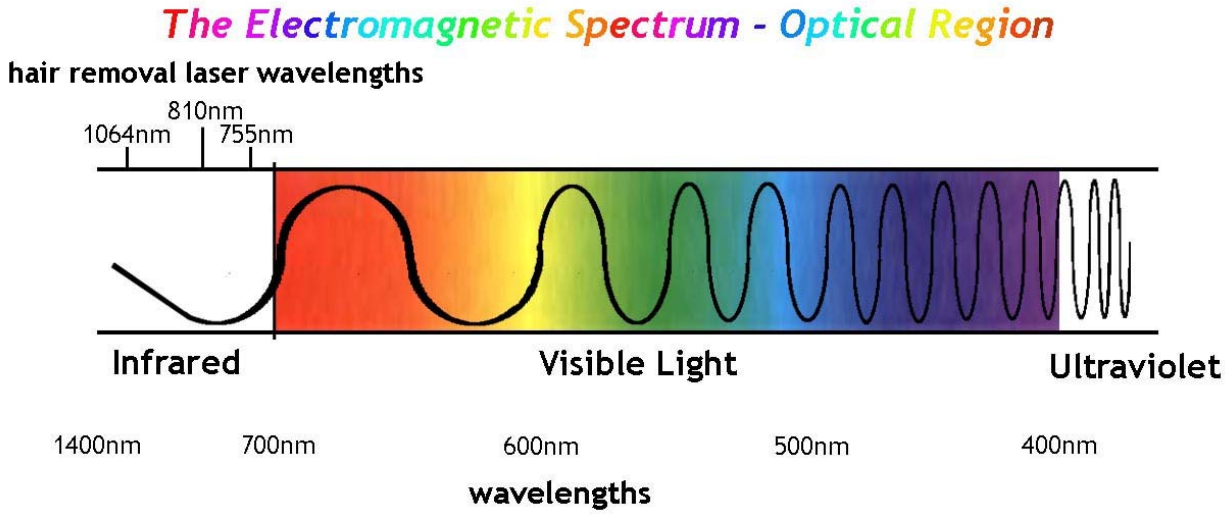
Skin

Skin is made up of two layers. The thin outer layer is called the epidermis and the thicker inner layer is called the dermis. Cells called melanocytes are located at the base of the epidermis. Melanocytes manufacture a dark pigment called *melanin* giving the skin a darker colour. Normal dark skin is dark because its melanocytes contain abundant melanin.

Skin cells in the epidermis move outward as they grow older. It takes approximately four to ten weeks for a new epidermal cell to mature, travel through the epidermis and die. The hair root is located inside a follicle of epidermal cells that extend down into the dermis so that hair follicles extend up through the dermis and epidermis to the skin's surface. Hairs grow outward from within the hair follicles. Melanocytes in the hair bulb release melanin within the hair giving it its colour.

Hair removal laser devices operate by emitting one or more pulses of infrared radiation which pass through the lighter colored skin and are absorbed by the melanin in the hair follicle. The laser energy is converted to heat which destroys the hair follicle.

Typical lasers in use today for hair removal emit infrared radiation, e.g. neodymium:yttrium-aluminum-garnet (Nd:YAG) operating at 1064nm, the alexandrite at 755nm, and the diode at 800-810nm. Lasers emitting infrared radiation are used because this radiation destroys hair by using a selective damage mechanism called photothermolysis. When infrared radiation is directed onto skin it is absorbed by and heats only the darker colored skin tissues but not the lighter colored skin tissues. This is photothermolysis. Melanin is the main, naturally-occurring, dark pigment in skin and hair. As the laser radiation enters the skin it is absorbed by this pigment within the hair. The heat generated is transferred to the surrounding hair follicle. Cells in the root of the hair that are actively dividing are most susceptible to injury and are destroyed. Since melanin is also the pigment that gives skin its darker colour, skin with little melanin, such as normal white un-tanned skin, absorbs less laser radiation and is only minimally damaged by the laser when briefly exposed. However, dark skin can be easily heated by infrared laser radiation due to its greater melanin content and is therefore more susceptible to damage from laser exposure.



There are also other devices used for hair removal that are not lasers. Intense pulsed light (IPL) systems are not lasers. They generate both invisible infrared radiation and visible light and emit high intensity pulses of a broad range of wavelengths from 500 to 1200 nanometers. 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 unnessesary proportion of the visible wavelengths. This device normally has a larger treatment application area than a laser.

