LASER SAFETY

Laser Safety

There are several agencies that are involved in the regulation of health clinics and the equipment that they use. Here are a few:

- ANSI = American National Standards Institute. This a non-governmental group made up of trade associations, technical societies, professional groups, and consumer organizations. Federal and state government uses ANSI standards for the safe use of lasers.
- CDRH = Center for Devices & Radiological Health. This is the regulatory arm of the FDA. They require all medical lasers to be registered as Class III. Class III means that the laser must be operated by a licensed health professional. More powerful lasers have an additional Classification as Type IV. Hair removal lasers have this Type IV classification.
- OSHA = Occupational Safety & Health Administration. This is a division under the US Department of Labor and is concerned with the safety of employees/workers. OSHA does not have any laser standards, and uses the ANSI standards. OSHA regulates businesses that have 3 or more employees. An owner/operator is considered an employee.

Safe environment for operating a Laser

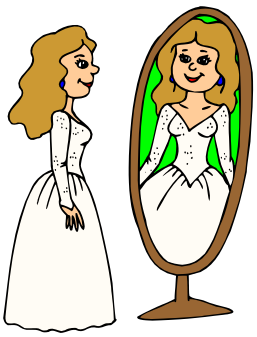
You laser should be set up in a room that has been specifically designated for the equipment. It needs an electrical outlet that is appropriate for the system that you have chosen, and properly grounded according to ANSI standards. While most lasers required a 220v power supply, you should be able to obtain the information that you need from the laser manufacturer. Most IPL's operate with 110v.

Window Protection

All windows in a laser treatment room should be covered with an opaque and flame retardant material to keep any laser energy from escaping from the room. This can even include a (preferably white) mini-blind! In the early days of laser safety, we were told that a special 'lead' protective cover was necessary, but now we know that the only requirement is a covering that will block any laser energy from escaping the room in the case of accidental energy going through the window. This could happen if a laser fiber 'blows', or if the operator just accidentally depresses the trigger.

Mirrors

What about mirrors in the room? While is not recommended that mirrors or shiny reflective surfaces be used in your laser room, many people use them with caution. Mirrors are no longer considered to be a problem within the treatment room as long as it is not placed too close to the treatment site where you might accidentally fire into the mirror at close range. Be aware that if a stray laser pulse is reflected off of one of these surfaces, the pulse could be dangerous. Many practitioners us a simple hand mirror that is kept in a drawer or turned upside down on a shelf or other surface. Just use come common sense with reflective surfaces!



Keys:

Keys must be stored separately and securely away from the laser when it is not attended by the laser operator.

Laser Signs

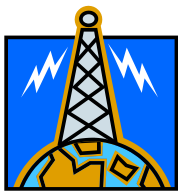
It is a federal requirement to have an appropriate laser specific sign on the door to each room that houses a laser. The sign must list the wavelength of the laser, its maximum joules of output, pulse width and class of the laser. All doors to the laser room should be closed during treatment, and be *capable* of being locked. ANSI laser signs can be downloaded for free from www.LaserTraining.org on the "free material" page.

What makes laser light "special"?

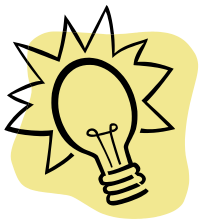
Laser light is *NON-Ionizing*. Other forms of *non-ionizing* light are:

Heat

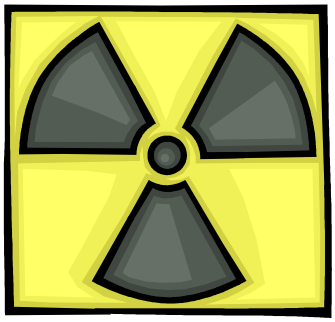
Radio Waves



Incandescent Light



Laser light is NOT this kind of radiation!



There will be occasions when your patients will ask you how you know that this laser is safe, and this is your answer. The energy that our hair removal lasers emit is NOT like nuclear radiation or x-rays or gamma rays, which are ionizing radiation. Ionizing radiation can cause cell mutation which can lead to conditions such as cancer or even death!

Laser Room Door

Some national organizations such as the ASLMS recommend that you keep a pair of laser specific eyewear on the door so anyone who may need to enter the room is protected. In smaller clinics where you may be the only operator in the facility, you may not feel the need to implement this recommendation.

