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• The current laser performance standard, last updated in 1985, (laser rule) is based on an outdated understanding of photobiological science and no longer reflects the current state of a technologically-evolving industry.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:

• 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?