For hair removal, both systems must be able to achieve penetration into the skin with minimal absorption and arrive at the hair root to be absorbed by the melanin in the melanocytes of the hair. Consequently, fair-skinned individuals with dark hair are more easily treated. For persons with natural dark skin and/or sun tanned skin it requires more care with less aggressive treatments. To protect the surface and upper areas of skin (i.e. the epidermis) from overheating, some lasers use cooling mechanisms. A variety of methods such as ice, gels, cold glass container, very low temperatures sprays, and cold airflow are used.

Hazards and Safeguards

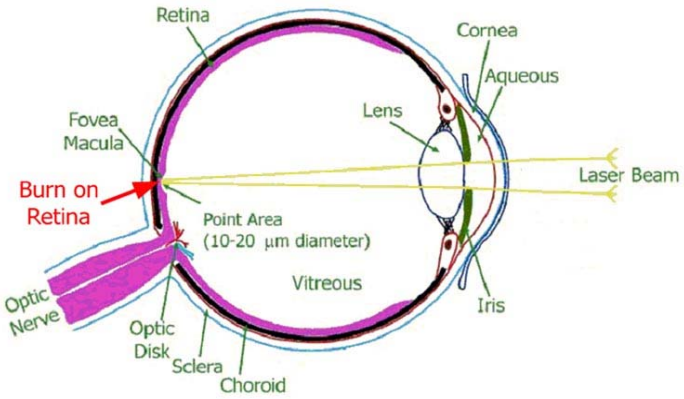
A. Hazards

The primary hazard associated with laser hair removal facilities stems from inadvertent exposure to laser emissions. Exposure to an individual may occur directly from the laser beam, or when the beam is reflected from a shiny surface such as a mirror, ring, glass picture frame, etc. The parts of the body at greatest risk are a person's eyes and skin. Persons at risk are principally the client and the staff carrying out laser hair removal procedures. Others at risk may include laser device service personnel. In addition, combustible materials can be ignited when exposed and may cause a fire.

The following sections describe the unique hazards presented by laser radiation to eyes, skin, and other materials, along with appropriate safety measures. The laser energy will not cause cancer or damage to internal organs in the body.

a) Eye Hazards

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, restricting the amount of light entering the eye.



When light passes through the curved cornea, the pupil and the 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 by the retina. Even though we cannot see it, near-infrared laser radiation from hair removal lasers also passes easily through the cornea, pupil and lens of the eye. It is focused on a small portion of the retina causing a very large amount of energy to be absorbed in a very small area. The energy or power per unit of area on the retina can be increased by 10,000 to 100,000 times! Brief exposures instantaneously burn the retina and other tissues around the impact area. Because the eye cannot see near-infrared

radiation it will not respond to protect itself by blinking or by looking away from the laser radiation. Hence eye damage can occur to a person without them being aware of an exposure having taken place.

Light which is seen by the eye, i.e. visible light, has wavelengths between 400 nm and 700 nm. The colors purple and blue have wavelengths near 400 nm and red colored light is near 700 nm. Infrared radiations are those wavelengths greater than 700 nm which we cannot see. However, as mentioned above, these infrared wavelengths, from 700 nm to 1300 nm, although invisible, are nonetheless focused onto the retina. Injury may even occur from reflected laser radiation with sufficient energy entering the eye. A client's eyes need to be protected from inadvertent exposure during treatment, by using a suitable method such as protective eye glasses, pads, or corneal shields.

People can receive an eye injury when they are not using eye protection. Laser induced eye injury 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 symptoms of a laser burn in the eye will be a pain in the eye or a headache shortly after exposure, excessive watering of the eyes or the sudden appearance of *floaters* in one's vision. Floaters are small specks or clouds that you may see moving in your field of vision. Individuals who had received laser eye injuries have reported seeing a "black" spot present in their field of view. A flash may be experienced during the actual exposure. Consequently, it is extremely important that all authorized personnel entering the area of the laser be provided with and **WEAR** protective eyewear.

b) Skin and Fire Hazards

In addition to presenting the possibility of instantaneous eye injury, intense laser radiation can burn the skin and initiate fires in combustible materials. When hair removal lasers are used unsafely or incorrectly, the laser radiation absorbed by the skin can cause localized skin burns. Consequently lasers must only be operated by trained and knowledgeable laser technicians or doctors, to avoid injury to clients.

Accidental and/or unintentional laser exposures to materials and items located within the area in which they are working may cause these items or materials to ignite. Since it may be necessary to have flammable or combustible materials near the laser treatment area, special precautions need to be taken. When dealing with fires involving lasers, the risk of an electrical hazard must be considered. Appropriate guidance should be sought from competent fire safety/prevention specialists for advice in dealing with fires in your facility. Keep a fire extinguisher in the treatment room or have immediate access to it. Know where the electrical circuit breaker panel is that controls the power supplied to the laser equipment.

