FDA'S PROPOSED CHANGE TO THE REGULATION OF LASER POINTERS

Paper #

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Abstract

On October 25-26, 2016, the U.S. Food and Drug Administration (FDA) proposed changes to the federal laser performance standard at a public technical advisory committee meeting. One proposed change addressed the risk of injury caused by visual impairment such as distraction, glare and flashblindness from laser pointers aimed toward operators of aircraft, vehicles and watercraft. Pilots are particularly vulnerable to disruptive visual impairment at night.

According to U.S. Federal Aviation Administration (FAA) data for 2016, of pilots who saw or were illuminated by laser light, 95% reported that it was green or blue light. Only 2.1% reported seeing red light alone or with other colors.[1]

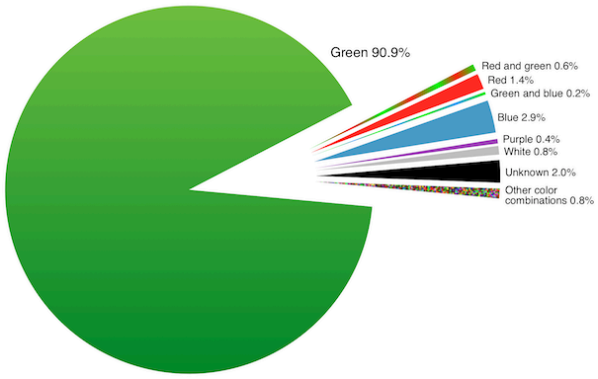

Figure 1: Color of laser illuminations reported to U.S. FAA, 2016

Compared to red light, human vision is highly sensitive to green light, and much more sensitive to green and blue light at night.

To manage the public safety risk, FDA proposes to define "laser pointers" as special purpose laser products based on certain uses, and to require that laser pointers not emit laser radiation at wavelengths between 400 and 609 nanometers. FDA's authority arises from Section 534 of the Federal Food Drug, and Cosmetic Act.

This paper gives background to the laser pointer problem, why FDA proposed this approach, what it expects will happen, and how pointers and other products may continue to emit green and blue laser light for certain applications in daylight conditions.

Laser pointer illuminations of aircraft

Reported incidents in the U.S. where a person aims a laser at an aircraft have risen dramatically, from 46 in 2004 to 7,442 in 2016.[2]

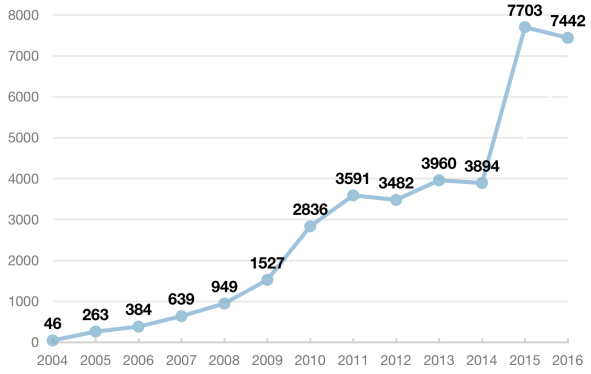

Figure 2: Laser illuminations reported to U.S. FAA, annual total

This topic has been covered in a number of previous ILSC papers and presentations[3,4,5,6] as well as in the general press so it will be briefly summarized here.

Visual interference hazards

For these aircraft incidents, the primary concern of laser safety experts such as the SAE G10-T "Laser Safety Hazards" and G10-OL "Operational Laser" committees[7] is with the adverse effects on pilot[8] performance.

Sudden, undesired bright light aimed at pilots can cause functional problems such as distraction and startle, and visual interference such as glare, flash blindness and afterimages.

When incidents occur during critical phases of flight such as takeoffs, landings, low altitude maneuvers and emergencies, there is potential for an aircraft accident.

Even if a pilot can safely handle the aircraft, there may be disruption of a task such as a police helicopter going after the laser perpetrator instead of completing its original mission.[9] (The Coast Guard has strict rules about returning to base after laser exposures, which have interrupted rescue missions.[10])

Pilot eye effects and injuries

Understandably, pilots are also concerned over the possibility of high-powered laser light causing temporary eye effects such as pain and watering eyes, or worse, temporary[11] or even permanent eye injuries.

