Medical Laser Product Compliance

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Objectives

- Laser in Medical Applications
- Type Of Medical lasers
- Laser Class and Hazard
- Laser Classification Responsibilities
- Laser Product Compliance Schemes
- Factors and conditions affecting Laser Classification
- Classification Criteria
- Laser Controls
Laser in Medical Applications

• **Cosmetic dermatology:**
  ➢ scar revision, skin resurfacing, laser hair removal, tattoo removal

• **Ophthalmology:**
  ➢ Cleaning vision complication after cataract surgery or Lasik
  ➢ Refractive surgery to correct vision or Reattaching detached retinas
  ➢ Treatment of diabetic retinopathy to forestall blindness

• **Dentistry and oral surgery**

• **Surgery and plastic surgery**

• **Cancer diagnosis and treatment**
Type Of Medical lasers

❖ Based upon the intensity of emission radiation

1. **Soft Laser - Class I (0.5 mW) or Class II (1 mW)**
   ➢ Weak emission and acts on the surface (e.g. dermatology)

2. **Mild Laser – Class IIIa (1 – 5mW) or Class IIIb (5 – 500mW)**
   ➢ Medium emission and uses for treatment of deeper tissues (e.g. Scanning)

3. **Power Laser – Class IV (> 500mW)**
   ➢ Strong emission and uses in surgery (e.g. cut, coagulate, evaporate tissues)
Laser Class

The class of a laser product indicates to the user of the potential of the accessible laser radiation for causing injury.

<table>
<thead>
<tr>
<th>CLASS</th>
<th>US: FDA/CDRH</th>
<th>IEC 60825 (AMENDMENT 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1</td>
<td>• No known hazards during to eye or skin <em>during normal operation</em> &lt;br&gt; • Note: Service Operation may require access to hazardous embedded lasers</td>
<td>• No known hazards to eye or skin, unless collecting optics are used</td>
</tr>
<tr>
<td>Class 1M</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Class 2a</td>
<td>• Visible lasers not intended for viewing. &lt;br&gt; • No known hazards up to maximum exposure time of 1000 seconds</td>
<td>N/A</td>
</tr>
<tr>
<td>Class 2</td>
<td>• Visible lasers &lt;br&gt; • No known hazard with 0.25 seconds (aversion response)</td>
<td></td>
</tr>
<tr>
<td>Class 2M</td>
<td>N/A</td>
<td>• No known hazard with 0.25 seconds (aversion response) unless collecting optics are used</td>
</tr>
<tr>
<td>Class 3a</td>
<td>• Similar to Class 2 with the exception that collecting optics cannot be used to directly view the beam &lt;br&gt; • Visible only</td>
<td>N/A</td>
</tr>
<tr>
<td>Class 3R</td>
<td>N/A</td>
<td>• Replaces Class 3a (with different limits) &lt;br&gt; • 5 x Class 2 limit for visible &lt;br&gt; • 5 x Class 1 limit for some invisible</td>
</tr>
<tr>
<td>Class 3B</td>
<td>• Medium-powered (visible or invisible) &lt;br&gt; • Intrabeam and specular eye hazard &lt;br&gt; • Generally not a diffuse or scatter hazard &lt;br&gt; • Generally not a skin hazard</td>
<td></td>
</tr>
<tr>
<td>Class 4</td>
<td>• High powered lasers (visible or invisible) &lt;br&gt; • Acute eye and skin hazard intrabeam, specular and scatter conditions &lt;br&gt; • Non-beam hazard (fire, toxic fumes, etc.)</td>
<td></td>
</tr>
</tbody>
</table>
Laser Class hazard

Eye injury hazard

- **Low**
  - Class 2: 0-1 mW
  - Class 3R: 1-5 mW

- **Medium**
  - Class 3B: 5 - 500 mW

- **High**
  - Class 4: 500 mW+

- **Severe**

Power, milliwatts

Nemko
Classification Responsibilities

❖ Manufacturers:

➢ Specify the application the laser product.
➢ Determine the effective class of the laser product.
➢ Provide correct classification of a laser product.

