

LASER SAFETY: RISKS, HAZARDS, AND CONTROL MEASURES

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Now that laser technology has emerged from hospital operating rooms, and has become available to office practices, clinics, and private enterprises, the burden of responsibility for safety has shifted from hospital staff to the individual user, often without benefit of appropriate or adequate resources.

What remains, regardless of the practice site, application, or system in use, is the constant goal of establishing and maintaining a laser safe environment for the patient, the staff, and the user, at all times. This should be the goal of all who are involved with the sale, purchase, application, and management of all medical laser systems - under all circumstances.

Laser safety is EVERYONE'S concern! A laser is as safe or as hazardous as the user - and that user's knowledge and skill, defines how well laser safety is managed.

Of all hazards, *complacency* is the most dangerous, and it is imperative to develop a risk management perspective on laser safety. Proper safety management requires a fourfold approach including: knowledge of standards, identification of hazards and risks, implementation of appropriate control measures, and consistent program audit to demonstrate quality assurance.

Risk Management Step One: Knowledge of Standards, Regulations, and Practice Guidelines

International standards are available through the International Electrotechnical Commission (IEC), documents 60601, 60825, and 60825-Part 8. These standards are the global benchmarks for laser safety, and include normative and informative guidance for manufacturers, professional clinicians, and administrators of laser use facilities. They are used as the foundation for most country's national standards. In some countries (USA, Australia, Canada), these standards are harmonized with the national standards, and are mandated as the basis for all additional regulations and professional recommended practices.

Standards are non-regulatory, but serve as consensus documents for best practice. As such, they are often considered as the usual and customary practice in a

given area, and are the basis for medical-legal decisions in cases of patient or staff injury, accident, or untoward occurrence. This serves as a strong motivation for laser users to gain knowledge of the established rules for safety, and mandate compliance with them.

In Australia, the AS/NZ 2211(Laser Safety), and the 4173, (Guide to the Safe Use of Lasers in Healthcare), have become the expected standard for laser safety in healthcare, and though not regulatory, have taken on the impact of regulation through its wide acceptance. It has been incorporated into state regulations, such as those adopted in Tasmania, Western Australia, and in Queensland under the Radiation Safety Act 1999. National licensure requirements, based on international (IEC) standards, is currently being considered, and if initiated, every user of Class 3b, or Class 4 medical laser systems, and Intense Pulsed Light Systems, will need to register for a license with validation that they have met specific criteria for education and training.

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In the United States, a number of states have regulations requiring registration of laser systems, and proof of administrative controls as defined in the American National Standard (ANSI Z136.3). ANSI standards are the basis for laser safety requirements as determined by the Occupational Safety and Health Administration (OSHA) which is a governmental branch of the Department of Labor, and carries the authority to issue citations and/or legal action, for non-compliance. ANSI standards are also used as the basis for evaluation of safe practice with lasers, by The Joint Commission, (formerly known as JCAHO) which awards accreditation of healthcare facilities, and ensuing government funding for Medicare patients.

In Europe, the guideline is the IEC-60825 document which offers non-regulatory guidance for identification and control of major hazards associated with medical lasers. The companion document 60825-Part 8, contains more informative sections with expanded descriptive procedures focused on laser users, and is a helpful outline for policy development, and safety management.

Most laser standards focus on the theoretical basis for safety, and include a mathematical approach. Laser users should have a working knowledge of the technical material, including exposure limits, nominal ocular hazard area, optical density levels, maximum permissible exposure, classifications, etc.. This material is not usually included in medical education programs, nor is it necessary for clinicians to know how to perform the calculations, however, they should be aware of the concepts and their implications on policy and procedure. Should technical assessments become necessary, such as in cases of accident investigation, or establishment of a research project, clinicians can utilize the services of medical physicist, a laser protection advisor (LPA), a laser safety officer (LSO), or a company specializing in laser safety.

Risk Management Step Two: Identification of Hazards and Risks

In order to assess potential hazards and risk of exposure to hazardous levels of laser emission, it is necessary for both users and operators to have a thorough understanding of laser science. This is not strictly physics, though many educational programs refer to it as such. The goal of laser science education is to provide an in depth and clinically relevant understanding of both the biological interactions and results of apply-

ing laser light to a variety of tissues, and the appropriate means of delivering and controlling the energy to obtain desired outcomes.

Many clinicians and nurses who choose to work with lasers, without a solid foundation in this science, are unable to perform risk assessment on a daily operational basis, and are therefore, jeopardizing the safety of everyone involved, including that of the patient.

Therefore, everyone who may work within a laser treatment room, must have that knowledge, including doctors, staff, assistants, students, and observers. Safety is only ensured, when everyone has appropriate training, responsibility, and understanding of what occurs when a laser is applied to a patient. And since not all lasers have the same hazards, this understanding must be specific to the user's equipment and the intended clinical application.

