DEXCOM'S LASER AND RADIATION SAFETY PROGRAMS

February 2021

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AGENDA

1. Background on Lasers
2. Laser Classification
3. Bioeffects
4. Safety Controls
5. Background on Radiation
6. FAQs

BACKGROUND ON LASERS

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WHAT IS A LASER?

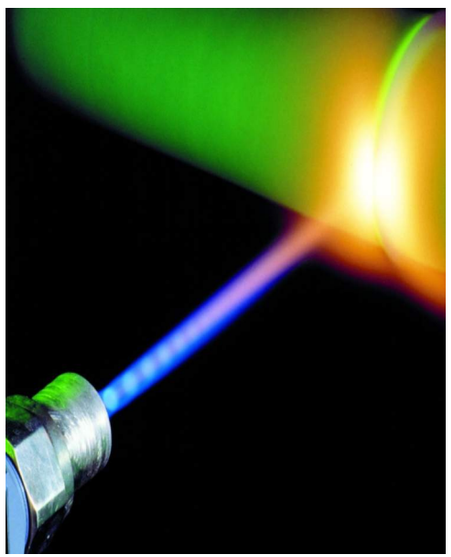
L = Light

A = Amplification

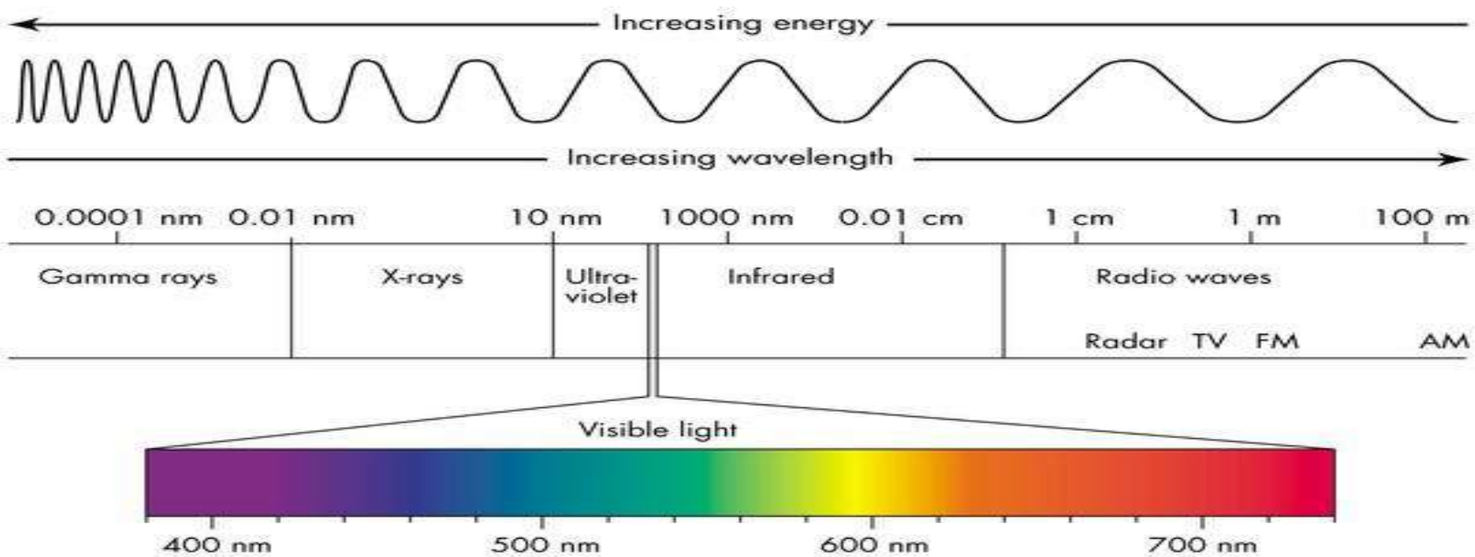
S = by Stimulated

E = Emission

R = of Radiation



Electromagnetic Spectrum



The Optical Spectrum

- Ultra-violet (100-400nm)
- Visible (400-700nm)
- Infrared (700nm-0.1cm)