Equipment Safety

Your laser should be installed by the equipment manufacturer or an experienced/qualified dealer. It is highly recommended that if you purchase a used piece of equipment, that you pay a trained professional to install your laser and assure that it is functioning correctly and that its calibration is correct.

Preventive maintenance (PM) should be scheduled & performed according to the manufacturer's recommendations. That varies with each laser manufacturer and it is your responsibility to schedule regular PM's for your laser. If your laser is older you may want to have it serviced more frequently than the manufacturer's recommendations.

Personnel operating the laser should be properly trained. If you are in charge of the clinic, then it is your responsibility to assure that anyone who is operating your equipment is doing so within the laws of your state and that they are properly trained!

Hazards

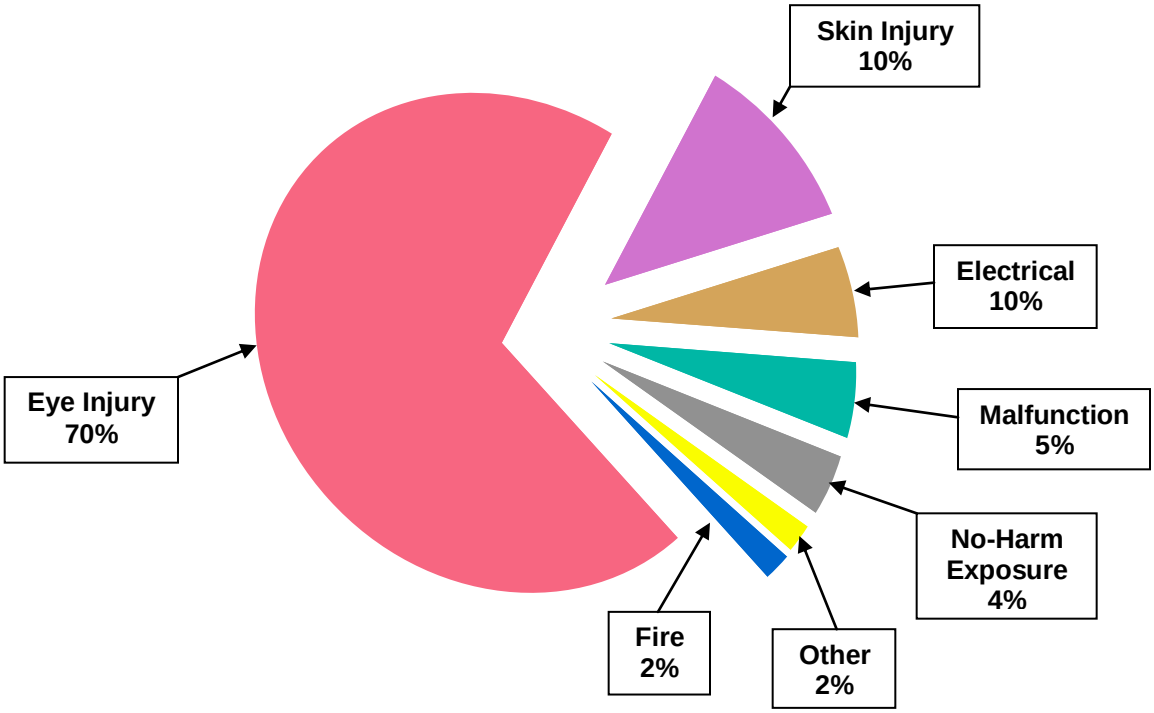
•Class I – No known biological hazard

•Class II – Chronic viewing hazard only

•Class III – Direct viewing hazard

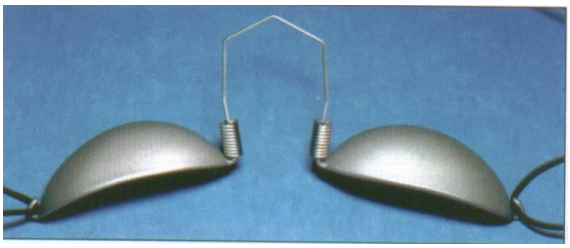
•Class IV – Direct & reflected hazard – category for hair removal lasers

Laser Accident Summary



As you can see, there is very little actual skin damage/injury to patients or technicians – which includes hyperpigmentation, hypopigmentation and burns. Most of the eye injuries reflected on this summary are the result of *service* techs who are not exercising proper precautions while servicing the equipment.