Laser science includes:

1. Properties of laser light
2. Characteristics of each laser wavelength
3. Absorbing chromophores of each wavelength (selective photothermolysis)
4. Dosimetry (power, power density, pulse parameters, fluence, energy density, etc.)
5. Spot size, delivery systems, instrumentation
6. Application (medical and surgical) techniques

Once these attributes are well understood, the clinician can anticipate potential hazards. Hazards are all of those potentially dangerous conditions that are associated with an unanticipated interaction or exposure of tissues or materials, to laser energy. These include both direct beam hazards such as tissue burns, eye damage, endotracheal tube fire, drape fire, and explosion of gases, or non-beam hazards (those that are secondary to the actual beam interaction) such as laser generated airborne contaminants (surgical plume), electrical damage, toxic dyes, and system failures.

Each wavelength, system, delivery device, and application, must be assessed for associated hazards, since they are all different, and will require different training, credentialing, policies and procedures.

Once the hazards are identified, risk must be assessed. Risk is often defined as the level of potential for exposure to, or injury resulting from, exposure to identified hazards. Risk levels may differ for each member of the laser team, and for each person involved with the laser

equipment. The level of risk may also vary with clinical applications of a system, depending on the delivery device, power parameters, and target tissues, as well as the levels of education, training, and experience of both operators and users.

While everyone in the laser treatment room has the risk of eye exposure when working with a Class 3b or Class 4 healthcare laser system, and damage to various structures in the eye depending on wavelength of the laser if they are unprotected, there are going to be varied risks for physician, assistant, nurse practitioner, patient, patient support person, technician, office manager, laser safety officer, scrub nurse, sales representative, biomedical engineer, and manager. Therefore, the LSO must understand each person's level of interaction with the system, and their job responsibilities, before developing appropriate policies and procedures.

For example; a Photothermal wavelength of 10,600 nm (Carbon Dioxide), creates enough heat to cause flammability hazards. Users of such a laser would need to follow procedures to prevent fire, including eliminating dry materials or alcohol containing solutions from the target zone, correctly placing an appropriate fire extinguisher, having an open container of water available, preventing specular reflections, observing the path of the beam for interference of any kind, evacuating surgical plume, and removing free sources of oxygen or other flammable gases from the field.

Another example; a low level laser emitting at 780 nm and delivered through a single point handpiece, might not need extensive safety controls, beyond those hazards such as electrical, controlled access, and the need for ocular protection. The need for policies for plume, fiberoptic management, or flammability of materials and solutions, would have to be assessed by the LSO.

Should a laser, based on its science, be assessed to have minimal hazards, the user may modify standards and procedures to reflect that individual level of hazard. This is the reason it is so important for users to write their own facility policies and procedures, and not simply adopt generic documents obtained from manufacturers, course materials, or other institutions. An example of how the same laser used in two different practice settings, may require different safety measures:

- Setting A - a suite on the fifth floor of an office building overlooking a parkland, sets up a Green diode

laser, emitting at 532 nm. Window barriers do not have to be installed to cover the windows on the outside facing wall, because the laser beam, even if transmitted accidentally through the window, would only reach the trees, and cannot harm anyone or anything in its path, or at its impact site.

- Setting B - a suite on the ground floor of that same office building, with a window facing directly onto a footpath and car parking spaces, sets up the same 532 nm laser. In this case, appropriate window coverings must be installed to prevent accidental transmission of the beam through the windows, to protect against injuries due to accidental transmission of the beam to those people walking past the window, or getting in and out of their cars. The specifications for appropriate window coverings will be addressed further on in this text.

Clinically relevant risk assessment provides safety in a sensible, and appropriate manner, often at lower cost to the user, and always, at greater levels of protection for all concerned.

Risk Management Step Three: Implementation of Control Measures Establishing Control Measures

Control measures are the actions taken by healthcare personnel, to prevent injury or exposure to identified hazards. Once hazard based risks are identified, and the potential of exposure to those risks assessed, the user can develop and implement control measures. These measures translate into policies and procedures, that have clear statements of scope (who does the policy affect), rationale (why is it necessary), who is responsible for implementation and enforcement, and methods for on-going monitoring.

Each policy should be updated on an annual basis, when new systems, accessories, or clinical applications are introduced, and whenever a new regulation or standard is published. It is the responsibility of the LSO to enforce compliance with all control measures.

Once control measures are written and approved by the facility, inservice should be provided to all employees. Copies of all policies and procedures should be distributed, so that everyone can read them. Some facilities require each medical, nursing, and technical staff member, to sign a form stating that they have received and read the procedure manual, as a supple-

ment to their documentation of safety training, credentialing, and certification.

