Laser LiDAR, Remotely Controlled Mobile Laser Products, and Laser Pointers

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# Laser Hazard Classifications

<table>
<thead>
<tr>
<th>FDA/CDRH</th>
<th>International Electrotechnical Commission (IEC)</th>
<th>Classification Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>1</td>
<td>Not recognized as hazardous</td>
</tr>
<tr>
<td></td>
<td>1M</td>
<td>Do not expose users of telescopic optics</td>
</tr>
<tr>
<td></td>
<td>1C</td>
<td>Users must follow instructions</td>
</tr>
<tr>
<td>IIa</td>
<td></td>
<td>Hazardous when looking directly for long periods</td>
</tr>
<tr>
<td>II</td>
<td>2</td>
<td>Hazardous – do not stare into the beam</td>
</tr>
<tr>
<td></td>
<td>2M</td>
<td>Hazardous – do not stare into the beam or expose users of telescopic optics</td>
</tr>
<tr>
<td>IIIa</td>
<td></td>
<td>Avoid exposure to the beam</td>
</tr>
<tr>
<td></td>
<td>3R</td>
<td>Avoid exposure to the beam</td>
</tr>
<tr>
<td>IIIb</td>
<td>3B</td>
<td>Direct eye or skin exposure hazard</td>
</tr>
<tr>
<td>IV</td>
<td>4</td>
<td>Hazardous for direct or scattered exposure</td>
</tr>
</tbody>
</table>
Trends

• Laser emissions are increasingly encountered outdoors and in the home, as opposed to academic or work environments.

• In the future, exposure to laser light radiation will be as commonplace as exposure to electromagnetic radiation from communication systems.

• Laser products intentionally or collaterally expose people to invisible laser radiation, so that laser radiation exposures are generally not noticeable.
LiDAR
What is LiDAR?

• Laser light (Li) Distance (or Detection) and Ranging (DAR)

• Laser products for distance, detection or ranging measurements.

• LiDAR generates a range-based dataset in 1, 2 or 3 dimensions.

• During operation, some of these products may intentionally or unintentionally expose people to hazardous levels of laser radiation.
LiDAR Platforms

Fixed or rotary wing, marine, ground, and autonomous vehicles
Specific Purpose Laser Products

• 21 CFR 1040.10(b)(39) specific purpose laser products have certain surveying, leveling or alignment (SLA) uses.

• 21 CFR 1040.11(b) SLA products are limited to no higher than Class IIIa or the CDRH recognized equivalent, IEC Class 3R.

• LiDAR products are not considered specific purpose laser products.
The Preamble at 39 FR 32098 (September 4, 1974) states, in relation to SLA products:

“Imposition of the requirements (class limit) of §1040.11(b) on distance measurement laser products is not appropriate since substantially higher powers and different beam configurations are required for ranging purposes.”  

[Emphasis added]

CDRH interprets this as specific to LiDAR applications.
LiDAR Safety Concerns

• No class limit for LiDAR products.
• Exposure to the emission.
• No pre-market safety review.
• Difficulty in detecting or associating injuries with the product due to invisible emissions.
• Manufacturers may instruct the LiDAR operator to terminate the emissions under unsafe conditions. This is an administrative control and is not reliable.
What Does FDA Want to Do?

• Propose an amendment to the performance standard for LiDAR products.

• Lessen the hazard from anticipated exposures to 1M, 2M, IIIb (3B) or IV (4) emissions.
What Does FDA Want to Do?

• Propose that LiDAR products integrate as many interlock(s) as are necessary for safe operation during intended use(s).

• These interlocks shall limit exposure to no greater than Class IIIa or 3R accessible emissions.
What Does FDA Want to Do?

• Propose that specific LiDAR products (rangefinders and speed detectors) shall not be either Class 1M or 2M and shall be limited to no higher than Class IIIa or 3R.
Questions for TEPRSSC

• What is your opinion of FDA’s LiDAR safety concerns (no class limit, public access to the emission, no pre-market review, difficulty in detecting or associating injuries with the product due to invisible emissions, reliance on operator control)?

• What is your opinion of a Class IIIa / 3R limit?
Questions for TEPRSSC

• What is your opinion on the viewing hazard that will require no allowable 1M and 2M accessible emissions?

• Is it appropriate for rangefinders and speed detectors?
Remotely Controlled Mobile Laser Products (RCMLP)
What are Remotely Controlled Mobile Laser Products?

- Remotely Controlled Mobile Laser Products (RCMLP) are mobile laser products that require remote operational control of the emission.
Examples of Remotely Controlled Mobile Laser Products
RCMLP Safety Concerns

• Potential public exposure to the laser emission that may require the operator to judge and maintain safe distances between the RCMLP and the public.
• No pre-market review.
• Difficulty in detecting or associating injuries with the product due to invisible emissions.
• Manufacturers may instruct RCMLP operators to terminate the emission during unsafe conditions.
• Loss of communication/control of product.
RCMLP Safety Concerns

- The operator of a RCMLP is not required to have a controller-based means of beam attenuation. Currently, the attenuator shall be provided with “one or more” permanently attached means.

- Upon signal loss, the operator cannot monitor beam attenuation and without manual reset, the product could emit laser radiation continuously or upon restart.
What Does FDA Want to Do?