An April 2016 overview of consumer laser hazards by laser safety experts John Marshall, John O'Hagan, and John Tyrer concluded that permanent eye injuries to pilots are highly unlikely: "Fortunately, these exposures are at irradiances that are incapable of producing irreversible retinal damage even at distances of 100 m."[12] They stated there had been only one case of alleged retinal damage; that this case was suspect for a number of reasons; and that they do not believe ground-to-air laser targeting caused the injury.

A call for restrictions on laser pointers

As of January 2017, there have been over 54,000 laser illuminations reported in five countries including the U.S.,[13] fortunately with no accidents and (apparently) no permanent eye injuries thus far.[14] But pilot groups in the U.K., Canada and New Zealand have called for restrictions on laser pointer sale, possession and/or use. Some examples:

- In January 2017, the head of the New Zealand Air Line Pilots' Association wanted a total ban on lasers over 1 milliwatt: "There is a current law that prevents the importation and sale of these high-powered lasers unless there is a specific reason for their use. But we see that the danger outweighs the utility of them and we would like to see a complete ban."[15]

- In September 2016, the British Airline Pilots' Association called for high-powered lasers to be treated as offensive weapons.[16]

- In August 2016, the head of the U.K. Civil Aviation Authority said that persons carrying high-powered laser pointers in public should be arrested even if they are not using them.[17]

- In February 2014, the president of the Air Canada Pilots' Association wanted stricter penalties and "we'd like to see a control put on them, some kinds of permits or access to these things that's somehow controlled."[18]

In the United States, a number of lawmakers including Sen. Chuck Schumer (D-N.Y.) have asked FDA to restrict laser pointers, especially green laser pointers which were used in over 90% of FAA-reported laser incidents. In February 2016 Schumer met with FDA Commissioner Dr. Robert Califf, after high-profile laser incidents in the New York City area. Califf agreed to consider having the FDA ban the sale of green laser pointers.[19]

Current FDA regulation of lasers and pointers[20]

FDA authority over lasers is contained in 21 Code of Federal Regulations (CFR) 1040.10[21] and 1040.11[22]. FDA regulates laser-emitting devices as well as three categories of laser products:

- Medical laser products
- Demonstration laser products[23]
- Surveying, leveling, and alignment ("SLA") laser products[24]

The word "pointer" or the concept of a handheld laser device does not appear in 21 CFR 1040.10 and 1040.11, which were issued in 1976 before consumer handheld laser devices were developed. Around 1989-1990 FDA began to take notice of these devices and to control them as SLA products "because they described a straight line from the lecturer to the point on the screen to which attention was being directed."[25]

Other "products that FDA has considered to be SLA products ... include products described as target pointer illuminator aiming, tactical laser illuminator, infrared zoom illuminator, and laser illuminator. Illuminator, alignment, target designation, pointing, or any similar description of a laser product for use in alignment or positioning provides a basis for classification of a laser product as a surveying, leveling, or alignment laser product."[26]

In addition, hand-held lasers promoted for entertainment purposes or amusement also meet the demonstration laser product definition.[27]

Both SLA and demonstration products are limited by 21 CFR 1040.11(b) and (c) to 5 milliwatts output power in the visible wavelength range from 400 to 710 nanometers.

Labeling

FDA requires caution labels on Class II laser pointers (IEC Class 2, up to 1 mW) and warning labels on Class IIIa (IEC Class 3R, 1-5mW) laser pointer products. These labels warn "Do not stare into beam" and "Avoid direct eye exposure."

FDA does not currently have regulations that require labels that warn of indirect (non-health) hazards such as visual interference with operators of aircraft, vehicles and watercraft. FDA does ask manufacturers to voluntarily add a visual effect caution statement when labeling SLA products.[28] The suggestion is automatically added to acknowledgment letters that FDA sends in response to an SLA laser product report submission. The suggestion reads:

> "CDRH recommends (but does not require) labeling on your product that cautions the purchaser with following or similar language: 'CAUTION - LASER LIGHT IS BRIGHT AND BLINDING - DO NOT SHINE AT AIRCRAFT OR VEHICLES AT ANY DISTANCE'."

As of January 2017, it appears that only a few laser pointer manufacturers have added such a statement to their devices.[29]

FDA public presentation of laser changes

On October 25, 2016, FDA made the first public presentation of its proposed changes to the federal laser performance standard, including the agency's desire to restrict manufacture of green and blue laser pointers.

To understand the nature and status of this proposal, it helps to understand the group to which FDA's proposal was made, and how it fits into FDA's regulatory program.

