Approved Provider

CE Activity provided by:

National Coalition of Estheticians, Manufacturers/Distributors & Associations (NCEA)

LASER & LIGHT THERAPY

INSTRUCTIONS

1. To reinforce your learning and retain the information, highlight or underline the answers to each of the (30) Study Objectives.
2. Take the Three (3) Self-Assessment Tests, and then attach the tests to the CE Registration Form. Total test scores must be 75% or higher in order to obtain your CE Certificate.
3. Complete the CE Registration (Section A) and Course Evaluation (Section B).
4. Section C - Enclose a check or money order payable to NCEA:

   ***NCEA Member Price:* $44.95** *Non Member Price:* $64.95
5. Mail completed CE Registration Form, payment, & three tests to: NCEA CE Program, 484 Spring Avenue, Ridgewood, NJ 07450-4624.

GENERAL PURPOSE STATEMENT

To provide the skin care professional with a review of Laser & Light TherapY. The COA has approved this activity for 4 CEs and is good through July 1st, 2015.

LEARNING OBJECTIVES

After completing this interactive medical esthetics CE activity, the skin care professional will be able to:

1. Evaluate the role of the esthetician pre and post-procedures.
2. Describe laser & light therapy treatments for cosmetic and medical indications.
3. Understand scope of practice and increased safety responsibilities when performing laser & light therapy procedures.
4. Summarize the history and physics of laser and light therapy.

LASER & LIGHT THERAPY

Section A - CE Registration:

PRINT CLEARLY (Illegible forms will not be processed)

Name: _____

Address: _____

City: _____ State: _____ Zip: _____ + _____

Tel: _____ Fax: _____

Email: _____

*Delivery Method used to send CE Certificate

Are you NCEA Certified? ___Yes___No If yes, NCEA Certified# _____

License# _____ State of Issue _____

Type of License:

Esthetician ___ Cosmetologist ___ Teacher ___ Medical Professional ___

Other ___ Please specify: _____

Section B - Course Evaluation:

1. Did this CE activity's learning objective relate to its general purpose? ___Yes ___No
2. Was the interactive format an effective way to present this material? ___Yes ___No
3. Was the content relevant to your skin care practice? ___Yes ___No
4. What type of setting do you currently work in? _____
5. How long in minutes did it take you to read the article_____, study the material_____, and take the self-assessment tests_____?
6. Suggestions for future topics_____

_____

Section C - Payments and Discounts:

The fee for this CE Activity for NCEA Members: 44.95 Non Members: $64.95

(Check or money order payable to NCEA)

*We offer special discounts for 6 or more CE Activities that are for institutional use..

Call (201) 670-4100 Ext 5, for visit **www.NCEA.tv** more information.

Laser & Light Therapy

Lea registered to attend an upcoming NCEA 42 hour laser light therapy course and she shared her exuberance with Anna, one of her colleagues at work. "You're wasting your money taking the class, physics is boring. Just get hands-on experience, that's all you need," exclaimed Anna.

Lea was concerned for the safety of Anna's patients because Anna had received only four hours of training from the manufacturer of the device. On one occasion, Anna had to perform a treatment on a client who came from multi-cultural background. She hoped her settings were correct so that the client would obtain good results. Sometimes in the rush of the day though, she failed to properly document her treatments. For all these reasons, at lunch time Lea took the time and sat down with Anna to show her the class curriculum outline.

"Wow!" exclaimed Anna. "Are you sure you will understand all of that?"

Lea shared with Anna that there was more to understanding light therapies than just doing the hands-on treatment. After spending some time one evening researching laser and light therapies, Lea concluded that there was more to learn regarding their effectiveness and use in esthetics. Laser hair removal was only one application of how lasers and light therapy devices can enhance the skin. The technology is very advanced. It is imperative to learn how the device works in order to better serve the needs of my clients. By this time Anna became more attentive.

"Did you know that LED light is used in the space capsule to help astronauts heal wounds in a non-gravitational environment?

I also earned continuing education units watching a webinar on basic phototherapy theory and what differences are in light-based modalities. I even watched a webinar on federal and state issues that will affect a laser practice," said Lea.

"Really?" exclaimed Anna.

Lea continue to share with Anna the importance of understanding the science of the biological effects of lasers and light emitting diodes, and their role in esthetic treatments. They can effectively be integrated as part of the new, innovative approaches to skin management programs. By gaining greater insights can only help her make better decisions for her clients, exclaimed Lea.

Lea continued to talk about some poor laser results due to operator error. It was really scary. She did not want to operate a machine without more knowledge about safe operation. After all, it was important to be concerned about client safety and good results.

And finally it was essential that she gain proper credentials and continue to attend advanced education in this growing field. Additionally, networking with other NCEA Certified Professionals and attending annual conferences supported her growth.

- *What challenges do you think Anna may incur during her treatments?*
- *Do you agree with Lea's attitude towards obtaining additional education?*
- *Can you think of a time when you were not sure of how to proceed with a procedure?*

History

Lasers represent a form of energy that can be manipulated to accomplish a number of medical procedures from the complex surgical removal of an acoustic neuroma in an operating room(OR) to the less invasive removal of unwanted body hair or facial rejuvenation in a salon or spa. Regardless of the procedure, it is important to understand the properties and safety aspects of laser utilization. This knowledge will enable you to manage a safe and successful laser and light therapy practice.