There are three kinds of controls measures:

1. Engineering controls which are inbuilt safety features supplied by the manufacturer in compliance with IEC and FDA (CDRH) standards. These include but are not limited to: guarded footswitch, audible and visible emission indicators, stand-by control, emergency off control, housing interlocks, and beam attenuators.

2. Procedural controls, which are policies and procedures in healthcare facilities. These are operational activities, specific to equipment and practice, and include but are not limited to: ocular protection, flammability hazard prevention, controlled access, management of plume, control of electrical hazards, and control of the delivery system and beam emissions.

3. Administrative controls are the infrastructure of the laser safety program. These must be in place before the laser can be used, and include: appointment of a Laser Safety Officer (LSO), organization of a safety committee (LSC), development of documentation tools, education and training of all personnel, compliance with Occupational Health and Safety rules, development of a formal audit and technical management plan. These are the control measures most often reviewed by outside inspection agencies such as OSHA, state health departments, or TJC.

A written safety plan should be completed, and kept in a book at the laser use site. This should include all policies and procedures, safety set-up checklists, procedure log sheets, verification of education and training of all personnel, credentials roster, documentation forms, audit reports, and materials supplied by the manufacturer regarding operation of the equipment and accessory devices. Everyone involved should become familiar with this book, as it is the medical-legal documentation of safe practices.

The Laser Safety Officer

The LSO is the person who has **responsibility** for the management of risk, and the **authority** to ensure compliance with all applicable standards and rules. This person should be competent to assess all systems, and validate the knowledge and skills of all personnel involved in the laser practice.

The LSO can be a risk manager, an Occupational

health and safety officer, an infection control officer, a practice manager, an outside safety consultant, a biomedical engineer, a physician, a nurse, or other properly qualified person.

The LSO is the contact person and spokesperson for the laser program, should there be an audit, a medical-legal situation, a compliance inspection, or questions from accrediting bodies.

There must be only one LSO but in his or her absence from the facility during any use of the laser, there should be someone designated as a deputy LSO, (DLSO) who has equal levels of authority, responsibility, and knowledge. The duties of the LSO will vary depending on the size and scope of the laser facility, however, standards do require the LSO to be responsible for:

1. Advising facility Administration
2. Hazard evaluation (determination of the NOHA)
3. Effecting appropriate control measures
4. Approving all policies and procedures
5. Approving and maintaining all protective equipment
6. Approval of all signage and labels
7. Authorization of laser technicians and service providers
8. Ensuring that all staff is properly educated and trained
9. Investigating all accidents and incidents
10. Ensuring that periodic audit is conducted, documented, and followed-up with remedial actions.

The LSO is often responsible for technology assessment, and advising users on potential laser purchases, as well as on compliance with standards and regulations. In some situations, especially in a private practice, the physician who owns and runs the practice or clinic, seems to be the likely candidate for LSO. Careful analysis of the duties of the LSO must be made before making this decision, remembering that if the laser is to be used by several clinicians, the LSO must be available during use, and must be responsible for safety regardless of who is operating the system. This may determine who is selected for the position.

It can often be a better decision to assign a permanent office professional, such as the nurse or physician's assistant, as he or she will be on site all the time, and can work with all the laser users in the practice. There are no rules as to who may serve as LSO, only that the person identified be appropriately trained and empow-

ered to establish procedures, and to enforce compliance.

Compliance with Occupational Health and Safety is an important component of a laser safety program. There are no specific OCH&S guidelines, for assessing a facility's level of compliance. Assessments are usually made under a broad, generic, general duty clause, which says, in summary that there is a shared duty of care between employer and employee for establishing and maintaining a safe working environment, kept free of known hazards.

The employer has a duty of care to provide the proper safety equipment, appropriate education and training, and a work environment free of known and potential risks and hazards. The employee has a duty of care to access the training, use the personal protective equipment, and to follow safe work practices at all times.

Though frequently seen as an adversary, an OH&S officer, can be a strong advocate for safety, if viewed as a professional partner. This resource person can be a member of the laser safety team, assisting the LSO with audit, compliance, education, and staff motivation. This approach can result in fewer risks of injury for patient and staff, less potential for legal entanglement, and overall lower costs for the program. Remember, even though it may seem that the cost of laser safety training is high, it is always far less than the cost of one injury.

Procedural Control Measures

Controlling hazards in the laser treatment room depends on: controlled access to the room and to the equipment, proper use of personal protective devices, monitoring testing and operations of the laser and its delivery systems, appropriate applications, and vigilance on the part of each laser team member.