A rule of thumb for determining which lasers represent a potential fire hazard is when flammable or combustible materials can be exposed to irradiances exceeding 10 watts/cm^2 or where the laser beam power exceeds 0.5 watts. Check the details on the output power/irradiance of your equipment to see if and under what conditions it presents a risk of fire.

B. Safeguards

a) Laser Safety Program

As previously mentioned each laser hair facility regardless of its size should establish and maintain an adequate safety program for the control of laser hazards. The program is the responsibility of the owner. The employer has the fundamental responsibility for assurance of the safe use of lasers owned and/or operated by the employer or employee. The management organization must designate a Laser Safety Officer (LSO) for the facility, to be responsible for implementing a laser safety program for all circumstances where there is human access to Class 3b and/or class 4 levels of laser radiation.

The **laser safety officer** is responsible for:

- Establishing the laser treatment controlled area.
- Approving standard operating procedures (SOPs), administrative and procedural controls.
- Recommending or approving protective equipment (i.e. eyewear, clothing, barriers, etc) as required assuring personnel safety.
- Auditing the functionality of control measures periodically to ensure proper operation.
- Approving the wording on area signs and equipment labels.
- Assuring adequate safety education and training are provided to laser area personnel.
- Determining the personnel categories (i.e. laser *personnel* or *incidental personnel*) for medical surveillance. See Part J on page 21
    - *Laser personnel* are those who work routinely in the laser environment and must be fully protected.
    - *Incidental personnel* are those whose work makes it possible but unlikely that they will be exposed to laser energy sufficient to damage their skin or eyes. For example clerical and/or supervisory personnel of staff who do not work directly with lasers.

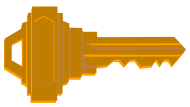
Large facilities having an owner(s), employer and several employees, may designate a laser safety officer and give him/her the authority he/she needs to carryout their responsibilities. In smaller facilities however, the owner may also be the laser safety officer.

In all cases a laser safety officer must be designated and must have authority to carry out a laser safety program in the facility. This individual must have the necessary training and experience to administer a laser safety program. He/she must be authorized by the employer and be responsible for monitoring and overseeing the control of laser hazards.

b) Standard Operating Procedures

Safety policies and procedures need to be established and copies kept posted. They should include authorizations for laser use, operating instructions, prior-to-use checklists, and maintenance/service instructions. Many lasers are computer based with 'smart' features, so that they will perform a number of these steps including calibration, safety checks and other parameter tests upon startup and can notify the user of equipment problems.

Newer lasers often come with sophisticated built-in safety features such as protective housings around the laser, interlocks on the protective housings, a key control and warning systems. Nevertheless, to prevent unauthorized operations your laser needs to be either securely stored when not in use or require a key or coded access to enable the laser.



Other safety features include:

- The switch which controls client exposure must be guarded to prevent inadvertent activation. Another way to accomplish this is to require two simultaneous actions, such as foot pedal depression and hand trigger, in order to operate.
- An emergency shutoff switch must be available to the operator or assistant to enable the rapid shutdown of equipment.
- Equipment must be serviced and maintained as recommended by manufacturer to ensure safeguards remain functional.
- The laser operator should periodically check electrical cords for damage.
- Check any skin coolant hoses supplied, for wear and any damage.

All testing of the laser should be done **before** the client enters room, by staff that are adequately protected.

c) Protective Eyewear

The laser treatment area needs to be supervised and occupied only by trained staff or other authorized persons who are sufficiently protected. It is extremely important that all authorized personnel and patients entering this area be provided with personal protective equipment.

Seventy percent (70%) of all laser accidents have been related to:

a) not wearing protective eyewear,

b) wearing inappropriate eyewear,

c) wearing damaged protective eyewear while using high power lasers!!

Protective eyewear is the single most important piece of protective equipment needed by persons within the treatment area**.**

The laser personnel and the clients often wear different types of protective eyewear:

- Laser protective eyewear for the **laser operator and staff**: this allows 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 eyewear.
- Laser protective eyewear for **clients**: this allows access to the clients face during some procedures and is designed to protect the clients' eyes from laser light coming from all directions since the client has no control over the laser.

Since most hair removal lasers emit the majority of their energy as a single invisible wavelength of infrared radiation, protective eyewear needs to protect against the specific wavelength that is emitted by the laser being used. In addition, protective eyewear for both the operator and the client needs to be able to stop laser radiation coming from all directions from striking the eye. This means the operator's eyewear must have side and top guards and fit snugly around the nose.