In 1917, Albert Einstein proposed the concept for the theory of stimulated emission of radiation. Lasers have existed in medicine since the early 60's when Theodore Maiman developed the first working laser using a crystal of ruby, based on *Shawlow* and *Townes* theories. Advancing the quantum theory developed by Albert Einstein, this laser was soon followed by a $C0_2$ gas laser invented in 1964 by *Kumar Patel, PhD*. Leon Goldman, M.D., often referred to as the *Father of Lasers in Medicine*, founded the *American Society for Laser Medicine and Surgery*.

Envision a tiny solar system with revolving planets around a central sun. This system can represent the atom or molecule. At the center of the atom, is the nucleus that contains protons and neutrons, with a balanced number of electrons circling around the center. In order for laser light to occur, additional energy must be added (stimulated). This added energy can come from electricity or another small laser for example. After the electrons are stimulated by this added energy, they shift or bump out of their normal orbit. The electron wants to stay in the system. To stabilize itself, the electron gives off a photon before returning to its normal orbit. This released photon, or unit of light energy, travels within the laser housing and strikes other like molecules stimulating the emission of more and more photons. Soon this avalanche effect of photons is captured as laser light. As this light strikes biologic tissue, light energy is transformed into heat energy to create a desired effect.

Laser & Light Applications

Many different types of lasers and light therapies have

Study Objectives

Highlight/underline the answers to the following questions as you read:

1. Who developed the quantum theory?
2. What is in the center of an atom?
3. What are 3 light-based modalities?
4. How are lasers differentiated?
5. What is the most common laser used today?
6. How can temporal output be described?
7. How do fractionated lasers deliver energy?
8. What are three principal parts of laser construction?
9. What are 3 characteristics of laser light?
10. List the chromophores tissue reaction and absorption?

since emerged utilizing different mediums of gases, solids, liquids and semi conductors. These laser mediums all have different wavelengths and therefore different effects on human tissue.

Light therapies have numerous applications. Light based modalities are

- Laser Light
- Intense Pulsed Light
- Non-laser Light Emitting Diodes (LED)

They can be used many ways including

1. Ophthalmogy: cornea repair or correction; retina repair.
2. Dermatology: removal of skin tumors, external ulcers, and warts, removal of tattoos, treatment of port wine stain, hemangiomas.
3. Esthetics/Cosmetic: hair reduction, skin rejuvenation.
4. Oncology: Tumor ablation.
5. Photodynamic therapy: photochemical.

Definition of Laser

The word **LASER** is an acronym that describes the physics of how laser light is generated.

It stands for "**L**ight **A**mplification by the **S**timulated **E**mission of **R**adiation". A laser is a device that uses a quantum mechanical effect, stimulated emission, to deliver a coherent beam of light from the lasing medium.

There are two types of lasers: ablative and non-ablative. Lasers, however, are further classified into subcategories with numerous variations. The main differences between laser types are their wavelength. Additionally, depending upon their wavelength, surgical lasers and cosmetic lasers have different degrees of invasiveness.

Ablative (Cutting)

Irradiation of cancer cells; optical (ophthalmology); surgical, skin resurfacing. Cutting lasers remove warts, skin tags, and are used to assist surgical procedures for cutting skin.

- $C0_2$ (gas laser)
- Erbium YAG (infrared 2940 nm)

Non-ablative (Aesthetic/Cosmetic)

Hair removal, laser skin rejuvenation, vascular (telangiectasias) treatment, pigmentation reduction).

- Nd:YAG (Continuous or Q-switched 1064 nm)
- Alexandrite (755 nm)
- Pulsed Dye (577-585nm)
- Diode laser (810 nm)

1. Lasers are differentiated by their wavelengths, and active medium which can be a solid, liquid, gas or diode.

Solid State

The term "solid-state," as related to lasers, refers to a laser that uses a crystal as the lasing medium. This crystal has an impurity called a "dopant." It is the "dopant" within the crystal that determines the wavelength of the laser emission. Solid State does not include semiconductor materials used in laser diodes. An example of a solid state laser is a Ruby laser which uses a ruby crystal as the lasing medium. Nd:YAG, Alexandrite, and Erbium also have crystals as the lasing medium. Most cosmetic (aesthetic) lasers are solid state. They can be operated as a continuous wave (CW) or pulse mode.

Liquid

The common liquid lasers utilize a flowing dye as the active medium, and are pumped by a flash lamp or by another laser, such as an argon laser. These are typically rather complex systems, requiring more maintenance. They may be operated either CW or pulsed, and have the advantage that they are wavelength tunable, perhaps over a 100 nm range. An example is the flashlamp-pumped dye laser operating between 585 nm through 600 nm. This laser is used for port wine stain, telangiectasia, warts and hypertrophic scars.

Gas

Gas lasers are not unlike fluorescent light bulbs and neon signs. In the helium-neon (HeNe) laser, a mixture of helium and neon gas is confined to a hollow glass tube. As in the neon sign, an electric current passing through the tube excites the atoms and causes them to emit light. In the HeNe laser, mirrors at the ends of the tube form a resonant cavity which helps create and aplifiy the laser beam. Gas laser systems include $C0_2$, Argon (Ar), Xenon-Chloride. They mostly operate as a continuous wave (cw) mode but can be used in a repetitively pulsed mode.