The TEPRSSC committee

The Technical Electronic Product Radiation Safety Standards Committee is a permanent statutory committee established pursuant to the provisions of the Radiation Control for Health and Safety Act (21 USC 360kk).[30] TEPRSSC consists of 15 voting members. Five are from governmental agencies, five are from "the affected industries" and five are from the general public of which at least one member is from organized labor.

The primary function of TEPRSSC is to provide advice and consultation to the Commissioner of Food and Drugs on the technical feasibility and reasonableness of performance standards for electronic products to control the emissions of electronic product radiation from such products and to review amendments to such standards before being prescribed by FDA.[31]

FDA is required to consult with TEPRSSC before prescribing standards for radiation emissions from electronic products.[32]

TEPRSSC meetings are called by FDA as needed to review proposed agency performance standards. From 1997 to 2003, TEPRSSC met 30 times.[33] After 2003, the next meeting was October 25-26, 2016 in Gaithersburg, MD.

At the October 2016 meeting, the committee was asked to review FDA questions and proposals on nine topics, one of which was "laser products." For the laser product topic, the areas of interest were: an update to amendments to the laser rule, light detection and ranging (LIDAR), laser data (Light Fidelity-LiFi)/energy transfer, illumination applications and infrared applications.[34]

The FDA's meeting summary notes "There was significant discussion about the best approach to reduce risks associated with laser pointers. There was also discussion related to the safety concerns and engineering controls for LIPs (Laser Illuminated Projectors). Members of the committee generally agreed with FDA's proposals, while also raising concerns that FDA should note for further consideration."[35]

Background to FDA's 2016 laser proposals

On June 24, 2013, FDA "proposed amending regulations applicable to laser products – those are found in 21 CFR Subchapter J – in order to update its standard."[36]

The 2013 proposed amendment was based on older IEC and ANSI standards, which had been updated during FDA's development of the proposed amendment. Many comments submitted to the agency wanted FDA to use the newer IEC and ANSI standards.

The 2013 proposal was dropped. As FDA said at the TEPRSSC meeting, "[A]lmost practically out of the starting block, our standard would need some revisions based on these updated standards that came shortly afterwards. So we have been in the process of drafting a re-proposed amendment. Numerous changes have been included…."[37]

Laser pointer-related changes proposed by FDA

FDA's representative[38] told TEPRSSC that the agency was responding to the increased use of laser products by consumers, and the increased exposure of the general public to laser radiation: "We feel that laser emissions are increasingly encountered outdoors and in the home, as opposed to academic or work environments where they typically have been found when the laser rule was first promulgated. So in the future, we think exposures to laser light radiation will be as commonplace as exposure to electromagnetic radiation, let's say, from communication systems like cell phones."[39]

The following items list FDA's October 2016 proposed changes that may affect laser pointers.

- Defining the term "laser pointer"
- "Exclude certain wavelengths [of laser pointers] to decrease the public health risk from flash blinding."[40]
- Modifying the definition of surveying, leveling and alignment (SLA) laser products.

The first two items are discussed below. The third item was not discussed at TEPRSSC, and might not affect laser pointers since they would have their own new definition and would no longer be classified as SLA laser products.

New definition of laser pointer

As discussed earlier, the term "laser pointer" does not appear in the U.S. federal laser regulations, 21 CFR 1040.10 and 1040.11. To update the regulations, FDA told TEPRSSC it is considering adding the following definition:

> 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.[41]

FDA clarified: "[I]n other words, just because a product points and it looks like a laser pointer doesn't mean it's necessarily a laser pointer if you're using the emission for a purpose that has a technological use."

The proposed definition then further states:

> Laser products are not excluded as laser pointers when used for visual entertainment, vision disruption, to startle, or novelty purposes.[42]

This appears to mean that laser products are included in the laser pointer definition if they are used for visual entertainment, vision disruption, to startle or for novelty purposes.

Use of color as a control mechanism

FDA reviewed the eye's sensitivity to green and blue light under dark-adapted (scotopic) vision, presenting the chart in Figure 3.