- FDA wants RCMLPs to have a IIIa/3R class limit and wants to exclude classes 1M and 2M, because these products attract attention and are likely to be viewed with optical aids such as binoculars or a telescope.
RCMLP Emission Indicator Requirement

Currently, under 21 CFR 1040.10(f)(5): (Paraphrased)

• Laser products such as RCMLP “that have separately housed laser and operation control”...”shall incorporate an emission indicator”...”if the laser or operation control can be operated at a separation distance greater than 2 meters”...”from any other separately housed portion of the (RCMLP) incorporating an emission indicator.”
What Does FDA Want to Do?

- We propose an amendment to the performance standard that requires:
  - A beam attenuator on the RCMLP and a beam attenuator actuator on the operation control, regardless of separation distance.
  - An emission indicator on both the RCMLP and operation control, regardless of separation distance.
What Does FDA Want to Do?

• We propose an amendment that the RCMLP must not permit human access to laser radiation in excess of the accessible emission limits of Class IIIa (3R) upon loss of operation control, including signal, machine vision or electronic guidance system failure.

• We also propose to exclude Classes 1M and 2M because these products are likely to be viewed through viewing optics.
Questions for TEPRSSC

• For laser products designed to be remote controlled, what is your opinion regarding (1) not requiring a separation distance of 2 meters, (2) requiring an emission indicator on both the operation control and RCMLP, and (3) requiring a beam attenuator actuator on the operation control that controls the beam attenuator on the RCMLP?

• What is your opinion of the Class IIIa/3R limit for RCMLP?

• What is your opinion on the likelihood that RCMLP will be observed using optics that increase the observer’s risk of injury?
Laser Pointers
We Propose Defining Laser Pointers

• Laser Pointers are handheld laser products designed for battery-powered operation that are manufactured, designed, intended or promoted to provide illumination, designation of a target or point of origin, or sighting, with no associated technological or scientific purpose for the laser’s emission.

• Laser products are not excluded as laser pointers when used for visual entertainment, vision disruption or startle or novelty purposes.
Laser Pointer Safety Concerns

• Laser Pointer “illuminations” in the visible wavelengths from 400 nm to less than 610 nm are a significant vision safety hazard to operators of marine vessels, aircraft, and motor vehicles.

• According to an FAA study, “Laser Illumination of Flight Crew Personnel by Month, Day of Week, and Time of Day for a 5-Year Study Period: 2004-2008” most illuminations occur at night (around 7 to 11 p.m.) by green lasers (88% of all illuminations) that are 28 times brighter than equivalently powered red laser pointers.

Source: https://www.faa.gov/data_research/research/med_humanfacs/oamtechreports/2010s/media/201107.pdf
Laser Pointer Safety Concerns

• Illuminations cause startle, distraction, glare, flash blindness, and a persistent afterimage of a reverse contrast shadow in the visual field, lasting minutes.

• This effect renders operators of aircraft particularly vulnerable since they rely heavily on reading instrument panels. Rotary wing aircraft that fly at low altitudes must also rely on night adapted vision to identify airborne and ground-based hazards.
Laser Pointer Safety Concerns

• Since 2006, there has been an eighty-fold increase in reported incidents of aircraft illuminations from laser pointers, according to FDA analysis of FAA public data. Source: (http://www.faa.gov/about/initiatives/lasers/).

• FDA has received numerous letters from congress requesting action on laser pointer illuminations of aircraft.
Changes in Technology

• Due to recent technological advancements, laser pointers with green or blue laser diode systems are now available. Previously, laser pointers emitted only red laser light.

• It is well established that humans are most visually sensitive to green light.

• Humans are also far more sensitive to green light at night. As a result, green laser pointers are a much more significant safety hazard than red laser pointers.

• Due to a 50 nm shift in color sensitivity toward blue wavelengths and away from red wavelengths at night, blue light appears to be much, much brighter than red light at comparable power outputs.
Laser Pointers

Human Photopic and Scotopic Responses

- 1700 lm/W at 507 nm peak
- 683 lm/W at 555 nm peak

Wavelength (nm)
Laser Pointers

- The hazard from flash blinding is significantly reduced when laser pointers emit red/orange wavelengths at 615 nm or longer.
- The hazard from laser aircraft illuminations would be effectively eliminated if green and blue laser pointers were not available.
- Colors at 615 nm and longer, viewed with night adapted vision, appear only 1.4% as bright as green at the commonly manufactured 532 nm wavelength.
Rationale: Blue and Green Pointers Are Defective
(Defective as applicable to Electronic Products)

21 CFR 1003.2: (Paraphrased)

- An electronic product “shall be considered to have a defect which relates to the safety of use by reason of the emission of radiation if:”
- …“(b) It is a product which utilizes electronic product radiation to accomplish its primary purpose and from which such emissions are intended”...and...
- …“(2) Without regard to the design specifications of the product, emits electronic product radiation unnecessary to the accomplishment of its primary purpose which creates a risk of injury, including genetic injury to any person.”

[Emphasis added]
What Does FDA Want to Do?

• FDA would like to amend the performance standard to require that laser pointer products must not emit laser radiation in the visible wavelengths from 400 nm to less than 610 nm (Deep Violet to Orange-Red).
Questions for TEPRSSC

• What do you think of the laser pointer definition?

• In your opinion, did a startle and flash blinding hazard exist when laser pointers were only available in red?
Questions for TEPRSSC

• Does the startle and flash blinding hazard with green and blue laser pointers justify calling them “defective”?

• What is your opinion regarding the exclusion of wavelengths from 400 to less than 610 nm for laser pointers?