Diode (Semiconductor)

In terms of sheer numbers, the diode laser is the most common laser today. The two common families of diode lasers are composed of GaAlAs,(Gallium/Aluminum/Arsenide), with output wavelengths in the 750-950 nm range, and InGaAsP (Indium/Phosphorus), whose wavelength is in the 1100-1650 nm range. The former group is commonly used in compact audio disk, CD ROM, and laser printer technology, while the latter forms the basis of modern optical telecommunications. Diode lasers used in aesthetic applications operate at 810 nm and 980 nm. The 810 diode is used for hair removal and the 980 nm is used for treatment of vascular lesions and telangiectasia.

2. Temporal Output of a laser can be described as Continuous Wave (CW), or Pulsed.

Continuous wave (CW)

These emit a continuous beam and include the $C0_2$ and Krypton lasers used for coagulating tissue (moles, warts), pseudo-continuous wave lasers emit a beam in such close pulses that the tissue effect is the same as a continuous wave laser.

Pulsed

The beam of energy is emitted in very short pulses normally separated by 0.1-1 second. Pulsed lasers are very selective in their destructive effect. They are used in selective photothermolysis such as hair removal lasers.

Q-switched lasers are pulsed lasers that produce high peak powers by use of a device called a quality switch. This device produces very short intense laser pulses by an electric discharge that is pulsed in and out of the lasing medium. Energy is stored in the laser cavity then released in one single, short and very powerful pulse. The pulse duration is from 10 ns to 250 ns. Power outputs are in the megawatt to gigawatt range (as opposed to milliwatt). They allow for mechanical destruction of a target instead of thermal. Q-switched lasers are used in tattoo, some pigment and birthmark removal.

Fractional

Older $C0_2$ lasers involved vaporization of the epidermis and upper dermis during facial resurfacing. Fractional lasers deliver energy in a limited way meaning that they split the laser light into thousands of microscopic columns of heat. Fractional pulses are termed as microthermal zones (MTZ). Through a process of fractional photothermolysis, targeted cells within theses columns are destroyed leaving the surrounding tissue intact. Fractional lasers can be used in an ablative or non-ablative mode. They are used to treat cosmetic issues such as acne scars, stretch marks, aging, and sun damaged skin.

Physics

In order understand the workings of a laser it is important to review the understanding of atoms and electrons. Atoms are what make up all matter. In a resting stage (zero stage), the electrons rotate around the nucleus and the atom is at its lowest state of energy. This "ground state energy" can soon change with the introduction of an energy source. The orbiting electrons can be moved to a higher state of excitement. When the energy source is removed, and the atom returns to its normal state (resting state), it releases a photon in the process (spontaneous emission of radiation). Photons stimulate other excited atoms in the active medium to release additional photons, causing a chain reaction. When the number of excited atoms exceeds the number of non-excited atoms, the energy is amplified which creates the laser action. Inside the tube this cascade of excited atoms releasing photons generates the laser beam.

Laser Construction

Lasers are constructed based on three principal parts: An *energy source* (usually referred to as to the pump or pump source), a *gain medium* or *laser medium*, and two or more parallel mirrors that form an *optical resonator*.

Pump Source (system)

This is the laser's power supply required to stimulate the lasing medium. Power source can include electricity or flash lamp or radio frequency.

The Laser Medium

This is the substance that is stimulated to produce the laser beam (gases: argon, $C0_2$, krypton, Helium-Neon), liquid (dye), or solid (solid crystalline materials: ruby or

alexandrite crystals. This medium determines the wavelength of energy.

Optical Resonator

This is the actual "cavity" or "tube" that encloses the lasing medium that is excited by the power source. This cavity consists of specially designed reflective mirrors opposite each other. One mirror is highly reflective, the other partially reflective. The highly reflectance mirror reflects 100% of the light which strikes it. The other mirror reflects less than 100%. The small fraction of light which passes through the partially reflective mirror is the beam output, the "doorway" where the beam exits. It is this buildup or amplification of energy that makes the laser beam so powerful.

Characteristics of Laser Light

Laser light is collimated, coherent, and monochromatic.

Collimated

The laser rays are nearly parallel or collinear. A beam of high energy light focuses precisely on the target. The light does not disperse but remains tight.

Coherent

Coherence are wavelengths that are in phase with one and other. This synchronicity increases its brightness (amplification).

Monochromatic

Monochromatic light consists of one wavelength producing a pure color.

Energy Measurement and Delivery

Energy from lasers is measured in *Joules.* Pulsed energy delivery is used in most aesthetic lasers that tend to provide quick, short pulses into the tissue, e.g., hair removal, skin rejuvenation, veins.

Single-pulsed lasers deliver in a slower way such as found in ablative lasers.

A *Joule* is a unit of energy. It describes the total amount of energy. For example, you may deliver 45 joules of energy in a laser pulse.

Fluence or Radiant Exposure is the amount of light energy delivered per surface area. The units of fluence are joule per square centimeter.