Eye Protection is Mandatory!



Different wavelengths require different eyewear! You cannot rely on color alone to determine which pair of eyewear is appropriate for use with your laser. Be familiar with your eyewear if you have more than one laser device in your facility. And be especially cautious if you are attending a laser workshop, and be certain that you are wearing the appropriate eyewear for the device that is being used in the operatory.

There are many different styles of protective eyewear. As you can see they come in all different sizes and colors. It is a federal law that all laser safety goggles must be appropriated labeled for the wavelength of laser and optical density for which it will protect the user. Only the metal style (which will protect the user from all wavelengths) is not labeled.

Always inspect the eyewear to make sure that they are protective for the equipment that you are using, and be on the lookout for any deep scratches or unusual wear and tear. Kleenex and paper towels can scratch your eyewear, so always clean patient eyewear after each use with a scratch-free cloth.

Most laser practitioners will put their patient a pair of goggles that wraps around their face and affords the most protection possible – especially if the patient is have facial work performed.

The Association of Operating Room Nurses (AORN) has published a position statement on the use of laser eyewear. They state that “Eyes of patients & health care workers should be protected from laser beams”, and “Laser safe eye protection with appropriate wavelength and optical density should be worn by all health care workers & all patients and labeled to protect against improper usage.”

Everyone in the room – patient *and* laser operator – must wear protective eyewear!

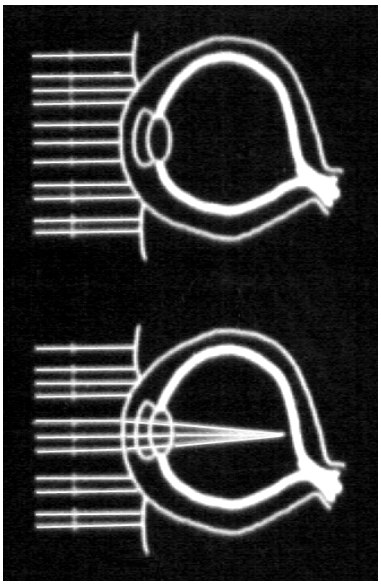
Optical Density

What is optical density? For a given wavelength, it is an expression of transmittance (transmission) of an optical element. The higher the optical density of your eyewear, the lower the transmittance. Most good quality goggles have an optical density of around "7".

ANSI Standards for Eyewear

- **Class III – Helium – Neon**
  - **Dangerous only if viewed directly**
- **Class IV – Dye, Alexandrite, Nd:YAG, Diode**
  - **Dangerous to view**
  - **Scattered Radiation**
  - **Safety eyewear mandatory**

Laser Eye Penetration



CO_2
Erbium

Corneal Absorption

Alexandrite
Nd:YAG
Diode
Pulsed Dye

Retinal Absorption

- **Lasers present either retinal or surface burns.**
- **Safety glasses DO NOT protect from *direct laser impacts*! They will offer some degree of help, but they cannot be relied upon to prevent eye damage from a direct laser beam!**

Fire Hazards and Combustible Material

- Alcohol
- Ointments
- Drapes

- Plastic
- Hair
- Methane!

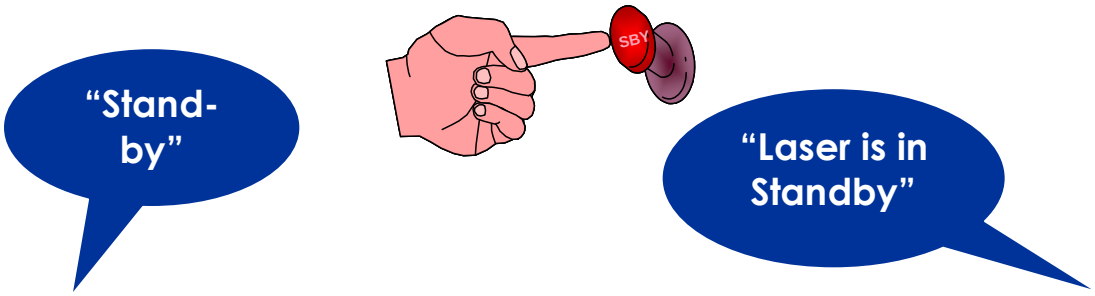
Why is methane 'important'? You may be asked to perform peri-anal work. Methane is the natural gas that humans can expel from their anus, and it is flammable! In the 'early days' we were taught to discuss this with our patients and even go so far as to place a protective gauze or cotton ball on the anus. Most laser technicians don't do that anymore. Just be aware that there *have* been cases of methane igniting during a laser hair removal procedure, and proceed with caution!