However the most important factor in selecting operator protective eyewear is that it must protect against the wavelength emitted by the laser. There is only **one way** to know whether the protective eyewear that you are using protects from the laser radiation that the laser is emitting. The protective eyewear **must be labeled with the same wavelength of laser radiation that your laser is using!** e.g. 810 nm (diode) or 1064 nm (Nd YAG), etc.

The number that is printed on the eyewear lens, e.g., 810 nm, or 1064 nm, is the wavelength of laser radiation that the eyewear blocks.

Eyewear will NOT provide protection for lasers that emit radiation of a different wavelength from that which the eyewear is labeled with. **Simple safety goggles or glasses must never be used for laser eye protection!**

In addition to providing protection for the appropriate **wavelength** of laser radiation, the protective eyewear must also be capable of reducing the intensity of laser radiation passing through the eyewear to a safe level. That is, the *Optical Density* or OD of the protective eyewear must be sufficient to provide the required protection. The following section on *Optical Density* addresses this requirement.

Optical Density (OD)

Suppose you have laser protective eyewear with a wavelength number printed on the lens that matches the wavelength that your laser emits, how do you know whether the protective eyewear is strong enough to protect your eyes?

Answer: the OD number

Optical Density or 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)

OD = 6 … etc

Without knowing the output power or energy of the laser wavelength used, an appropriate OD for protective eyewear for a specific laser cannot be determined. Consequently protective eyewear must have an OD that is recommended by the laser equipment manufacturer. This would likely be at least an OD of 5 or greater. Since the common laser hair removal wavelengths used at the time of the writing of this document are 694nm, 755nm, 810nm or 1064nm, check your protective eyewear for one of these numbers to ensure it matches the wavelength emitted by your laser. Then check for the OD number to ensure it is adequate for your laser system.

The optical density (OD) needed for protection is simply the logarithm of the potential eye exposure, divided by the maximum permissible exposure (MPE) i.e.

$$OD = \log_{10} (\text{potential eye exposure}/\text{MPE}).$$

Eyewear Dos and Don'ts

1. **Do** put protective eyewear on BEFORE the laser is turned on.
2. **Do** provide protective eyewear for <u>everyone</u> in the room.
3. **Do** provide face sealing eyewear that protects the patient/client against laser radiation from all directions.

4. **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.

5. **Do** inspect protective eyewear regularly.
6. **Do** follow the manufacturer's recommendations on shelf life, storage conditions and appropriate cleaning methods.
7. **Don't** use eyewear that is cracked or loose, as light can pass through tiny gaps.
8. **Don't** wear eyewear which is **not** designed for laser safety and **not** suitable for the wavelength that you are using.
9. **Don't** use laser protective eyewear for intense pulsed light (IPL) systems. Protective eyewear appropriate to protect against IPL systems with their multi-wavelength emissions must be used.

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 permanent eye damage!

d) Safety Zones

Laser radiation exposure may be unsafe within a specific distance, beyond which it is not harmful as a result of the laser beam spreading out (divergence) and being attenuated or scattered by air. The distance beyond which it is safe to view or be exposed to a laser beam is unique for each type of laser. Consequently knowledge of this distance can be used to protect oneself and others from laser exposure injury. Laser standards define the area **inside** this distance as the **"Nominal Hazard Zone" (NHZ),** being "*the space within which the level of the direct, reflected, or scattered radiation during normal operation exceeds the applicable maximum permissible exposure*". Unfortunately most laser device manufacturers do not provide this distance in their operator information. Some lasers are provided a different measure of laser safety called the "**Nominal Ocular Hazard Distance" (NOHD).** This is "*the distance along the axis of the unobstructed beam from a laser … to the human eye beyond which the irradiance or radiant exposure, during installation or service, is not expected to exceed the appropriate MPE".* For typical hair removal lasers the NOHD's can be in the range 30 to 120 meters! Therefore distance alone cannot be used as a means to protect operators or other persons against the laser beam if scattered from reflective materials inside the treatment room. The treatment room must be designed to prevent an inadvertent scattered beam from exiting the room through open doors, windows or other breaks in the treatment room enclosure. Access into the treatment enclosure must be restricted to essential personnel during treatments (see part h).

Laser safety standards make use of the concept of *maximum permissible exposure* (MPE), which is a number representing the amount of energy (joules) or power (watts) in the cross section of area (cm^2) of a laser beam *to which a person may be exposed without hazardous effect or adverse biological changes in the eye or skin*. Specific information for maximum permissible exposures to eyes and skin for every type of laser can be found in an appropriate laser safety standard such as ANSI Z136.1 – 2000 available from the Laser Institute of America (http://www.laserinstitute.org/) and also Rockwell Laser Industries (http://www.rli.com/). WorksafeBC expects that owners/operators should have knowledge of this standard. A similar standard is available from the Canadian Standards Association (CSA) Standard CAN/CSA-Z386-01: Laser Safety in Health Care Facilities".