Controlled Access

Controlled access is based on the identification of the nominal ocular hazard area (NOHA), or in American Standards, called the Nominal Hazard Zone (NHZ). This is the area within which the level of exposure to laser radiation, can exceed the maximum permissible exposure (MPE) levels. The MPE is a mathematical calculation based on variables including; wavelength, power, distance, and time of exposure, that results in a length of time (usually milliseconds) an unprotected eye can be exposed to laser radiation, without produc-

ing injury. The NOHA is a mathematical calculation, resulting in an area around the laser, within which laser hazards may exist, and protective devices are required.

These values should be readily available from the laser manufacturer's documentation, they can be calculated by the LSO, or the LSO can designate the entire room as the controlled area. If the entire room is so designated, everyone in the room must follow all safety procedures at all times, including wearing of protective eyewear.

Standards indicate procedures for maintaining a controlled access area. Some of the key points are:

1. Regulation warning signs (must comply with specific countries' standards), posted visibly, at eye level, on each entryway into the NOHA and removed when use of the laser is completed.
2. Appropriate protective eyewear for laser in use, is placed with the signs at each entryway. These are posted for staff to use in case of emergency entry into the laser room, and are removed from the entryways only at conclusion of the procedure.
3. Windows are covered with blinds, shades or other non-flammable barriers that reduce transmission of the beam to acceptable levels below the MPE for laser wavelengths that can penetrate glass (long wavelengths that absorb in water do not need window barrier protection). These should be labeled according to their levels of protection, to comply with IEC standards.
4. Everyone within the NOHA is authorized by the LSO.
5. Doors are kept closed, but never locked at all times during laser use.

Control of access to equipment is accomplished by two procedures: key storage away from the console, and positioning a dedicated operator at the control panel whenever the laser is in use. When an individual is operating (activating the equipment) and using (delivering the energy to the target tissue) the laser without assistants present, he or she is responsible for controlling access to all components of the device, and to the NOHA.

Protective eyewear, corresponding to the laser in use, should be placed with each door sign posted at NOHA entryways, to be used by anyone who must enter the laser room in an emergency. Signs should only be

posted when the laser is in actual use, and removed or covered when the laser is turned off and key removed. These are indicators to others in the facility that there is a potentially hazardous situation in the room, and safety procedures are in effect. If the sign is left up all the time, it loses its meaning, and staff tends to become casual about entering the room. For safety reasons, and for compliance with most fire codes, doors must not be locked or employ automatic interlocking systems, for any patient care area or room in which electrical equipment is used.

Windows and doors should be covered with barriers for all wavelengths that transmit through glass. The LSO must assess the facility to determine what type of coverings are required, and the options vary from black barrier curtains, to purpose built window films marked with the actual OD of protection. The criteria for selection of window covers include non-flammability, infection control guidelines, and ability of the material to reduce the laser transmission below the MPE.

The control panel of the laser should never be left activated and unattended. If the operator has to leave the room, the laser should be turned off, and the key removed and either stored, or taken with the operator or LSO. If the operator sets up and tests the laser, but then must wait while the patient comes into the room, the laser must be kept in stand-by. This mode deactivates the shutter, and prevents accidental misfiring. The only time the laser should be turned to the ready mode, is when the clinician is aimed at target tissue, and is ready to deliver the energy to the target.

Any properly educated and trained individual can operate a laser under the supervision of either a physician or a nurse. In an operating theatre, a technician operating a laser should be supervised by a licensed medical professional. In private practice, the laser user (clinician) frequently functions as the supervisor. No untrained individual should ever be allowed to operate a laser under any circumstance.

In the case of rental lasers, the renter and the staff must be educated as to the laser and its delivery systems, accessory equipment, mechanism of action, all safety measures, and minor troubleshooting. Clinicians should insist on comprehensive staff training in order to meet standards, but also, because regardless of what equipment is being used, or who owns the equipment, the professional staff is still responsible for patient advocacy, management and safety.

The footswitch for activating the laser must be given only to the credentialed laser user. Position all other footswitch activated devices away from the laser and clearly indicate to the user, which pedal is for the laser, and which ones are for other devices. Accidental activation of the pedal is one of the most commonly reported accidents.

Ocular Hazards and Protection

Class 3b and Class 4 lasers, have the potential to damage the eye through both direct and reflected impact, and should NEVER be operated without first assessing the need for proper protective eyewear.

The classification of the laser is based on whether or not the Maximum Permissible Emission (MPE) is longer or shorter than the human aversion response. MPE is a calculation that determines how long an unprotected eye can be exposed to a laser beam before injury occurs. The aversion response is that autonomic response (within .25 seconds) of the eye blinking and moving away from an intense light.

The lower classifications (1, 2) have extended MPE measurements, and do not require protective eyewear, since the human eye will avert from the bright light long before the beam can injure the unprotected eye.

In the case of a higher classification (3b-4) the MPE is shorter than the aversion response, and therefore, protective eyewear must be worn at all times during laser activation.