❖ Test Agencies (e.g. CSA, UL, TUV, Intertek, etc)

➢ Perform evaluation to determine the effective class of the laser based on the level of its accessible emission in accordance with IEC 60825-1 and may be also with IEC 60601-2-22.
➢ Issue IEC test report and certificate upon manufacturer’s request.
Laser Product Compliance Schemes

❖ FLPPS/CDRH 21 CFR 1010 and 1040
  ➢ For countries that recognize U.S. FLPPS. This should be considered once the laser product is only sold in U.S.

❖ IEC 60825-1
  ➢ For countries that recognize IEC 60825 series. This should be considered once the laser product is only sold in Europe.

❖ IEC 60601-2-22
  ➢ Class 3B and Class 4 medical laser products (e.g. surgical, therapeutic, medical diagnostic, cosmetic)
    ➢ Class 3B or Class 4 laser products for veterinary applications.
Laser Product Compliance Schemes (cont.)

❖ FLPPS/CDRH + Laser Notice # 50

➢ For international market. This scheme should be considered. It meet requirements for all countries that have national standards.

➢ IEC 60825-1 Ed. 2 and IEC 60601-2-22 Ed. 3 are the alternative method for meeting FDA/CDHR requirements.

❖ FLPPS/CDRH + Laser Notice # 56

➢ FDA has not harmonized the requirements of 21 CFR Part 1040 through rulemaking with those of the IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 standards.

➢ IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 are not the alternative method for meeting FDA/CDHR requirements.
Classification - General

❖ The class of a laser product gives an indication to the user of the potential of the accessible laser radiation for causing injury.

❖ Classification of a laser product is based on:

➢ Determination of the accessible emission level and comparison of that level with the accessible emission limit (AEL) associated with each class.
➢ The maximum level of laser radiation that is accessible during conditions of normal operation.
➢ The evaluation for determining classification shall include consideration of any reasonably foreseeable and Single-fault condition during operation.
Factors affecting Laser Classification

- Wavelength
- Continuous Wave or Pulsed Operation
- Power or Pulse Energy
- Repetition Rate (PRF)
- Beam Divergence
- Beam Diameter and Profile
Conditions affecting Laser Classification

• **In normal operation**
  - Start-up
  - stabilized emission
  - shut-down of the laser

• **In maintenance and service**
  - configuration that operation may require removal of portions of the protective housing and defeat of safety interlocks.
Classification Criteria

- Classification of the accessible emission radiation based on:
  - Combination of Output power and wavelength and time base.

- Continuous wave (CW) or repetitively pulsed laser
  - The average power output (Watts)
  - limiting exposure time (sec)

- Pulse Lasers
  - The total energy per pulse (Joule)
  - pulse duration
  - pulse repetition frequency
  - Emergent beam radiant exposure
Laser Controls

❖ Engineering

➢ Protective Housings
➢ Remote Interlocks / Interlocked doors
➢ Access Panels
➢ Master key Switches
➢ Enclosed beam baths
➢ Beam attenuators/stops
➢ Activation warning system
Laser Controls (continued)

❖ Documentation

➢ Accompanying document – operational manual or user manual
➢ Standard Operating procedures
➢ Maintenance procedures
➢ Administrative procedures
➢ Alignment procedures
Laser Controls (continued)

- Labelling per IEC 60825-1: 2007 (2nd Edition)
  - CLASS 1 LASER PRODUCT
  - LASER RADIATION DO NOT EXPOSE USERS OF TELESCOPIC OPTICS CLASS 1M LASER PRODUCT
  - LASER RADIATION FOLLOW INSTRUCTION CLASS 1C LASER PRODUCT

Laser Controls (continued)

- Labelling per IEC 60825-1: 2007 (2nd Edition)

-LASER RADIATION
DO NOT STARE INTO BEAM
CLASS 2 LASER PRODUCT

-LASER RADIATION
DO NOT STARE INTO BEAM
OR EXPOSE USERS OF
TELESCOPIC
CLASS 2M LASER PRODUCT

Laser Controls (continued)

- Labelling per IEC 60825-1: 2007 (2nd Edition)

    ![Laser Radiation Label]

    ![Warning - Laser Radiation Label]


    ![Alternative Laser Label 1]

    ![Alternative Laser Label 2]
Laser Controls (continued)

- Labelling per IEC 60825-1: 2007 (2nd Edition)

Thank you!

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