LASER SAFETY STANDARDS AND GUIDELINES

- American National Standards Institute, Inc. (ANSI)
  - ANSI z136.1: Safe Use of Lasers

- Occupational Safety and Health Administration (OSHA)
  - OSHA 29CFR1910 (132, 133, 134 and 147)
  - General Duty Clause (Section 5(a) of the OSH Act of 1970)

- Food and Drug Administration (FDA)
  - 21 CFR Subchapter J- Radiological Health
    - Any laser system that has a power output of greater than 5mW MUST be registered with the Food and Drug Administration (FDA) and the Center for Devices and Radiological Health (CDRH) if it has an exposed beam.
    - The Laser Product Report must be prepared, in accordance with the requirements of the CDRH, and the documentation that certifies compliance with all regulatory requirements must be attached.
    - Annual Reports must also be conducted by the manufacturer to ensure device meets CDRH requirements.

- California Department of Public Health- Radiological Health Branch

LASER CLASSIFICATION

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LASER CLASSIFICATION

All lasers are classified by the manufacturer and labelled with the appropriate warning labels. Any modifications of an existing laser or an unclassified laser **must be classified by the Laser Safety Officer** prior to use.

The following criteria are used to classify lasers

1. Wavelength.
2. For continuous wave (CW) or repetitively puled lasers, the average power output (Watts) and limiting exposure time inherent in the design.
3. For pulsed lasers, the total energy per pulse (joule), pulse duration, pulse repetition frequency and emergent beam radiant exposure are considered

NOTE: It is not the laser itself that is given a class number, but the whole system.

CLASS 1

Safety Hazard

- Safe during normal use
- Incapable of causing injury

- Low power or enclosed beam

Label Requirements

- Label not required
- May be a higher class during maintenance or service

Example

- CD/DVD Player/Laptop or Personal Computer

CLASS 2 & 2M

Safety Hazard

- Staring into beam is an eye hazard
- Because of normal aversion responses, (blinking) does not normally present a hazard

- Visible lasers only

Power Output

- Less than 1mW

Label Requirements

- Caution
- The wavelength of emission
- Category of laser
- Laser symbol

Class 2 Laser

Class 2M Laser

Example

- Presentation Laser Pointer, Barcode Reader

CLASS 3R

Safety Hazard

- Aversion response may not provide adequate eye protection
- Injury to the eye if viewed momentarily
- A hazard if viewed using collecting optics (magnifier or telescope)

- CDRH includes visible lasers only
- ANSI includes invisible lasers

Power Output

- 1mW - 5mw

Label Requirements

- Danger
- The wavelength of emission
- Category of laser
- Laser symbol
- Avoid direct eye exposure

Example

- Some Measuring and Targeting Devices, Higher Power Pointers

CLASS 3B

Safety Hazard

- Skin and eye hazard if viewed directly.
- Visible or invisible

Power Output

- 5mW – 500mW (0.5W)

Label Requirements

- Danger
- The wavelength of emission
- Category of laser
- Laser symbol
- Avoid direct exposure to beam

Example

- Higher power laser products intended for professional applications

CLASS 4

Safety Hazard

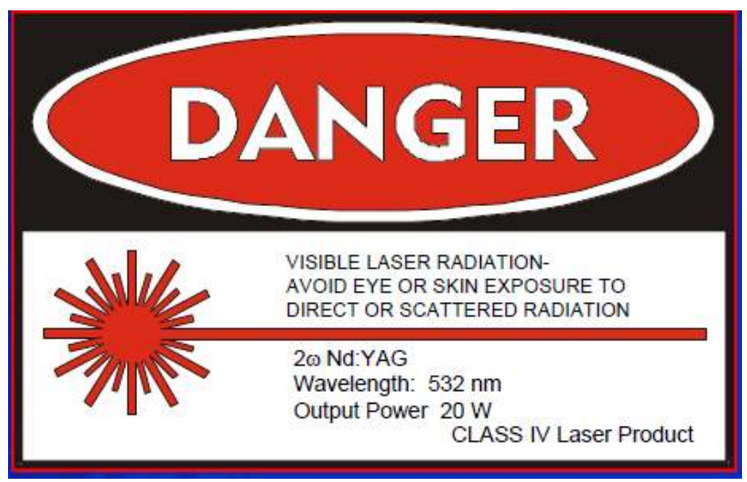
- Exposure to direct beam and scattered light is eye and skin hazard.
- Visible or invisible

