Update to Amendments to the Laser Rule

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History

- The current laser performance standard, last updated in 1985, (laser rule) is based on an outdated understanding of photobiological science and no longer reflects the current state of a technologically-evolving industry.
- In 2013, FDA proposed amending its regulations applicable to laser products (21 CFR Subchapter J) in order to update its standard.

History

- Through this action, FDA intended to better harmonize its standard applicable to the laser industry with the then current International Electrotechnical Commission (IEC) 60825-1 standard for the safety of laser products.
- The proposed amendments were posted in the Federal Register (Vol. 78, No. 121, Docket FDA-2011-N-0070) on June 24, 2013.
- FDA received 40 comments on its proposed rule.

History

- The relevant IEC standards have since been amended:
  - IEC 60601-2-22 Medical electrical equipment—Part 2-22 (IEC 60601-2-22:2012)
  - IEC 60825-1 Safety of laser products--Part 1(IEC 60825-1:2014)
  - IEC 62471-5 Photobiological safety of lamps and lamp systems – Part 5 (IEC 62471-5:2015)
- The International Commission on Non-Ionizing Radiation Protection (ICNIRP) revised "Guidelines on Limits of Exposure to Incoherent Visible and Infrared Radiation," (ICNIRP:2013)
- The American National Standards Institute (ANSI) made changes to Safe Use of Lasers, Maximum Permissible Exposure levels (ANSI Z136.1:2014)

Re-Proposed Amendments

- Since 2013, FDA has been in the process of drafting a re-proposed amendment. Numerous changes have been included (see details in the briefing materials).
- Topics in **bold type** will be discussed further in the Laser LiDAR, Remotely Controlled Mobile Laser Products, and Laser Pointers presentation.

Re-Proposed Amendments

Adds/Defines:

- IEC Classes 1C, 1M and 2M.
- Finished laser product.
- Installed laser product.
- Laser illuminator.
- Laser-illuminator image projector.
- **Laser (or Light) distance and ranging.**
- **Laser pointer.**
- **Laser rangefinder or speed detector (speedometer).**

Adds/Defines:

- Non-laser product.
- **Remotely controlled mobile laser product.**
- Electric toys (if laser products).
- Certain 1M, 2M, 3B and 4 class limits for specific purpose laser products.

Defines:

- Maximum Permissible Exposures (MPE) as U.S.-based ANSI MPEs.

Re-Proposed Amendments

Adopts:

- Portions of the latest IEC medical equipment and laser safety standards.
- Portions of the IEC lamp standard.

References:

- ICNIRP radiation limits.
- ANSI Maximum Permissible Exposure Levels.

Improves:

- Children's toy laser product definition.
- Removable laser systems definition.

Refines:

- Laser product definition.

Modifies:

- Surveying, leveling or alignment definition.

Re-Proposed Amendments

Retains:

- Collateral radiation definition and x-ray radiation limit.
- Demonstration laser definition.
- Laser radiation definition.
- Useful life testing requirement.
- Requirement for fail-safe or redundant interlocks.

Retains:

- Emission indicator function prior to emission requirement.

Limits:

- **Laser pointers to exclude certain wavelengths to decrease flash-blinding.**

Excludes:

- Certain non-applicable IEC definitions.

Re-Proposed Amendments

Excludes:

- IEC subclause covering products designed to function as conventional lamps.

Adopts:

- All IEC Accessible Emission Limits (AELs).
- Certain IEC Medical equipment standard clauses.

Requires:

- Additional warning label for 1M and 2M laser products.

Rejects:

- IEC's allowance for no remote interlock connector for handheld battery powered Class 3B laser systems.

Clarifies / Adds:

- "Incorporation" in context within laser product definition.
- Children's toy laser product failure is due to disassembly or breakage.

Re-Proposed Amendments

Clarifies / Adds:

- Laser illuminated projectors (LIPs) as demonstration laser products, qualifying and test conditions, and risk group limits.

Requires:

- **Specific controls for remotely controlled mobile laser products.**

Removes:

- FDA's non-adoption of single fault conditions.

Removes FDA / Adopts IEC:

- Security master key control requirement.
- Class 3B or 4 beam stop requirement.
- Alternate labeling scheme.
- User information requirement.

Questions for TEPRSSC

- Does the committee have any comments on the proposed amendments?


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