Chromophores Tissue Reaction and Absorption

Chromophores

Hair removal – melanin

Pigmented lesions – melanin

Vascular lesions – hemoglobin, dark protein

Skin rejuvenation – water, collagen, hemoglobin

Tattoo removal – dye

Acne - porphyrins

Biological tissue–specifically melanin, blood, and water–contain chromophore molecules to which specific wavelengths of light energy are absorbed. Different molecules absorb different wavelengths of light. In other words, each chromophore has a characteristic absorption spectrum and particular wavelengths of light that are

Self Assessment Exercise 1

1. Lasers
   a) Function with filters
   b) Are collimated
   c) Deliver across a broad spectrum of wavelengths
   d) All of the above
2. The energy of a laser occurs when:
   a) The energy source is removed
   b) Excited atoms exceeds the number of non-excited atoms
   c) Photons are released from the tube
   d) Photons stimulate other excited atoms
3. Laser mediums can be
   a) Solid crystals
   b) Gas or liquid
   c) Rubys
   d) All of the above.
4. Chromophore molecules
   a) Attract specific wavelengths
   b) Have a selective absorption spectrum
   c) Are found in all biological tissues
   d) All of the above
5. LASER stands for: _____ _____ _____

   _____ _____

more selectively absorbed compared to other chromophores at that wavelength.

Once a photon (light) is absorbed the energy is transformed into thermal, chemical or mechanical energy. The law of *Grotthuss-Draper* directs all laser light tissue interaction – light must be absorbed to create an effect.

In laser hair removal, for example, the laser is attracted to the melanin in the hair shaft in the follicle. Wavelength could be anywhere from 755 nm – 1064 nm depending upon the type of client. The laser must "see" the color in order to damage the follicle so that the hair doesn't grow again. There is no target in the absence of color, e.g., white or gray hair.

The type of laser (wavelength) to be used with hair reduction or with vascular or pigmented lesions is highly dependent upon the Fitzpatrick type of the skin. For example, certain wavelengths of energy have a greater affinity for brown pigment. Selecting a wrong laser wavelength could burn a client with darker skin type.

Therapeutic Properties of Lasers

Thermal energy that destroys a target has variable effects on tissue.

1. Tissue Heating: e.g., Skin rejuvenation
2. Rapid heating: Causes vaporization of tissue (thermal destruction) e.g., $C0_2$ skin resurfacing.
3. Incision or bulk ablation
4. Extremely rapid heating such as demonstrated in a Q-switch laser leads to the shattering or explosion of tissue.

Selective Photothermolysis and Thermal Relaxation Time

A key principle behind the success of the laser is a process known as selective photothermolysis. "Photo" means light, "*thermo*"= heat, and "*lysis*" means destruction. This process refers to the precise targeting of a structure of tissue using a specific wavelength of light. A target is destroyed through a rapid heating without destroying surrounding tissue. Aesthetic lasers are designed and

Study Objectives

Highlight/underline the answers to the following questions as you read:

11. What is the law of Grothus-Draper?
12. What are four therapeutic properties of lasers?
13. What is selective photothermolysis?
14. What is thermal relaxation time?
15. Who should establish laser safety protocols?
16. What is the Nominal Hazard Zone?
17. Who is in charge of the laser room?
18. What is the Laser Safety Officer responsible for?
19. Where do you find the "Indications for Use" of a device?
20. What are the 4 Laser Hazard Classes?
21. Who regulates esthetician licenses and use of laser/light therapy devices?

engineered to perform precisely the goal of the treatment, avoiding injury to surrounding tissue.

Thermal Relaxation Time (TRT)

Thermal relaxation time of a mass is the time required for it to cool down to the normal temperature of the surrounding area after being heated. TRT is dependent upon the size and shape of the target. When the laser energy hits biological tissue, the generated heat must remain confined in the target (thermal diffusion), long enough to destroy the target BEFORE the heat defuses. In a hair follicle, the damage of the hair bulb (bulge) must take place before the thermal relaxation time.

Depth of Penetration and Spot Size

Three variables control the depth of penetration; wavelength, spot size, and power.

Wavelength – the longer the wavelength, the deeper the penetration.

Spot size – the bigger the size the greater the divergence. A laser spot size is normally a little larger than the target. It could be the size of a pencil eraser. Depending upon the target – e.g., hair follicle, vein, and collagen – the requirement for the spot size is different.

Irradiance - Technique is very critical to an effective outcome. Hand movements during the lasering process are vital to results and outcome.

Summary of Laser Effects

When laser light strikes tissue it can be

- Transmitted
- Scattered – longer waves experience less; shorter more
- Reflected
- Absorbed – through selection

Dependent upon

- Type of tissue
- Wavelength (color nm)
- Fluence (intensity) amount of energy delivered per unit of surface area (J/cm^2)
- Pulse width – time interval over which energy is delivered
- Diameter of beam (spot size) measure in mm
- Repetition rate – number of pulses/second (Hz)
- Cooling methods

What Is The Difference Between A Laser and Intense Pulsed Light (IPL)?

IPL systems are not lasers. Each delivers energy differently. Lasers deliver light in a single wavelength targeting one specific chromophore. An IPL functions with filters. Non-chromatic (or poly-chromatic meaning multiple different wavelengths) light is created by an energy source and then filtered. IPL light delivers energy across a broad spectrum of wavelengths (500-1200 nm) through a pulse sequencing process. Special cut-off filters are used to block out wavelengths of light. There are a range of conditions that can be treated with an IPL device. There are multiplatform machines that have both laser and IPL devices right on the unit allowing for great flexibility for treatment.

The spot size for an IPL is larger than a laser. It delivers a bigger application of energy to the skin area. IPLs deliver energy through a short burst of emitted light from a flash lamp for a specific condition. A laser and an IPL are two different sources of energy. They are not the same. IPLs are used for hair reduction, vascular lesions, and pigmentation as well as skin rejuvenation.