Power Output

- Greater than 500mW (0.5W)

Label Requirements

- Danger
- The wavelength of emission
- Category of laser
- Laser symbol
- Avoid direct eye or skin exposure to direct or scattered radiation



Example

- Medical Lasers, Industrial Cutting/Welding, Scientific Applications and most Laser Light Show Equipment

BIOEFFECTS

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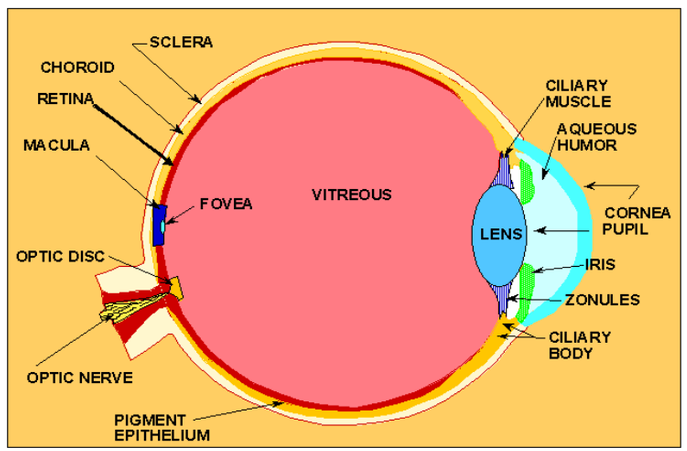
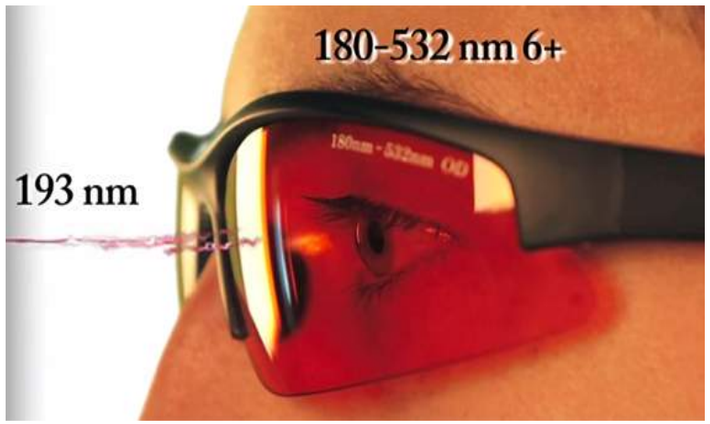
BIOEFFECTS- EYES

- Retinal Injury
  - *Photoretinitis*
  - *Retinal Burns*
- Corneal Injury
  - *Photokeratitis*
  - *Corneal Burns*
  - *Superficial Injury*
  - *Deep Burns*





- Personal Protective Equipment (PPE)
  - Eye protection is mandatory for class 3B and class 4 lasers
  - Contact LSO for assistance in selecting protective eyewear

BIOEFFECTS- SKIN

- Skin Injury
  - *UV Sunburn*
  - *UV Delayed Effects*
  - *Thermal Skin Burns*

Laser damage can be:
- Thermal
- Acoustic

- Engineering Controls
  - Beam shields
- Personal Protective Equipment (PPE)
  - Skin Covers and/or “sunscreen” creams are recommended
  - Tightly woven fabrics, laboratory jackets and opaque gloves

BIOEFFECTS- NON-BEAM HAZARDS

- Non-beam hazards do not result from direct human exposure to a laser beam.
- These hazards are from subsequent exposure of a material to a laser beam or are associated with
  - Components of a laser system
  - Materials used to generate the laser beam
  - How and where the laser system is used

- Non-beam hazards can be:
  - Electrical- *most common*
  - Fire
  - Noise
  - Collateral Radiation
  - Plasma Radiation
  - Explosion
  - Ergonomics
  - Mechanical hazards associated with robotics
  - Compressed Gases
  - Cryogenics
  - Laser Dyes and Solvents
  - Laser Generated Airborne Contaminants