Safety precautions, including eye protection, flammability, reflection, and administrative control measures, are determined by the classification of the laser, which must be included by the manufacturer on the device and aperture labels. Current classifications have been adopted by the IEC as follows:

Class 1: safe under every conceivable condition of use
1M: safe for viewing without optical aids, but potentially hazardous with magnification aids (microscopes, loupes, binoculars, etc.)

Class 2: Visible wavelengths (400-700 nm) safe if viewed for less than 0.25 seconds
2M: Visible wavelengths (400-700 nm) not safe with optical viewing aids

Class 3R: Marginally unsafe for intrabeam viewing of beams with diameters >7 mm

Class 3B: Unsafe for intrabeam viewing, causing skin and eye injury from direct but not necessarily diffuse energy

Class 4: High power causing skin and eye injury from direct and reflected energy

Low power lasers (e.g. those used in physiotherapy), are usually lower classifications, but can also be Class 3b and Class 4, and the LSO must determine what control measures are appropriate, for each individual system.

Ocular Hazards

Levels of ocular injury are determined by the interaction with the tissue, and absorption chromophores that are present in the structures that are exposed. Delivery systems, power and energy density, and clinical application techniques also contribute to the type and severity of damage that can occur.

Long wavelengths (CO₂ and Er:YAG) are absorbed by water in the tissues, and therefore, can absorb at the tear layer covering the cornea. As the water is vapourised away, the beam interacts with the tissues of the cornea to cause burns. This is not permanent but can be painful and temporarily disabling. It can be particularly hazardous should it occur intraoperatively, when the staff and patient are at risk of injury should the user lose control of the delivery system due to a "flash blinding" type of injury.

Mid range infrared (Ho:YAG) can partially absorb, and yet partially transmit through water, and can cause both corneal and injury to the lens, but not to the retina.

Short wavelengths (near infrared through visible range), penetrate through water, and can transmit through all anterior structures of the eye, absorbing in the haemoglobin in the retina, causing permanent damage to central vision. Furthermore, the human lens acts to cause convergence of stray, low power, reflected or scattered beam emissions, which can increase power density to a significant level of exposure. This is why regardless of delivery system (including fibreoptics used in endoscopic instruments) protective eyewear must be worn.

Protective eyewear specifically designated for the wavelength and classification of the laser in use should

be worn in addition to other controls that may be in place to ensure that personnel will not be exposed to laser energy in excess of the MPE.

This means that everyone in a laser treatment room, within the designated controlled area, must wear appropriate protective eyewear at all times when a laser is in use. An exception to the rule is when the physician is working through a properly filtered microscope.

There is no such thing as an "eyesafe" Class 3b or Class 4 laser!!!

Criteria as follows should be used to select eyewear with emphasis on the fact that all eyewear must be approved by the LSO.

1. Permanent labels stating wavelength in nanometers
2. Permanent label stating the optical density (OD)
3. Side shield protection
4. Adequate visible light transmission
5. Resist shock, scratching, and front surface reflection
6. Have proper fit and be comfortable (no slippage)
7. Be free of damage to lenses or frames

This means that personnel should *NEVER* use splash glasses, prescription eyewear, face shields, solarium goggles, contact lenses, or any other devices not specifically designed, tested, and labeled, for laser safety use. Infection control goggles and prescription glasses do not meet the eyewear selection criteria, and are not tested for levels of laser protection.

If the LSO has determined the entire treatment room as the NOHA, then everyone in the room must wear eye protection having the same level of optical density, eliminating the use of observer glasses (low O.D. or marked "for observation only"). It is important that users wear glasses that will allow enough adequate visible light transmission (VLT).

Each individual should be responsible for examining their glasses before use, to verify the correct labels, and to assess whether or not the glasses are in proper condition. Look for scratches, cracks, or discolourations in the lenses, as well as loose connections or damage to the frame. If the lenses are discolored as a result of improper cleaning (alcohol can damage or degrade optics) or prolonged light exposure (photo-bleaching), the optical density will be less than expect-

ed, and the glasses will not provide proper protection.

Regardless of routine safety inspections by the LSO, or assurance by the laser company personnel, each individual user must ensure that the glasses he or she uses are the right ones, and that they are in safe condition, every time they are used.

During fibreoptic procedures, when the physician is working from the video monitor, safety glasses must still be worn. Fibre breakage is a known hazard, and can result in unanticipated transmission of laser energy in the room. Should that happen, the user and certainly staff may be exposed to laser radiation above the MPE.