However, this is complex information, given the variety of laser wavelengths, power levels, pulse durations and beam divergence etc. To simplify the situation, a laser classification system was adopted which categorize lasers according their capability for causing eye and skin injury. The use of warning **labels** on the laser provides immediate guidance on whether or not the laser is harmful and what one should do about it. The laser hazard classification system and the applicable warning labels are described in the following two sections.

e) Hazard Classification

Since August 1, 1976 commercially produced lasers in the United States have been classified and identified by labels affixed to the laser. Many of the lasers used in British Columbia come from the United States where laser manufacturers are required by law to label their lasers with an appropriate hazard classification number. This number indicates the laser system's capability of injuring personnel. Lasers that are imported from other countries into Canada may have this labeling as well.

The classification labeling numbers are simply: 1, 2, 3 or 4 and are based upon maximum output power and/or energy available for the intended use. Class 1 lasers cannot emit harmful accessible laser radiation levels and are exempt from all control measures. To protect oneself around Classes 2, 3 and 4:

a) **READ** the "signal word", i.e. Danger, Caution, or Notice.

b) **READ** the "class number" of the laser i.e. 2, 3, or 4 that is on the laser classification warning sign.

c) **COMPLY** with the pertinent information written on the sign. This safety information is appropriate for the laser containing the label.

d) **CHECK the laser safety requirements specific to your laser in the equipment operating manual**.

Using the "signal word" and pertinent safety information on the labels will be straight forward, whereas the classification numbers need an explanation. The numbers 2, 3 or 4 indicate the laser's potential for producing injury under conditions which include the possibility of a laser emission being concentrated by optical aids (such as with telescopes or binoculars) and entering the pupil of the eye, or burning exposed skin.

Class 2 represent lasers or laser systems emitting only visible beams, which can be viewed without injury for up to the normal blink aversion response time of an eye, which is **0.25 seconds.** Skin will **not** be injured by unmagnified Class 2 laser beams.

Class 3 lasers and laser systems include lasers emitting invisible, ultraviolet or infrared beams. Viewing of the direct beams or mirror-like reflections of the beams is **not normally safe.** Class 3 is further subdivided into 3a and 3b. Class 3a in most cases may be treated as Class 2 lasers except when viewed with optically aided instruments. **Class 3b may not be viewed under any circumstances**. Skin will be injured by focused or magnified Class 3 laser beams.

Class 4 lasers and laser systems emit visible or invisible beams which **can not be safely viewed** directly. Beams reflected off mirror-like surfaces and in some cases, diffusely reflected off matt surfaces may be hazardous to the eyes. Skin can be injured by the direct beam and fires can be started if flammable materials are exposed.

f) Warning Labels

The hazard classification system requires lasers to have attached warning labels showing: the class number, a warning "signal word" and warning information. They must also contain a "sunburst" laser symbol with its long tail (see left), as this is a unique identifier for lasers.

This symbol is also required on all entrance warning signs to controlled area(s). Taking action based on these warnings will help protect against laser radiation injury.

Hair removal lasers are **Class 3b** and **Class 4.** Exposure is always an immediate and serious threat to eyes from both mirror-like and diffuse reflections. **Class 3b** and **4** lasers emit beams that can damage the retina of the eye in less time than it takes to blink. Infrared laser beams are invisible and can damage the eye without giving a visible warning such as brightness. In addition to eye injuries all **Class 4** lasers and focused **Class 3b** lasers present a hazard to skin.

g) Warning Label Styles

Examples of warning labels for lasers are shown below. The DANGER label is also acceptable for posting as a warning sign laser treatment controlled area in a facility once the appropriate wording is added and the sign is enlarged. These are taken from ANSI Z136.1-2000. *WorkSafeBC inspectors will specify the use of signs from the most up-to-date version of the ANSI standard as a legal requirement, i.e. those from ANSI Z136.1-2000.* The following are examples of laser labels and posting signs found on various laser Classes.

- **Class 2** laser warning label is always **CAUTION** followed by wording explaining how to protect oneself and a description of the specific laser that is in use: **"LASER RADIATION DO NOT STARE INTO BEAM"** and/or **"AVOID LONG-TERM VIEWING OF DIRECT LASER RADIATION"**
- **Class 3a** laser warning label can be either a **CAUTION** sign and/or a **DANGER** sign depending upon the specific laser. In addition there is wording explaining how to protect oneself for example: **"LASER RADIATION DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS"** or **"LASER RADIATION AVOID DIRECT EYE EXPOSURE"**

Hair removal lasers are always class 3b or class 4!