SAFETY CONTROLS

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SAFETY CONTROLS- ENGINEERING

Devices that are incorporated into the laser systems and are designed to limit the potential for accidental exposure to the laser beam

- Beam Housings
- Shutters
- Attenuators
- Remote viewing devices
- Interlocks/Twist-lock receptacles
- Emergency Disconnects
- Key control

SAFETY CONTROLS- ADMINISTRATIVE

Methods or instructions which specify operating procedures and rules that supplement engineering controls

- Warning signs
- Labels
- Standard Operating Procedure (SOPs)
- Education and Training
- Security
- Authorized Personnel

SAFETY CONTROLS- PERSONAL PROTECTIVE EQUIPMENT

- And as a last resort- PPE can be used to control harmful effects of radiation. PPE can include eye wear fitted for the proper wavelength, gloves and viewing devices.
- When stocking PPE you want to remember to stock enough for users and visitor and store them in an easily accessible area

- Eyewear
  - Proper wavelength
  - Enough for users and visitors
  - Centrally stored
- Gloves
- Viewing Devices

BACKGROUND ON RADIATION

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EXPOSURE TO RADIATION

External

- All or part of the body is exposed to penetrating radiation.
- Some is absorbed by the body and some passes completely through
- You will not become radioactive!

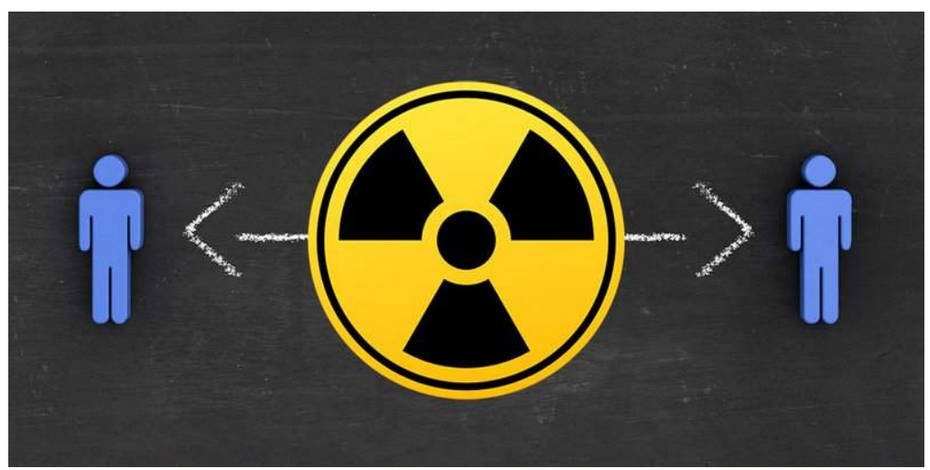
Internal

- Radioactive material can enter the body through
  - Injection
  - Inhalation
  - Injection
  - Absorption
- Two ways to remove radioactive materials
  - Biological clearance
  - Radiological decay

Regulatory Limits:

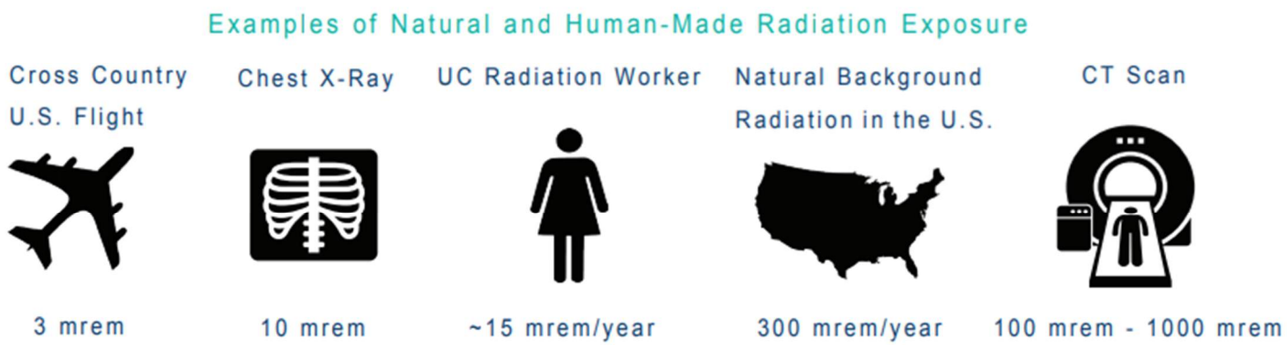
- Whole Body- 5,000 mrem per year
- Extremity- 50,000 mrem per year
- Lens of eye- 15,000 mrem per year
- Fetus- 500 mrem/gestation period