Radio Frequency

Radio frequency (RF) devices have a very low frequency represented in devices such as Thermage™ (Solta Medical, Inc., Hayward, California). Radio frequency produces heat (thermal injury) deep within the dermis causing tissue tightening and remodeling. There is a controlled thermal heating of collagen fibers including the fibrous septae. There is a difference between Radio Frequency and lasers. Lasers convert light to heat and target specific superficial structures or chromophores through a process of selective photothermolysis. RF produces heat to a greater volume of tissue when the tissue's electrical resistance converts the electric current to thermal energy deeper in the dermis.

Light-Emitting Diodes (LEDs)

LEDs are neither a laser nor IPL. Through a process of thermolysis, Lasers and IPL selectively destroy a specific target. LED's have a much lower energy output and stimulate biological tissue by supporting collagen synthesis, repair, circulation, support the reduction of inflammation, and the appearance of some pigment. LED's do not destroy tissue.

A light therapy unit functions with LED diodes (not to be confused with a diode laser). LEDs can emit pure wavelengths between 400 nm and 700 nm (visible light). After 700 nm the energy moves out of the visible range and into more heat producing thermal effects onto the skin.

Biological Effects of Various Wavelengths – LED

Blue Light 470 nm (visible spectrum)

- Penetrates into follicle
- Destroys acne-causing bacteria
- Removes redness and irritation

Green Light 525 nm (visible spectrum)

- Penetrates to dermal capillary beds
- Decreases melanin production
- Regulating and soothing effects

Yellow Light 590 nm (visible spectrum)

- Absorbed by body fluids; effects lymph and blood circulatory systems
- Promotes wound healing
- Reduces inflammation

Red Light 640 nm (visible spectrum)

- Reduces inflammation
- Absorbed by all tissues, specifically in dermis
- Possesses the most regenerative properties

Laser Safety

Each laser and light facility regardless of its size should establish and maintain an adequate safety program for the control of laser hazards. The employer has the fundamental responsibility for assurance of the safe use of lasers owned and/or operated by the employer or employee.

1. Signage, warning signs shall be conspicuously displayed on all doors entering the treatment room. (Nominal Hazard Zone) Appropriate goggles need to be hung on the door. Sign needs to be removed when laser is not in use.
2. Skin safety, protective measures include non-flammable preps, shielding of tissue, availability of water, non-reflective instrumentation, removal of reflective jewelry.
3. Following infection control procedures and using personal protective equipment when working with bodily fluids, and laser plumes.
4. Electrical safety, proper grounding and insulation.
5. Fire safety, protective measures include fire extinguishers, wet drapes and fire blankets.
6. Laser generated airborne contaminate (LGAC) use of high flow smoke evacuators and vacuum filters. Gases from laser procedures needs to be removed with smoke evacuator systems.
7. All equipment must be maintained according the directions from the manufacturer. Most laser companies DO NOT allow laser operation personnel to open a machine for maintenance. This must be done by a certified company technician.
8. Non-laser personnel should not be in the area of treatment.
9. The person operating the laser is in full charge of the laser room and assisting personnel during the actual laser operation.
10. 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.
11. 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.
12. 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:

13. The switch or a stand by mode 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.
14. An emergency shutoff switch must be available to the operator or assistant to enable the rapid shutdown of equipment.

15. Equipment must be serviced and maintained as recommended by manufacturer to ensure safeguards remain functional.

16. The laser operator should periodically check electrical cords for damage.

17. Check any skin coolant hoses supplied, for wear and any damage.

18. The laser key must not be left in the machine. It should be stored in a safe place.

19. All testing of the laser should be done before the client enters room by staff that is adequately protected.

LASER SAFETY OFFICER

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. **According to the American National Standards Institute (ANSI) Z136.1* The laser safety officer is responsible for:

1. Establishing the laser treatment controlled area.

2. Approving standard operating procedures (SOPs), administrative and procedural controls.

3. Ocular safety, protective eyewear is mandatory and shall be marked with the appropriate wavelength and optical density.

4. Auditing the functionality of control measures periodically to ensure proper operation.

5. Approving the wording on area signs and equipment labels.

6. Assuring adequate safety education and training are provided to laser area personnel.

7. Determining the personnel categories (i.e. laser personnel or incidental personnel) for medical surveillance.

8. Laser personnel are those who work routinely in the laser environment and must be fully protected. It should be supervised and occupied only by trained staff or other authorized persons who are sufficiently protected. Protective eye wear must be worn at all times during laser operation by both the patient and personnel.

9. 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.

10. 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 carry out 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.

FDA Device Classification

FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

* Radiation-emitting Electronic Products

Medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval.

The Food and Drug Administration, Department of Health and Human Services, oversees the regulation of devices for safety and effectiveness, as well as many other responsibilities, which are not covered here.

The FDA has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. Section 510(k) of the Act requires a person who wishes to introduce a device into commerce to notify the Center at least ninety days in advance. This premarket notification is referred to as a "510(k)." The Agency uses 510(k)s to determine if new devices are, or are not, substantially equivalent to another device already cleared to market.