- **Class 3b** laser warning is always "**DANGER**" followed by the wording explaining how to protect oneself and a description of the specific laser that is in use for example: **"INVISIBLE LASER RADIATION AVOID DIRECT EXPOSURE"**

- **Class 4** laser warning is always **DANGER** followed by the wording explaining how to protect oneself and a description of the specific laser that is in use, for example: **"INVISIBLE LASER RADIATION AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION"**

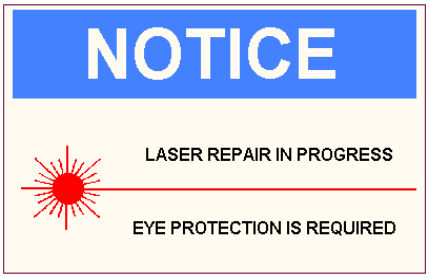
h) Controlled Area

Lasers used by laser hair removal facilities are either **Class 3b or Class 4** lasers, since they emit visible and/or invisible infrared radiation which is harmful to eyes and skin, and can ignite fires in combustible materials. Care must be taken to ensure that the patient/client is appropriately protected before exposure and that the laser beam contacts only those areas being treated and for the appropriate amount of time. The optimum method for ensuring protection against stray direct, reflected or scattered laser radiation is to provide a *'laser treatment controlled area'* within the facility. This is an area that the laser standards describe as a Nominal Hazard Zone or NHZ (see 'Safety Zones' above and ANSI Z136.1-2000 3.4.1).

A laser treatment controlled area is simply an area that is appropriately enclosed so that laser radiation which is above the maximum permissible exposure does not inadvertently escape the area to injure unsuspecting persons or ignite materials. The occupancy and activity of those within this area are subject to supervision for the purpose of protection against all hazards associated with the use of the laser(s). This laser treatment area is usually a separate room with a closeable door and covered windows. Appropriate warning signs such as those shown below **MUST** be identified at all entrances to the area. The entry warning sign(s) can be a large version of the laser warning label that is attached to the laser (i.e. as shown below). Note that the sign is the ANSI standard recommended sign and is the style required when interpreting the requirement of the WorkSafeBC, Occupational Health & Safety Regulation.

Other additional wording and style recommended in the ANSI standard for entrance signs are:

- "Eye Protection is Required"
- "Laser Protective Eyewear Required"
- "Invisible Laser Radiation"
- "Knock Before Entering"
- "Restricted Area"



Since the infrared radiation used by hair removal lasers can travel through window glass and other openings, and can be reflected off mirrors and other shiny surfaces, these should be covered or restricted to prevent the radiation leaving the treatment room i.e. stays inside the laser controlled area. It follows that only trained and/or authorized persons with protective equipment are allowed to enter or be in the treatment room. Similarly, reflective items must not be used or worn by persons in this area. Although access to the laser treatment area must be restricted, it must not prohibit rapid entry and exit to deal with any emergency situations.

i) Training

Those using or working in the vicinity of class 3b or 4 lasers **must** have received detailed laser safety training appropriate for the safe use of their laser. All training activities shall be documented and retained on file.

j) Medical Surveillance

The only medical examinations required for all personnel prior to participation in laser work are a pre-assignment eye examination and an examination following suspected laser injury. 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.

Laser personnel require a baseline eye examination and *Incidental personnel* need only have an eye examination for visual acuity upon termination of the person's responsibilities with the laser. At present, no chronic health problems have been linked to working with lasers. Also, most uses of lasers do not result in chronic exposure of employees to even low levels of laser radiation.

For further information on eye examinations see ANSI Z136.1-2000, Appendix E2.

k) Fire Hazard Assessment

Class 4 laser beams represent a potential fire hazard if flammable or combustible materials are exposed to an irradiance exceeding 10 W/cm^2 or beam powers exceeding 0.5 W. It is also possible that some class 3 lasers could initiate fires.

However 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 the above information to determine whether a laser beam could be a fire hazard, simply calculate the number of joules that can be delivered in one second. This value is equal to the number of watts and can be compared with the 0.5 W level. If the beam area (cm^2) is known, then divide the number of watts by the area in cm^2 to get the irradiance (W/cm^2) and compare this with the value 10 W/cm^2.