*Remember ALARA- As Low As Reasonably Achievable

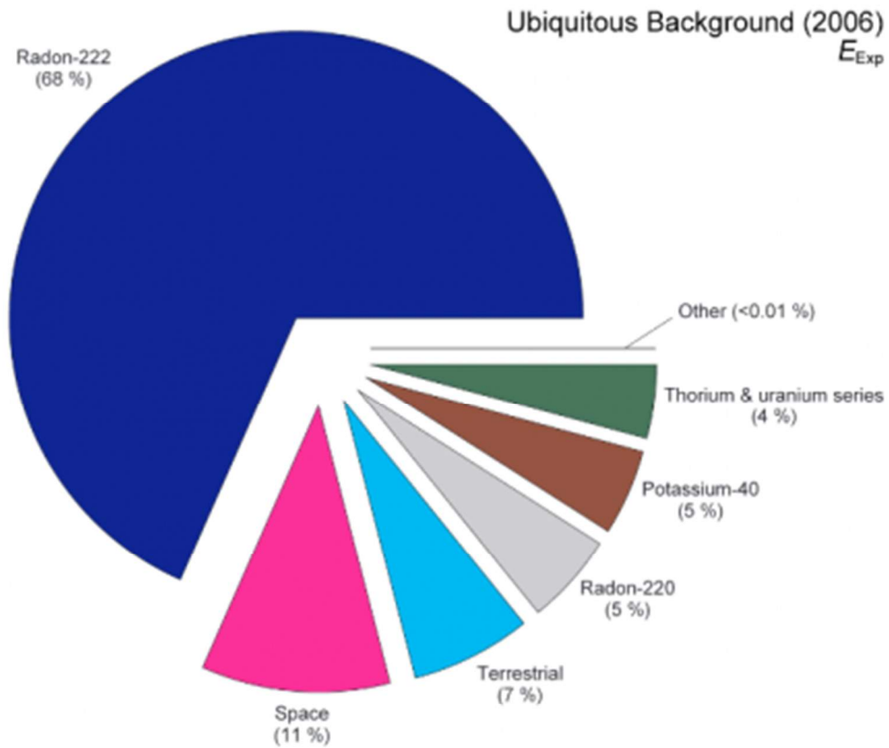


BACKGROUND RADIATION

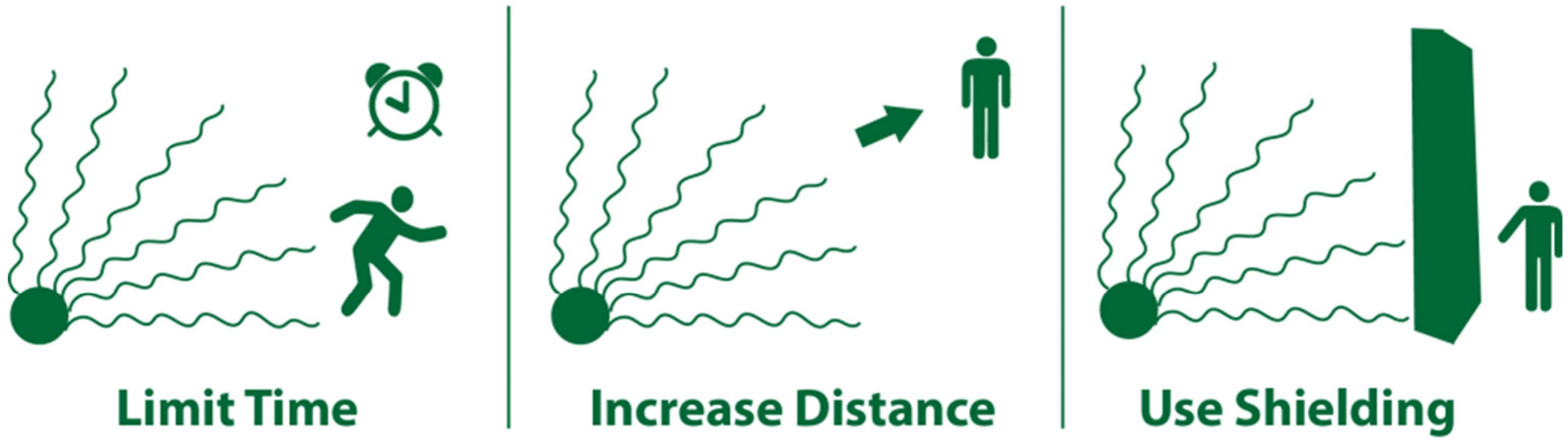
- Everyone is routinely exposed to naturally occurring background radiation.
- Radiation can be found in the sun and stars, rocks and soil, and radon gas from the earth.