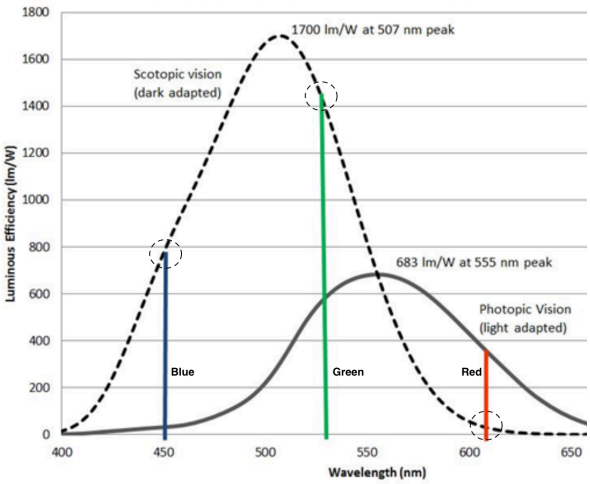

Figure 3: Human Photopic and Scotopic Responses

The three circled areas show how, for a dark-adapted human eye (dashed curve), red light is perceived as much dimmer than equivalent amounts of blue and green light.

FDA noted that "the hazard from flash blinding is significantly reduced when laser pointers emit in the red/orange wavelengths of 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."[43]

Green and blue laser pointers are defective

Based on this analysis and considering the thousands of laser illuminations of aircraft each year in the U.S. (95% of which were green or blue in 2016), FDA is proposing that it is defective for a laser pointer to emit green or blue light.

This determination uses a definition of "defective" as applied to electronic products which is in 21 CFR 1003.2:

> For the purpose of this part, an electronic product shall be considered to have a defect which relates to the safety of use by reason of the emission of electronic product 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 as a result of its design, production or assembly it; …
>
> (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….[44]

Defective products cannot be manufactured (except under a variance)

Under this designation, "manufacturers would be prohibited from manufacturing laser pointers"[45] from 400 nm (deep violet) to 609 nm (red-orange). A manufacturer could apply for a variance from FDA: "Let's say you have a good reason to have a green laser pointer for sighting purposes, the FDA could grant a variance [to manufacture a green pointer] for a specific use."[46]

Manufacture of pointers from 610 nm to 710 nm (deep red) would be permitted. As under FDA's current enforcement, the maximum power output would be limited to Class IIIa (3R), e.g. less than 5 milliwatts.

Lasers outside the range of 400 – 710 nm are not visible to the human eye under FDA's definition of visible emissions. They do not pose a visual interference hazard to aviation and so would not be regulated as a visual interference hazard under the definition of laser pointer.

FDA does not have authority to ban individual possession of 400-609 nm laser pointers. Persons already owning such pointers, or who build their own for personal, non-commercial use would not be restricted from possession by FDA. (There may be some state or local laws that currently apply[47] and FDA noted that "as a practical matter, we envision that just like any other hazardous product that has been determined to be defective, that state and local … ordinances and laws would be put in place that would likely deal with the use of green and blue laser pointers.")[48]

The "risk of injury" listed in 21 CFR 1003.2(b)(2) refers to injury caused by an aircraft accident. The FDA presentation and questions for TEPRSSC were focused on the problem of aircraft illumination hazards.[49] The proposal to limit laser pointers to the 610-710 nm range was not presented as a way to reduce eye injuries.[50]

"Defective" gives additional authority

The designation of 400-609 nm laser pointers as "defective" gives FDA additional enforcement authority over newly manufactured pointers.

Dr. Donald Miller, Chief Medical Officer for Radiological health at FDA's Center for Devices and Radiological health told the TEPRSSC committee "Defect has a very specific meaning in our regulations, and defect or a failure to comply to EPRC [electronic product radiation control] regulations gives us very specific authorities and powers amongst which are the ability to require the manufacturer to repair, replace, or repurchase a defective device, defective product. Whether that would be practicable, effective, or even possible in the situation of laser pointers, I don't know, but it is an authority that we have under existing regulations for a defective product."[51]

Restrictions based on color make control easier

A key feature of the FDA's proposal is to make laser pointer control easier for importation and manufacture; and for any state or local restrictions that might be enacted to regulate the sale, possession or use of laser pointers.

If a laser pointer's beam is any color other than red or red-orange, it would be defective. For example, a customs official would know instantly that such pointers could not be imported. Similarly, if color-based state and local restrictions are enacted, a police officer or other authority could take action such as confiscation based solely on the color of the beam.

Enforcement officers still would need to use power meters to determine whether a legal red (610-710 nm) pointer exceeded the 5 mW power limit.

However, this is not as critical from a visual interference standpoint. First, red laser pointers have a dark-adapted visual efficacy about 1.4% that of a green laser pointer.[52] So even if a red pointer was ten times the 5 mW limit, it still would visually appear less bright than a 5 mW green pointer, according to FDA.[53]

Second, the vast majority of laser illumination incidents reported to the Federal Aviation Administration involve non-red lasers.