Fire Control

While fires are possible, it is not as likely with hair removal lasers or IPL's. It is recommended that you have a standard electrical fire extinguisher positioned immediately outside the laser room.

Stand – By Mode

The laser should *always* be in stand-by mode when not in use.



Key Control

•Key should be accessed only by those authorized by the Laser Safety Officer. The laser safety officer is the person in your office or clinic who has the most training and experience with lasers. This designation should be included in your laser registration.

•Key should NEVER be left in the control console of the laser. (OSHA)

Electrical Safety

High voltage energy can be very dangerous, and electrical charges can be held for a long time. Accidental discharge can be dangerous and cause injury. The picture below shows that there is enough energy still in the laser to illuminate the lights on the control board, even though the laser is unplugged.

Plume Issues

Plume is the by-product of thermal damage to tissue. Plume can contain toxic gases and vapors such as benzene, hydrogen cyanide and formaldehyde, bio-aerosols, dead and live cellular materials including blood fragments and viruses. General room ventilation is not enough to capture contaminates for procedures that ablate (destroy/vaporize) tissue. For those applications smoke evacuators with HEPA filters must be used. Do we generate 'plume' with laser hair removal procedures? What is in Plume? For ablative procedures it can include:

- Carbon
- Aerosolized blood
- Bacteria
- Viral particulates (including blood-borne pathogens)
- DNA

What about the 'odor' during hair removal? What are we smelling? Hair contains these elements:

- Keratin
  - Sulfur dioxide – is this what we are smelling during a laser hair removal treatment?
  - Hydrogen sulfide
  - Cysteine
- Melanin
  - Tyrosine
  - Dopamine
- Chemicals & Dyes
- Heavy Metals
- Drugs

It is generally accepted that laser hair removal is safe to perform without elaborate evacuation systems in place. It is recommended that the room be well ventilated. Many facilities use the assistance of devices such as ionic air filters which work very well. Aerosol sprays and candles only mask any odor issues in the facility.

The Use of Topical Anesthetics in the Laser Clinic

This is a controversial issue in the hair removal industry. Many clinics use them, and many do not. There is information at the end of this booklet from 3 different cases where topical anesthetics were used irresponsibly and it resulted in patient death. It is important for your clinic to make an office policy of how you will address the use of topicals in your facility.

Laser Safety Officer

The Laser Safety Officer (LSO) may or may not be the person in the treatment room who is delivering treatment. There are no specific 'certifications' or background requirements for a person to be the LSO. Experience, training and resources for numerous other sources can be the criteria for this job. Although not tightly enforced, Florida law requires a LSO in facilities that use lasers.

The LSO establishes controls over administrative, procedural and engineering components in the facility.

Administrative controls include making sure that all laser personnel have obtained initial and on-going education, operator credentialing documentation is kept up-to-date, license renewals are kept current, etc.

Procedural controls involve making sure that policies are followed, safety glasses are in good order and being used, signs are appropriately placed, etc.

Engineering controls mean that the equipment is being kept up-to-date with regularly scheduled PM's, fibers in good working order, etc.

Nominal Hazard Zone

The Nominal Hazard Zone (NHZ) is the actual area where one could get hurt (burned) with the laser. It is determined solely by the LSO. In small offices or clinics where laser hair removal is performed, the NHZ should generally be the entire treatment room.

Once the NHZ has been defined, all personnel must wear safety glasses within this area, in addition to observing all other safety precautions prescribed by the clinic's safety policy.

LASER SAFETY IS NO ACCIDENT!