Percentages of background radiation dose received annually from natural sources



THREE BASIC ELEMENTS CAN REDUCE OR ELIMINATE RADIATION EXPOSURE

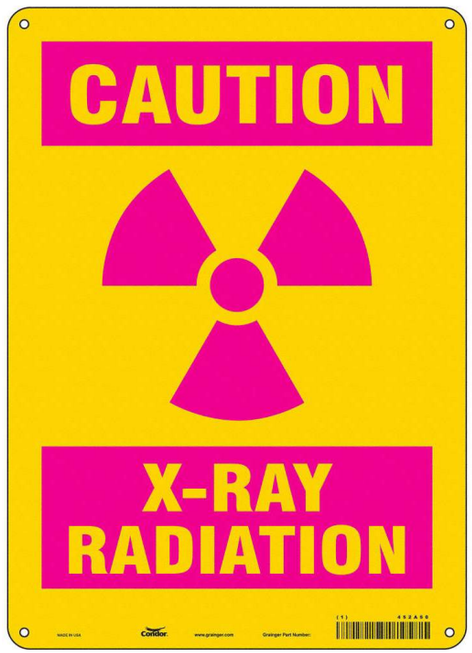


Time spent in room with radiation emitting devices

Physical distance between you and the radiation emitting device

Barriers placed between the individual and the source of radiation

POSTING, LABELING AND ACCESS CONTROL



- The tre-foil is the internationally recognized symbol for identifying radiation hazards.
- All rooms where radioactive materials and radiation producing machines are used or stored are posted with this warning symbol
- The authorized radiation use areas will be controlled via employee badge access

QUESTIONS/CONCERNS

For questions or concerns

Contact Sandra Bitowft via email at Sandra.Bitowft@dexcom.com

FAQS

1. **Why are lasers uniquely hazardous?**
   - Two characteristics of laser light contribute to the hazard:
     - Laser light can be emitted in a tight beam that does not grow at a distance from the laser. This means that the same degree of hazard can be present both close to and far from the laser.
     - The eye can focus a laser beam to a very small, intense spot on its retina, which can result in a burn or blind spot.
2. **Is the brightness of the laser light a good indicator of its power and eye hazard?**
   - NO! Never assume the color brightness of a laser beam indicates its power.
   - In lighted conditions (indoors or outdoors), a beam from a powerful laser can appear to be the same brightness or dimmer than the beam of a less powerful laser.
3. **What is the FDA's role in regulating lasers?**
   - The FDA regulates both medical and non-medical lasers.
   - The FDA may inspect manufacturers of laser products and require the recall of products that don't comply with federal standards or that have radiation safety defects.
4. **Does laser radiation cause cancer?**
   - Some lasers emit radiation in the form of light. Others emit radiation that is invisible to the eye, such as ultraviolet or infrared radiation.
   - In general, laser radiation it not in itself harmful, and behaves much like ordinary light in its interaction with the body.
   - Laser radiation should not be confused with radio waves, microwaves, or the ionizing x-rays or radiation from radioactive substances such as radium