Device Class and Regulatory Controls

1. Class I General Controls
    - With Exemptions
    - Without Exemptions
2. Class II General Controls and Special Controls
    - With Exemptions
    - Without Exemptions
3. Class III General Controls and
    - Premarket Approval

These standards are met by the manufacturer of the device and submitted to the FDA in the form of a 510(k) Summary of Safety and Effectiveness. The device's summary includes the submitter's information, device information, predicate devices, intended use, device description, performance and clinical data, and substantial equivalence. Upon review by the FDA, the device may be given approval to go to market, subject to the general control provisions of the Federal Food, Drug and Cosmetic Act. These provisions include requirements for annual registration, listing of the device, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Laser and light therapy devices fall under the classification name: Laser surgical instrument for use in general and plastic surgery and and dermatology (21CRF 878.4810)

Device classification depends on the intended use of the device and also upon indications for use.

The Meaning of Intended Use

While a new device must have the same 'intended use' as a predicate device in order to be substantially equivalent(SE), the FDA does not require that the new device be labeled the same. Label statements may vary. Certain elements of a predicate device's labeled indication may not be critical to its intended therapeutic, diagnostic, prosthetic, surgical, etc., use. The Center's scientific expertise enables it to exercise considerable discretion in interpreting 'intended uses' in the labeling and promotional materials for predicate and new devices. Thus, a new device with the same intended use as a predicate device may have different specific indication statements, and, as long as these label indications do not introduce questions about safety or effectiveness different from those that were posed by the predicate device's intended use, the new device may be found SE. However, many have misinterpreted to mean that these devices are for medical use only–which is incorrect.

For the purposes of determining whether or not the new device has the same intended use as a predicate device, the Center assesses any difference in label indications in terms of the safety and effectiveness questions they may arise. The Center considers such points as physiological purpose (e.g. removes water from blood, transports blood, cuts tissue), condition or disease to be treated or diagnosed, professional or lay use, parts of the body or types of tissue involved, frequency of use, etc. If a new device is determined to have the same 'intended use', the Center may then proceed to determine whether or not it is substantially equivalent. (Devices which do not have the same intended use cannot be substantially equivalent.)

The classification system is a way to categorize *like* devices and allow marketing of devices when substantial equivalent devices have already received approval. In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

As indicated above all classes of devices as subject to General Controls. General Controls are the baseline requirements of the Food, Drug and Cosmetic (FD&C) Act that apply to all medical devices, Class I, II, and III.

There are currently five laser light devices that have been cleared for consumer use:

a) Flash N'Go (Home Skinnovations, Ltd.) (K082298)
   - Light based hair removal device
   - Class II, Over The Counter Use
b) ABC Hair Removal System, (Palomar Medical Technologies, Inc. (K060839)
   Light Based Hair Removal System
   Class II, Over the Counter Use
c) SpaTouch® PhotoEpilation System, (Radiancy Ltd.) (K020856)

Pulsed Light Hair Removal System
Class II, Prescription Use

d) Silk'n , (Home Skinnovations, Ltd.) (K072906)
- Light based hair removal device
- Class II, Prescription Use

e) Spectra Hair Removal Laser System, (SpectraGenics, Inc.)
- Pulsed Diode Laser
Class II, Over the Counter Use

f) TRIA Laser Hair Removal System (TRIA Beauty, Inc. (K090820)
- Pulsed diode laser
- Class II, Over the Counter Use

Laser Hazard Classes

The Food and Drug Administration (FDA) also recognizes four major hazard classes (I to IV) of lasers, including three subclasses (IIa, IIIa, and IIIb). The classes are based upon a scheme of graded risk. They are based upon the ability of a beam to cause biological damage to the eye or skin. In the Federal Laser Product Performance Standard (FLPPS), the classes are established relative to the Accessible Emission Limits (AEL) provided in tables in the standard. In the American National Standards Institute (ANSI) specifically the ANSI Z 136.1 standard, the AEL is defined as the product of the Maximum Permissible Exposure (MPE) level and the area of the limiting aperture. The higher the class the more hazardous the laser. The labeling for Classes II -IV must include a warning symbol that states the class and the output power of the product.

State Regulatory Board Oversight

It is up to each state regulatory board that oversees licensees to determine who can use laser and light therapy devices. Some states have limited use of lasers and light therapy to physicians only. Yet other states allow estheticians who are under medical supervision to use them, and a few states have now included laser and light therapy training in the esthetician curriculum. Some states are now requiring certification or credentialing that include a mandatory number of hours of training prior to operating a laser. Anyone operating a laser or light therapy device should be thoroughly educated, trained and/or certified and understand the physics and biological effects.

Medical Supervision & Corporate Practice of Medicine

Many states have not yet defined 'medical supervision' in their statutes or rules. The interpretation of medical supervision can mean anything from a physician available by telephone to being physically in the same office.

If 'medical supervision' becomes a state requirement for use of laser and light therapy devices, it could mean that the esthetician would more than likely, have to become an employee of the physician.

The corporate practice of medicine is a legal doctrine, which generally prohibits corporations, entities or individuals from practicing medicine. This would also prohibit lay entities (estheticians, salons/spas, etc) from hiring a physician to work as a medical director or provide 'medical supervision.'

The advice of a health attorney to explore these legal issues in your state is recommended prior to purchase of a laser or light therapy device.

NCEA's Equipment Evaluation Form

Equipment Identification and Information

Name of equipment:

Type of equipment:

Model number:

Price:

What is the manufacturers' Intended Use Statement'?

Company profile information:

Sales Contact Information:

Name:

Address:

City: State: Zip:

Tel:

Fax:

Email:

Website:

Length of time in business:

Distributor Contact Information:

Name:

Address:

City: State: Zip:

Tel:

Fax:

Email:

Website:

Length of time in business:

Registrations/Certifications

Is the manufacturer registered with the FDA?