Safety eyewear is the best method of providing patient eye protection. Straps or elastic bands should be in place to keep the goggles from slipping out of place when the patient moves or is repositioned. If unable to wear goggles, due to treatment in the periorbital area, metal corneal eye shields or tightly fitting peri-orbital goggles, should be used to prevent damage to the eye. Plastics may not withstand the impact of a laser, and most have not been properly tested for this type of use. Regardless of which commercial products are selected, be sure the manufacturer supplies applicable testing specifications.

This written material must include product tested with the wavelength and within the clinical parameters to be used. If the documentation is not available, do not use the product.

Remember that eye injury is completely preventable if everyone is properly trained, and uses proper eye protection.

Flammability and Reflection

The skin and other tissues of all patients and all personnel present in the laser room must be protected from unintended exposure to the laser beam.

Flammability is a potential laser hazard associated with most high power systems, but only rarely in the use of low power or diffuse beams. Many flammable products are used routinely in clinical procedures, and the LSO, as well as the everyone on the laser team, must continually assess products and devices in use in the laser target site, for compatibility with the beam, and potential hazards. These items may include: dry or non-

woven fabrics, plastic, rubber, solutions containing alcohol, tape removers, skin degreasers, foam devices, and skin preparation solutions.

Solutions that contain iodophors, (Hibiclens, Betadine, etc.) must be thoroughly dry before firing the laser, as heat can cause a chemical burn to the skin if it interacts with wet solution. All of these, as well as many other products, can become a fire hazard, when exposed to the heat produced by a high intensity laser beam.

Some drapes are non-flammable, but melt when heated. These may not cause flame, but can still present a severe hazard by containing heat and in some cases, flames, under the material, and as it melts. These non-woven fabrics must be smothered to extinguish them. Those facilities that use such drapes must read and follow the manufacturer's instructions for use and safe management.

An open basin of water should be available whenever a high powered laser is used. This serves to extinguish fires caused by ignition of fabric, sponges, etc., on the surgical field. The basin should be position near the laser operator.

A standard electrical equipment fire extinguisher should be conveniently installed near every laser room. Do not attach the device to the laser, the supply cart or the plume evacuator. It is best not to keep the fire extinguisher in back walls of the laser room, because should the room fill with smoke, it may not be possible for staff to find it. If it is positioned just outside the room, it is quickly available by someone either inside or outside the room. All medical, nursing, and technical staff should be inserviced and have current knowledge of how to operate the fire extinguisher.

When patients present for procedures at the hairline, the area must be washed free of any cosmetic preparation (hair spray, gels, mousse, nail polish, etc.) that may contain alcohol, or other flammable components. This should be a standard nursing procedure to be completed at the time of pre-treatment patient admission and preparation.

Eliminate all sources of oxygen, (nasal cannulas) from the laser target site. Flammable gases of any kind should be eliminated in the laser room.

Reflection is a hazard, when a laser beam comes into

contact with specular materials, instruments, or surfaces. The beam path extends from the aperture (point of emission from the delivery device) to the target, and must be kept free of obstruction and reflective products.

It is unlikely that a beam can cause a reflection hazard from a wall or cabinet, unless it is directed at that surface. The LSO should assess the potential for hazards from any metal cabinets, wall coverings or furniture in the laser treatment room, before recommending the costly removal or replacement of such equipment.

Specular surfaces may include: speculum blades, retractors, non-anodised black instruments, foil masks, or front surface glass lenses. Surface dulling (sandblasting, anodising, etching), *not* blackening or ebonising, will result in diffusion of the incident laser beam, and prevent reflection. If anodised instruments are not available, the exposed surfaces should be covered with wet drapes or towels to prevent reflection and unintended burn hazards. This is not dependent on colour as black can be as reflective as silver and diffusion will depend on the preparation of the surface.

All non-reflective coatings or processes should be tested by the LSO, to determine whether or not they are truly effective, before instruments are sent off to be resurfaced, or new ones purchased.

Plastic or rubber devices (teeth guards, mouth gags, tongue blades, etc.) should not be used in the beam path, unless they are tested for safety by the LSO with the intended laser wavelength, and at surgical levels of power intended to be used. If testing specifications are not available from the manufacturer, the LSO must conduct appropriate tests, and verify safety of such devices and instruments.

External, non-targeted tissues in the direct beam path should be draped with wet towels. Never use metal foil material, or any other device that may reflect the beam, or heat up upon laser impact.

Testing and Calibration

It is important to test fire and/or calibrate a laser prior to use, and this test must be documented in the operative records. Infrared lasers with coaxial visible aiming beams must be tested for alignment and for the presence of an appropriate beam mode, while fiberoptic lasers must be calibrated for adequate transmission

across the fiber, in order to ensure accurate and consistent power density delivery to tissue.