Example:

If a laser delivers 2 J in 100 ms (or 0.1 s) in a beam area of 1 cm^2 area, it is equivalent to 2J/0.1s or 20 J/s = 20 W. Over an area of 1 cm^2, this equals $20W/cm^2$. This could initiate a fire in an appropriate combustible material if exposed.

l) Toxic Gases, Vapors & Viruses

Studies have shown that when Class 4 lasers & high-power focused Class 3b lasers are utilized for treating human tissues, then toxic gases, vapors & 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. To avoid the inhalation of these aerosols, appropriate air evacuation systems must be used. The required system is determined by the laser beam power (i.e. irradiance – W/cm^2)

For irradiances:

- Less than 1 kW/cm^2 (potential for light odors) - adequate building ventilation may be satisfactory.
- 1 - 10,000 kW/cm^2 (air contaminants associated with noxious odors) – use localized exhaust ventilation, limited worker access, training and education
- Greater than 10,000 kW/cm^2 (air contaminants associated with chronic effects) - process isolation, localized exhaust ventilation, limited worker access, training and education.

Airborne contaminants need to be captured as near as practical to the point of production (e.g. within 2- 5 cm of treatment area on patient) 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.

According to ANSI Z136.3-2005, section 7.4.2.2. - Respiratory Protection: "At present there is no suitable half-mask respirator (fitting over nose and mouth) used for the specific purpose of excluding all laser generated plume particulates, bacteria, viruses, gases, vapors, or other irritants. **Surgical mask are not designed to provide protection from plume contents.** Surgical mask are intended to protect the patient from the contaminated nasal or oral droplets of anyone with access to the surgical field." Therefore, local exhaust ventilation techniques should serve as the first line of protection from occupational exposure.

m) Other Hazards

Adequate and effective means to prevent the spread of infection shall be taken utilizing standard precautions for cleaning and disinfection. See Appendix A.

Other types of hazards which this guideline does not deal with may also exist such as electrical hazards, electromagnetic interference and room design/layout.

n) Documentation and Records

Owners need to keep records and have them available on site. Required records include:

- Laser operator qualifications
- Laser operator educational and safety training
- Standard Operating Procedures (SOP) for laser use.
- Safety Checklist
  - Setup of laser controlled area with signs, window barriers, etc.
  - Confirmation of eyewear type and availability
  - Client/patient protection
  - Safety equipment such as smoke evacuator, fire safety equipment, etc.
- Protective eyewear information
- Previous safety inspections
- Staff Medical Examination results
- Reports of accidents or incidents
- A record for each client showing the client's name, address, and dates of treatment along with type of treatment, etc.
- All records must be typed or legibly written in ink and retained.

Appendices follow this page. Appendix A refers to the Personal Service Establishments Regulation against which a laser clinic may be assessed by Public Health Officials. 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 short questionnaire which each laser operator and those employees who from time to time work inside the laser treatment room or laser treatment controlled area while the laser operating, should complete in order to evaluate their knowledge of laser safety.

Editor's note, September 2011: The Personal Service Establishments Regulation has been repealed and is now covered under the Regulated Activities Regulation.

Appendix A:
Guidelines for Personal Service Establishments (PSEs)

In addition to the laser related guidelines above, a laser facility may be assessed by public health officials in accordance with the *PERSONAL SERVICE ESTABLISHMENTS REGULATION* **(**BC Reg. 202/83, Filed June 17, 1983). This Regulation states that:

> "Operators of personal services establishments in British Columbia must comply with the Personal Services Establishment Regulation … and must maintain and operate their establishments in a way that prevents health hazards from occurring."

It contains six helpful sections of information to assist the laser owner and operator: 1. Introduction, 2. Premises and General Operation, 3. Equipment, 4. Infection Control & Sterilization & Disinfection, 5. Other Materials, and 6. Personnel.

Note: the Guidelines are in the process of being updated and will be released soon.

For a copy of the Personal Services Establishments (PSE) regulation see
http://www.health.gov.bc.ca/protect/ehp_pse.html

Editor's note, September 2011: The Personal Service Establishments Regulation has been repealed and is now covered under the Regulated Activities Regulation, which will be posted shortly.

Section 4: Infection Control, Sterilization & Disinfection of the PSE must be reviewed for information on cleaning and sanitizing procedures for laser tips, skin preparation and eye goggles. A determination will have to be made between:

> **Critical Items:** are defined as those items which puncture the skin, or enter sterile tissue e.g. body piercing instruments, tattooing needles, and razors. Critical Items must be purchased as sterile and properly disposed of after a single use, or sterilized between each use as per Appendix A - Methods of Sterilization and Disinfection of the Personal Services Establishments Regulation.
>
> **Semi-Critical Items:** Defined as those items which come in contact with the mucous membranes, e.g. eyes, ears, nose, mouth or any other body orifices, or with skin that is not intact, e.g. instruments used for acne treatment. These items must be purchased as sterile and disposed of after a single use, or treated using high level disinfection after each use.
>
> **Non-Critical Items:** Defined as those items which come in contact with intact skin but not with mucous membranes, e.g. suntan bed surfaces. Non-Critical Items must be purchased as sterile and disposed of after single use, or treated using low level disinfection. For specifics on sterilization and disinfection refer to Appendix A - Methods of Sterilization and Disinfection of the Personal Services Establishments Regulation.