If yes, what is the registration number?

Is the equipment registered with the FDA?

If yes, what is the registration number and class?

Is the device registered with the state, if required?

Safety Considerations and Equipment Specifications

What safety certifications does this equipment have (i.e. UL, CSA, CE)?

What kind of power source does the equipment require?

Does the manufacturer carry liability insurance on this equipment?

Is a certificate of insurance available?

Does the equipment have any cross-contamination safeguards, if applicable?

What are the contraindications for use of this equipment?

If purchasing a used device,

a) What was the date of the last preventative maintenance?

b) Is the preventative maintenance report available?

Warranty and Service Policies

What are the terms of the warranty?

Is there an extended warranty available?

Is there an additional cost?

Do you have an equipment loaner program?

Are references available?

Training and Education

What type of training is included with purchase?

Where? Total hours?

Who are the educators?

Is there an additional cost?

Skin care professionals are required to check in their state as to whether training on the use of equipment is required prior to purchasing, and/or if they can use device under their scope of practice.

Self Assessment Exercise 2

1. The bigger the size the greater the _____.
2. What is the effect of the laser dependent upon?
   a) Pulse width
   b) Type of tissues
   c) Diameter of beam
   d) All of the above
3. List two biological effects for each of the the following wavelengths:

   Blue light _____
   _____

   Green light _____
   _____

   Yellow light _____
   _____

   Red light _____
   _____

4. FDA's Laser Hazard Classifications are based upon:
   a) Ability of a beam to cause biological ocular or skin damage
   b) Permissible radiation exposure
   c) Four major hazard classes including three subclasses
   d) None of the above
5. The precise targeting of a tissue structure for the purpose of destruction is called _____.
6. Purchase of used laser equipment should include a _____ _____ report.
7. Classes II -IV must include a warning symbol that states the class and the output power of the product. True or False

Client Medical & Lifestyle History, Consultation, Documentation and Skin Evaluation

I. Client History

A. The skin care professional should take a client history of conditions related to the receiving of laser and light therapy procedures. Relevant topics include but are not limited to, irritant/allergic reactions, Herpes Simplex Virus (cold sore) predisposition, frequency of sun exposure or tanning bed use, topical and/or oral medications (prescription and over-the-counter) all of which may increase an individual's susceptibility to adverse reactions. Particular attention should be paid to the use of topical prescription retinoids and use of AHAs, BHAs, and other chemical exfoliants (enzymes, proteolytic).

B. An in depth consultation should always be performed prior to the first laser or light therapy treatment with a review and update of information prior to each subsequent treatment.

II. Review of Forms

A. Client Consultation Form

B. Client Medical and Lifestyle History Form

C. Treatment Documentation Form

Specific, detailed documentation of initial and all subsequent treatments in this form includes:

1. Settings
2. Number of pulses
3. Client response to treatment
4. Next return for treatment
5. Pre treatment regimen
6. Use of ice or gel sheeting
7. Use of chiller
8. Use of anesthetic cream
9. Skin care professional's name
10. Test spot documentation

Study Objectives

Highlight/underline the answers to the following questions as you read:

22. What relevant topics should be included in a client history?
23. When should a consultation be performed?
24. What scale determines UV sensitivity?
25. List 8 precautions to treatment?
26. What are 4 indications for a skin rejuvenation treatment?
27. What pretreatment requirements does the client need to follow ?
28. What are 4 post treatment recommendations?
29. What is paramount to performing treatments effectively?
30. What does a laser operator need to comprehend to make accurate treatment choices?

11. Notation of treatment reaction if applicable

12. Area treated

13. Photographs taken

D. Informed Consent and Signed Release Form

Written documentation signed by the client that the skin care professional has taken a client history, performed a skin evaluation and discussed the planned procedure and post treatment home care, i.e. avoidance of direct sun exposure, use of sunscreen, etc.

III. Client Expectations

A. Address client questions, concerns and expectations.

B. Set short and long term goals.

IV. Detailed Skin Evaluation

A. Wood's Lamp/Skin Analysis Device

1. Pigmentation evident to the naked eye but that disappears under a Wood's Lamp/skin analysis device is generally seated in the epidermis and will respond favorably to some laser and light therapy treatments.

2. The best results will be achieved when used in combination with home use of tyrosinase-inhibitors and skin lightening/brightening products.

B. Fitzpatrick's Skin Type Classification

presents a useful scale to determine sensitivity levels based on pigmentation and sensitivity to UV radiation exposure.

C. Clogau Classification Chart of Photo

Age Groups is an ideal method for managing client's expectations while educating them as to problems associated with future UV radiation exposure.

Precautions and Contraindications to Treatment

I. Precautions to Treatment

A. History of sun exposure and/or tanning bed use.

B. History of irritant/allergic reactions/compromised barrier function.

C. Herpes Simplex Virus (cold sore) disposition.

D. Previous chemical and/or mechanical exfoliation procedures and outcome.

E. History of topical medications, i.e. Tretinoin: Retin-A™, Renova™ (Ortho Dermatological), Avita™(Bertek), Altinac™ (Upsher-Smith), Solage™ (Galderma).

F. History of oral medications, i.e minocyline, erthromycin, isotretinoin, hormone replacement therapy, birth control methods.