Infrared testing consists of firing the beam at a dampened tongue depressor, and watching to see that a burn appears in the same spot where the aiming beam is visible. The test must be done in the delivery system intended for use (handpiece, microscope, etc.) and the delivery system must be held at right angles to the target in order to allow for assessment of the beam mode. Beam mode must be TEM00 (fundamental mode) indicated by a clean circle without distortion. Mode is critical to being able to maintain power density in tissue, and therefore resulting clinical effects.

Testing should be done before the first patient of the day, and then repeated if the laser is moved or if the delivery system is changed. The nurse or operator can test, however, should there be a question of suitability, the user must make the decision as to whether or not the laser beam is appropriate for use on the patient.

Electrical Hazards

Lasers are electrical devices, and should be treated with the same caution as any other electrical equipment. This may be overlooked by individual users, especially those using hand held or small, mobile devices. It must be remembered that all electrical safety procedures should be followed, and an occupational health and safety plan for response to fire, should be in place and included in staff education programs.

The laser operator should examine the unit while setting up and testing, to be sure that all electrical cords, plugs, chargers, and connections are intact and in safe working condition.

Airborne Contaminants

As with all potential hazards, airborne contaminants are associated with only certain wavelengths and applications, and the LSO must evaluate this for each system and use, providing appropriate protection as needed.

This hazard is not present when using low power lasers.

Research has proven that thermal disruption of viable human cells results in the release of carbon particles, virus, bacteria, DNA, and over 41 toxic gases. These

hazardous particulates are found in all surgical plume, regardless of the energy source used (laser, ESU, Argon Beam Coagulator, Ultrasonics) in similar distribution patterns, and in all types of surgical procedures.

This means that mutagenic material, aerosolised blood, blood borne pathogens, and known hazardous gases such as benzene, formaldehyde, and acrolein, are forcefully ejected when the cell disrupts, and become airborne in the steam created by heating of intracellular water.

There is a global trend towards eliminating the hazards of plume from our daily lives. The main focus has been on public smoking in confined areas, such as airplanes, restaurants, offices, hotels and other public places. The hazards contained in cigarette smoke are well documented and governments around the world, such as America, Canada, United Kingdom, Australia, New Zealand, Germany, and Singapore, have taken action. It should be understood that surgical plume contains all of these same hazardous materials, as well as the organic materials released from human tissue during vaporisation, including HIV, HPV, and HBC as well as carbon which is a known carcinogen.

Surgical plume is more than an inconvenience, and must be treated as an occupational hazard with a high level of risk. Effective removal results from both proper filtration equipment, and good work practices, including: use of appropriate capture devices (handheld, ESU pencil sheath, laparoscopic system, etc.), positioning the capture device not further than 2 cm from the point of evolution of the plume, closed loop systems for laparoscopy, in-line filters for wall suction, patient protection during airway procedures, and evacuation systems known as local exhaust ventilation systems (LEVs).

Plume evacuation systems should be selected after careful evaluation of need and options available, however, all systems must meet international filtration specifications. Filters must remove particulates to 0.1 micron, (mean average diameter of viral particulates), and should be rated to 99.999% efficiency. This is known as an ULPA (Ultra Low Particulate Air Filter) filter required for capture of the viral particulates in the plume. Filters should have a filter life monitor, indicating when to change the filters.

HEPA (High Efficiency Particulate Air Filter) filters are NOT adequate, filtering only to particle sizes of 0.3

microns which is the mean average diameter of bacteria, and not the area of greatest concern in medicine.

Masks are not meant to be a first line protective device. According to current research, there are no masks on the market today, capable of filtering out all airborne contaminants. Furthermore, high filtration media works only while dry, so after 20 minutes, the filtration media stops working when the mask gets damp from breathing, defeating the purpose of the mask. Also a factor is fit and wearing technique. Masks should be fit tested for each employee, to be sure of a tight seal, and must be tied and worn properly at all times, if they are to be effective. If a facility is going to follow standard precautions (blood borne pathogens standard), then high filtration masks should be worn for all surgical plume producing cases - about 95% of all procedures. This can be a costly and relatively ineffective control measure, and it is recommended that infection control nurses work with facility managers to develop a reasonable policy and procedure for the use of protective face masks.

Wall suction lines should always be protected with in-line filters that are placed between the wall inlet and the floor canister. Though these filters may decrease suction strength, they will prevent the build-up of particulates and debris in suction lines in the wall, that often resulting in expensive repairs to the central vacuum system.

All materials used to collect and handle surgical plume, should be considered as biohazard, and disposed of according to infection control procedures. Staff must wear masks, goggles, and gloves, to change and handle filters, and should place all used materials in biohazard bags.

Risk Management Step Four – Audit for Safety Program Monitoring

Safety audits monitor compliance with facility policies and procedures. The LSO will determine the frequency of the audit, which is based on the number of lasers, number of users, case numbers, and number of people involved. The greater the numbers and heavier the use, the more frequent the audit should be. Audit should be done at least once per year.