Appendix B:
Laser Hair Removal Devices/Facilities Inspection Form

(Available at: http://www.bccdc.ca/NR/rdonlyres/91EC5F3D-E545-4916-9F2C-E460A942992C/0/LaserHairRemovalCheckList.pdf)

Date: _____

Location: _____

Inspector: _____

Laser Treatment Controlled Area

1. Is the laser located in a separate room with a closeable door? Y☐ N☐
2. Does this room have laser warning signs posted at the entries? Y☐ N☐
3. Are transparent windows and other openings covered? Y☐ N☐
4. Are only trained & authorized persons with personal protective equipment allowed in the treatment area? Y☐ N☐
5. Persons **must not** wear reflective items or uncovered jewelry in the treatment area. Y☐ N☐
6. Some Class 4 laser procedures are capable of releasing toxic gases, vapors & viruses. Is there smoke and smell removal and adequate air evacuation/filtering? Y☐ N☐

Protective Equipment

7. Are persons in the treatment area wearing protective eyewear when the laser is on? Y☐ N☐
8. Is client protective eyewear designed to stop laser radiation coming from all directions? Y☐ N☐
9. Is operator protective eyewear:
   a) labeled with the **same** wavelength as the laser operates at? Y☐ N☐
   b) labeled with an OD (optical density) as recommended by the laser manufacturer (normally 5 and higher)? Y☐ N☐

Laser Device

10. Is an emergency shutoff switch available to the operator or assistant? Y☐ N☐
11. Can the laser be disabled when not in use, by removal of a key or coded access, etc? Y☐ N☐
12. Is the switch that controls client exposure guarded or else require two simultaneous actions, such as foot pedal depression **and** hand trigger, in order to operate? Y☐ N☐

Procedures

13. Laser safety training **must** be provided for those using or working in the presence of Class 3b or 4 lasers. Has the operator(s) received laser safety training? Y☐ N☐
14. Do operators follow standard operating procedures? Y☐ N☐
15. Does the operator remove their hand/foot from the trigger switch placing the laser on standby, when conversing, changing position, etc? Y☐ N☐

Eye Examinations

16. Have personnel working with Class 3b and 4 laser radiation within the laser treatment controlled area had a baseline eye examination? Y☐ N☐

Appendix C: Laser Operator Knowledge Questionnaire

Name: _____ Date completed: _____

This questionnaire may be used to ascertain an indication of laser safety knowledge. It is recommended that laser operators not be permitted to work with the laser until they can answer all of these questions correctly.

1. Laser operators need to be trained in laser safety and knowledgeable of local regulations. (see page 7) **T** ☐ **F** ☐

2. What parts of the body are at greatest risk from laser radiation? (see page 9 & 10) _____

3. Only the client and laser operator need to wear laser eye protection in the treatment room. (see page 14) **T** ☐ **F** ☐

4. When infrared laser radiation from hair removal lasers passes into the eye and is focused on the retina, the energy per unit area on the retina increases by. (see page 9)
   - ☐ a) 1 to 2 times
   - ☐ b) 5 to 10 times
   - ☐ c) 20 to 25 times
   - ☐ d) 10,000 to 100,000 times

5. Who is responsible for implementing a laser safety program? (see page 7) _____

6. A higher OD number provides more protection than a lower OD number. (see page 14) **T** ☐ **F** ☐

7. When the wavelength number printed on the eyewear is the same as the wavelength of infrared radiation emitted by the laser, it will protect eyes. (see page 13) **T** ☐ **F** ☐

8. Protective eyewear that is cracked or loose is okay to wear. (see page 15) **T** ☐ **F** ☐

9. A laser treatment room is enclosed and access into the room is only restricted for the sake of privacy of the client undergoing treatment. (see page 19) **T** ☐ **F** ☐

10. The laser treatment area is a separate room with a door at the entrance to the room that only needs to have an "Occupied" sign on the door. (see page 19 & 20) **T** ☐ **F** ☐

11. What three different factors related to eyewear are seventy percent (70%) of all laser accidents related to? (see page 12)
    1. _____
    2. _____
    3. _____