G. History of skin cancer.

H. Previous facial plastic or reconstructive surgery.

I. Current skin care product usage.

J. Client expectations.

K. Clients taking oral anti-coagulants (blood thinners).

L. Tattoos and permanent cosmetics.

M. Avoid raised moles, skin tags, keloids and scars less than six months old.

N. Vitiligo.

II. Contraindications to Treatment

A. Current isotretinoin users (must be off medication for at least one year). Isotretinoin: Amnesteem™ (Bertek Pharmaceuticals), Sotret® (Ranbaxy Pharmaceuticals, Inc.).

B. History of seizures.

C. Any type of dermatitis including eczema, psoriasis and seborrhea.

D. Viral lesions including herpes simplex virus (cold sore), impetigo, warts.

E. Opened or unidentified skin lesions.

F. Sunburn.

G. Clients who are exposed to sunlight on a regular basis, i.e. sunbathe, play sports or work outdoors.

H. Autoimmune diseases (lupus and scleroderma).

I. Bacterial (impetigo, cellulite, boils).

J. Fungal (tinea versicolor).

K. Parasitic (scabies).

L. Cancer/Skin Cancer.

M. Uncontrolled diabetes (poor healing prone to infection).

N. Anyone receiving radiation, chemotherapy for cancer or related conditions.

O. Pregnant and or lactating women.

Indications for Treatment

I. Indications for Treatment and Mechanisms for Action

A. Hair Removal

1. All areas except eyebrows, moles and suspicious lesions.
2. Light hair colors respond with variations in outcome.

B. Skin Rejuvenation

1. Hyperpigmentation
2. Telangiectasia
3. Rosacea
4. Fine lines and wrinkles
5. Skin laxity
6. Texture
7. Acne and surgical scar revision
8. Actinic keratosis
9. Seborrhea keratosis
10. Other

C. Vein Treatment

1. Spider veins
2. Vessels 1 - 2 mm

D. Tattoo Removal

E. Acne Prone Skin

F. Psoriasis

G. Body Contouring

H. Other

Pre Treatment Protocol

I. Pre Treatment Preparation of the Skin

A. Stop using three days prior to treatment or as per manufacturer's recommendation:

1. Alpha and beta hydroxy acids.
2. Benzoyl peroxide.
3. Tretinoin and retinols.
4. Enzymes.
5. Adapalene.
6. Azaleic acid.
7. Other

B. Follow prescribed home care regimen including sunscreen.

C. No sunbathing, use of tanning beds or tanning products. No prolonged direct sun exposure for four weeks prior to treatment.

D. No waxing, electrolysis, or depilatory use for four weeks prior to treatment.

E. Remove all products prior to treatment.

F. Shave prior to treatment.

G. Do not exercise for 24 hours after tx.

Laser and Light Therapy Treatment Protocol

I. Steps in Procedure

A. Complete Client Consultation and Obtain Informed Consent and Signed Release Form.

B. Preparation and Procedure. This time can be used for manufacturer's demonstrations of various laser and light therapy procedures.

Post Treatment Protocol

I. Post Treatment

A. Cool compress after treatment. (if applicable)

B Use aloe or soothing products as per manufacturer's recommendation.

C. Apply and instruct on continuation of use of non irritating sunscreen if client leaves in daylight hours.

D. Provide client with a list of post treatment product recommendations.

II. Recommendations

A. For 24 hours avoid extreme exercise or anything else that might cause extreme temperature fluctuations.

B. Use tepid water; do not use hot or cold water, avoid extreme temperatures for initial 24 hours.

C. No unprotected sun exposure.

D. No exfoliation for five days following treatment.

E. No waxing, electrolysis, or depilatory use for one week following final treatment.

D. Advise client of what to expect and what to report to the skin care professional.

Recommended Home Care

I. Recommendations for Post Treatment Home Care

A. Provide client with a list of post treatment instructions and product recommendations.

Client Follow-up

I. Frequency of treatments.

II. Side Effect, problems or concerns.

III. Outcomes from the treatment.

Summary

The advancement of lasers and light therapy devices continue to flood the marketplace. State regulatory boards that oversee estheticians using these devices need to update scope of practice and curriculums. While this section may have covered many of the essentials regarding laser and light therapy devices, the esthetician must be aware that education and practice is paramount to understanding how to perform treatments effectively and safely.

A laser operator needs to comprehend electricity, physics, safe operation, and the differences between each device's Indication for Use. Obtaining a solid foundation of theoretical and practical knowledge will help you to make accurate treatment choices. These devices can provide valuable tools for estheticians to obtain remarkable results for the improvement of numerous skin conditions.

Self Assessment Exercise 3

1. A client history should contain:
   a) History of allergies
   b) Herpes predisposition
   c) Medication history
   d) All of the above.
2. An informed consent and signed release should be done every treatment.
   True or False?
3. List 5 details that should be documented in the treatment notes:

   _____ _____ _____
   _____ _____
4. Fitzpatrick Skin Type Classification is a useful scale used to determine:
   a) Allergic reactivity
   b) Aging in relation to UV exposure
   c) Sensitivity to UV exposure
   d) Tyrosinase-inhibitors
5. Contraindication to treatment means you can do the treatment, just be careful.
   True or False?
6. A Wood's Lamp provides evidence of:
   a) vascularity
   b) location of pigment
   c) collagen content
   d) dermatitis
7. List four indications for treatment with laser or light therapy:

   _____ _____
   _____ _____