Death Prompts Calls for More Drug Scrutiny

Compound Pharmacies Face Threat of More Regulation After Student's Death

Apr. 21, 2005 - Shiri Berg, 22, was just a young woman looking to look a little better. But earlier this year, she prompted more scrutiny of a little-known drug industry, and helped expose a system that puts lives at risk.

On Dec. 27, 2004, the North Carolina State University student was driving on route I-40 in North Carolina when she felt woozy and pulled over. She was later found inside her locked car, unconscious and having convulsions. She soon went into a coma.

Her father Ron says it was not drugs or alcohol. Bizarrely, Berg's lower body underneath her clothes was wrapped in cellophane, and her legs were covered in a strange gel.

One of Berg's roommates remembered that she had told him she was going for a laser hair removal session at a local spa to take care of unwanted hair on her legs.

Laser hair removal can be safe and effective, but Berg was concerned about pain associated with the procedure. As some clinics do to address the discomfort, the spa provided her with what they call a numbing cream.

Her friends say Berg was told to apply the cream right before her appointment and wrap herself in cellophane to intensify the anesthetic effect.

It was called Laser Gel 10-10, a prescription compound whose two major ingredients are serious anesthetics: 10 percent Lidocaine, 10 percent Tetracaine. It came with no warning about potential side effects, nor risk of coma.

Over the course of 10 days, Berg never regained consciousness. She died on Jan. 10.

Potent Combination

Dr. Howard Sobel, a New York dermatologist, says the combination of this strong medication spread over too large an area was too much for Berg's system.

Shiri Berg was apparently not the first to have this happen to her. Almost three years earlier, Blanca Bolanos went into convulsions in her car driving to a Tucson, Ariz., laser hair removal clinic. Bolanos was in a coma for two years before dying. Court papers say she used a cream of 6 percent Lidocaine and 6 percent Tetracaine.

David Kirby, the Berg family lawyer, says after Berg's coma hit the news, 20 other patients in North Carolina approached him. He says, like Berg, they used a highly potent Lidocaine-Tetracaine combination. He also says none received a prescription or saw a doctor.

Two of those patients went into cardiac arrest, but survived, Kirby told "Primetime."

Calls for Regulation

The Bergs blame the beauty spa and its doctor. But the cream that led to their daughter's death was not made by the spa. It was mixed by something called a compounding pharmacy. Compounding pharmacies have been around for years and can do lots of good customizing medicines for patients.

Patsy Angelle, who owns and runs a small mom & pop compounding pharmacy in Baton Rouge, La., with a good safety record, gave "Primetime" an example of how her operation helped a child: "The child had a tonsillectomy. And his throat was hurting really bad. [His] physician contacted [us] and we prepared a medicated lollipop and the pain went away and the child was able to eat."
As long as they stay small, the FDA says it has left their regulation to individual states. But these days, mega-pharmacies are changing the industry, filling huge numbers of prescriptions for drugs that aren't regulated by the FDA.

A compounding pharmacy called Triangle mixed the cream given to Berg. It was a combination never reviewed -- or approved -- by the FDA. Critics like pharmacist Sara Sellers say that can be dangerous.

"Compounders will say that they fill unique market niches where products aren't in the marketplace," she said. "Maybe they're not in the marketplace because it's not safe for them to be in the marketplace."

In all, the government has documented over 200 incidents over the past 15 years, involving 1.4 million potentially tainted doses of medicine.

"Patients have a right to know the medications they are using, are not approved by the Food and Drug Administration," Sellers said.

However, Angelle, president of the International Association of Compounding Pharmacies, said while mistakes have been made, her industry's quality control standards are very high. Angelle said the industry already is regulated by state boards of pharmacy.

But the industry does not test the effect of their compounds on patients, like the FDA requires for manufactured drugs. The industry has lobbied hard against federal regulation. They say state regulation is sufficient, and that the Bergs' tragedy was not their fault.

"The practitioner that dispensed the medication is responsible for the consultation and education of that patient," Angelle said.

Because the tube was marked "for office use only," compounders say it was up to the spa's doctor to safely dispense the cream himself -- and only in his office.

Others disagree that the pharmacy shares no blame. "If you're going to promote a product in the marketplace, you have a duty to disclose that it is not produced according to strict federal standards," Sellers said.