A laser safety audit is simply an assessment of staff compliance, equipment, supplies and documents involved in performing laser treatments in a facility. It

can be performed by anyone familiar with the systems, but must be supervised by the LSO, who is ultimately responsible. Audits help identify areas of deficit requiring further education and training, purchase of new equipment, or the need for additional control measures. Audits should always be done when new systems or procedures are initiated.

Audit requires completing each of the following steps:

1. Inventory all equipment and develop a checklist
2. Inspect every item on the checklist, assessing its condition, placement, and handling
3. Interview staff working with the laser systems
4. Observe laser procedures (set up, testing, and intraoperative management)
5. Document results
6. Remedy deficiencies identified
7. Monitor outcomes and follow-up

An inventory/checklist includes: laser unit, keys and storage system, delivery devices, signs, protective eyewear, window barriers, logs, tanks, supply carts, plume evacuation systems, lens filters for microscopes and endoscopes, cleavers and strippers for fibers, operation manuals, adapters, and policy/procedure manuals. Include all lasers and all systems in all areas of the facility, including ophthalmology, clinics, hospital owned professional offices, emergency room, day surgery, cardiac cath lab, dental unit, physiotherapy, or any other clinical or research area. If the facility operates a mobile service or satellite centers, all lasers in those areas must be included as well.

Questions to ask during an audit are:

1. Is it where it should be? (stored, covered, cleaned)
2. Does it work properly? (test all delivery systems and controls)
3. Is it being handled and used properly? (observe staff, sign posting, eyewear etc.)
4. Is it safe? (all parts present and correct, policies present, etc.)
5. Is it intact?
6. Does it need repair or replacement?
7. Has it been misused or abused?

Results should be documented and reported to the safety committee or program administrator, for action. The purpose of an audit is to identify potential hazards in equipment or work practices, and to lead to corrective actions.

An example of deficiency identified during an audit, might be: the discovery that the CO₂ laser arm is not replaced properly, potentially leading to damage and misalignment of the optics. If such an item is noted in the audit report, the resulting action could be to require every staff member to attend an inservice on handling the laser arm, and validate skill by performing a return demonstration for the LSO.

Audits should also include calibration and output testing, which can be delegated to biomedical engineering or the company laser technician. The LSO should keep a copy of audit reports in the laser program files, along with user credentials, equipment history, staff training validation, service agreements, logs, and other documentation.

Should there be an accident, incident, or occurrence, documentation of a current audit will help substantiate that the user maintained both safe systems, and staff compliance, in accordance with expectations of standards, and the requirements of Occupational Health and Safety.

Education and Training

Education (didactic knowledge) and training (operational skill) equip clinicians with the foundation information needed to establish a laser safe environment. This is an individual responsibility without universal criteria, and with varied levels of resources available in different regions of the world. It is the responsibility of the individual facility or practitioner to establish acceptable criteria for certification and credentialing, and to approve applicants.

Course certificates can only verify attendance at a program.

Some courses offer written examinations, which validate a certain level of knowledge, but competency and operational skills must be validated with the user's own equipment, in a suitable manner, in his or her clinical workplace. Education must be an on-going effort to stay current with the technology through journals, conferences, networking, and professional organizations.

Documentation

Of all "safety" procedures, documentation should become a priority. Logs, operative records, audit

reports, policies, repair and maintenance records, and committee minutes all contribute to claims that a clinician established and enforced a laser safe practice. Without proper documentation, there is no factual, objective, or sustainable support for that claim.

Inaccurate, incomplete, and absent documentation is an area of liability for many laser clinicians around the world. More and more emphasis is being placed on compliance with known safety standards, and knowledge of and compliance with, standards, is an imperative.

Each facility must develop its own forms and decide on its own requirements for collecting data. Documentation should be included in the formal audit process, with a focus on identifying areas not being completed properly, and recommendations for remedies.

Safety is everyone's responsibility!

Routine audit, troubleshooting, training, policy and procedure development, and compliance enforcement, are duties of the LSO, but case by case, day by day,

patient by patient, laser safety depends on each and every healthcare professional's commitment and vigilance.

Lasers can offer patients a wonderful range of treatment options, from standard of care to experimental innovation. Laser users are constantly challenged to redefine who they are, what they do, and their scope of practice, with each new laser system or application.

It must be remembered that every new system demands risk assessment and a review and revision of facility safety policies and procedures. Only through teamwork, communication, continuing professional education and training, and respect for the technology, can we establish the foundation for a truly effective laser safety program.

**Knowledge Of Laser Science =
Ability To Perform Risk Assessment =
Development Of Appropriate Safety Policies =
Safer Staff =
Safer Patient Care !!!**