One of those federal standards is an appropriate warning label. The tube of numbing cream that Berg used had no warning information. But Angelle said, "That's where the role of the pharmacist and the compounding pharmacist is so important. We are trained to properly educate the patients."

Kirby points out that the Bergs' daughter received no "education" about the product.

Working for Shiri

The Bergs are now pushing to make more people aware of the risks their daughter faced -- so that she will be remembered for something more than just her death.

"She wanted to make a difference in the world. She wanted to be remembered," said Ron Berg. "One of the reasons we're doing what we're doing now … [is] because we somehow want to be the voice of Shiri." The FDA and the North Carolina pharmacy boards are currently investigating the Berg case.
The spa's lawyer said the spa owners never knew that a prescription was needed for the gel, and they thought it was a safe and approved product. The spa has gone out of business, and its house doctor has been brought up on charges by the state medical board.

As for the compounding industry, it is beginning an accreditation program to improve compliance with industry standards.

http://abcnews.go.com/Primetime/print?id=692826

- Berg's death certificate lists the cause of death as *"anoxic brain injury due to seizure & respiratory arrest, due to elevated blood lidocaine level"*.
- Anoxic = reduced oxygen supply
- Rate at which creams are absorbed by the body is unpredictable.
- Used on mucous membranes or on a break in the skin can make it be more readily absorbed into the skin.
- Height and weight must be taken into consideration when administering the drug.

Symptoms of lidocaine overdose:

- Ringing in the ears
- Funny taste in the mouth
- Convulsions

January 2001, West Virginia

Jonathan Briese

- 20-year-old cadet at the U.S. Coast Guard Academy
- Volunteer Fairfax County firefighter
- Father is a paramedic and author of textbooks on emergency response
- Brother is a firefighter and paramedic
- Simple procedure -- outpatient laser hair removal.
- His father had checked out the clinic.
    - "It was a no-brainer,"
- He had already undergone one treatment successfully.
- Wasn't given any drugs on his first visit.
    - "he was ecstatic"
    - "he had a clear back"
- He was given a combination of a pain reliever (Lortab), a relaxant (Xanax) and an anesthetic cream.
    - "something went wrong"
- While the physician was applying an anesthetic cream, he noticed Briese lower his head and begin to snore before losing consciousness.
- Briese vomited and the physician tried to clear his airway before leaving the room to call 911.
- No CPR or other lifesaving treatment was administered by the doctor.
- Paramedics arrived within minutes and began CPR, intravenous and cardiac treatment, and then rushed Briese to Inova Fairfax Hospital.
- Twelve minutes after he arrived there, he was dead.
- The medical examiner ruled that Briese had died of anaphylaxis, or an allergic reaction.

Blanca Bolanos, Age 25

- Died January 25, 2002 from a compounded anesthetic cream in Arizona.
- "Photocaine" Cream (6% lidocaine & 6% tetracaine) was applied to her legs and then wrapped in plastic.
    - Had secondary burns on her legs from the ointment.
- Became disoriented while driving
- Had seizures & fell into a coma
- Never regained consciousness & died of respiratory failure
- Was 'hooked' to a respirator in her mother's home for nearly two years prior to death.

References:

American Society of Lasers in Medicine & Science (ASLMS)

American National Standards Institute (ANSI)

Laser Training Institute

Candela Laser

INSTRUCTIONS FOR SUBMITTING EXAMINATION ANSWERS

- Please take the final exam on line!
- Use the same link that took you to the page that was emailed to you to access the course. You can also use the "back" arrow (⟵) on the top left corner of the PDF page to go back to the 'home' page to take the exam.
- At the bottom of that page is a "start exam now" button for you to click for taking the exam on the 'Judy Adams Training Center of America' website on the internet.
- When prompted, be sure to spell your name *exactly* the way you want it to appear on your certificate of completion.
- As soon as you have completed the exam, you will be sent an email with a link to a PDF file so you can print your certificate. You can also save that PDF file for your reference. You also have an option of printing your certificate as soon as you pass the exam – before you even get your email with the link.
- The license number (if applicable) that you provide is the number that will be used to enter your hours/credit into CEBroker
- "Judy Adams Training Center of America" will be copied on your certificate and will then enter your hours into CEBroker for you!

Thank you!