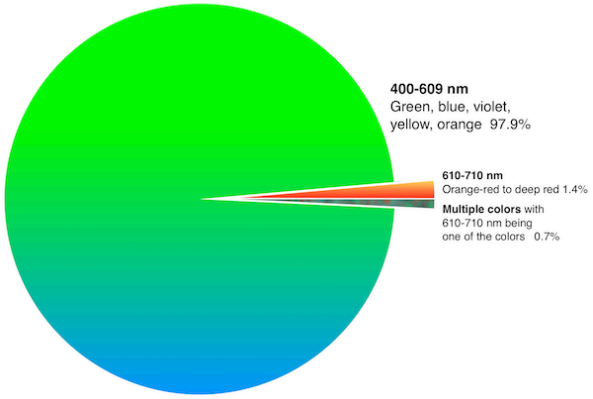

Figure 4: Wavelength of laser illuminations reported to U.S. FAA, 2016

Stopping the manufacture of non-red laser pointers would prevent those pointers from being used in any future incident. In addition, any new state and local regulations on sale, possession or use could help reduce the number of future events.

There are two additional potential benefits of color-based laser pointer control which were not discussed by FDA or TEPRSSC members, but which are listed here: 1) making it easier to manufacture and use pilot protective eyewear, and 2) increasing public awareness of the laser misuse issue.

Keeping protective eyewear simple & effective

The FDA's proposal will likely slow the adoption of 520 nm green diode laser pointers, which are poised to replace the current 532 nm green DPSS laser pointers.

Essentially all glare protection that pilots currently wear protects them against a 532 nm green laser exposure[54]. It is more costly for eyewear manufacturers to attenuate both 532 and 520 nm green wavelengths simultaneously, without adversely affecting other colors of green such as cockpit indicator lights and airport lighting.

Therefore if FDA's proposal results in fewer exposures from 520 nm green diodes, the current 532 nm eyewear will remain effective against green laser exposures and eyewear manufacturers will not have the difficult task of simultaneously blocking 532 and 520 nm while allowing accurate color recognition of other green lights.

Restrictions may increase public awareness

Restricting certain colors may increase public awareness of bright-light hazards.

To use an analogy, as incandescent light bulbs are phased out in favor of compact fluorescent and LED bulbs, and can no longer be easily found for sale, the public becomes aware of the reason: energy efficiency.

Similarly, when the public can no longer purchase certain colors of laser pointers, they will become educated that this is being done to help protect operators of aircraft, vehicles and watercraft.

Variances for special applications

As noted earlier, FDA said that if a manufacturer wants to make non-compliant laser pointers, they can apply to FDA for a variance. If approved, the manufacturer would then be able to manufacture pointers in the 400-609 nm range and/or pointers over 5 mW for a specific market and/or specified persons; for example, law enforcement.

FDA does not have a mechanism for individual use variances.[55] So if a person felt they had a valid purpose – such as pointing out features outdoors in daytime during an architectural tour – that required a high-visibility or high-powered laser pointer, they would not be able to purchase a newly manufactured pointer. (This assumes no manufacturer had a variance to sell to such a user). The person might be able to find a used laser pointer made prior to enactment of the color-based regulations, or they might simply have to choose a different method to point out or highlight features.

Reaction to the proposal

A TEPRSSC member supporting FDA's proposal was Dr. William E. Irwin, Radiation Control Program director for Vermont, and a certified health physicist. Irwin told FDA's representative "In your presentation you said it presents a public health hazard, and I would agree. I believe that these lasers should be classified as defective. I don't really care that there's anybody that's using a green laser and getting a better emphasis with their slideshow. That makes no difference to me when the comparison is to an aircraft pilot suffering some sort of momentary or even longer debilitation that may put people at risk of a safe landing."[56]

Committee member Dr. Cynthia McCollough, Professor of Medical Physics and Biomedical Engineering at the Mayo Clinic College of Medicine in Rochester, Minnesota, initially disagreed with FDA's proposal: "[O]ne of the questions specifically was do

we think that these hazards, when they are misused, justify calling them defective, and I don't think so. I think that's a misappropriation of that term. The documents gave us what 'defective' means. The blue and the green do help very much to accomplish their primary purpose, and so I don't think they are defective at all in having that. The risk of injury is the misuse of them, and that cat is out of the bag."[57]

But after some discussion by FDA's representative, which included a statement that Senator Schumer had written to FDA three times "asking us to do something about it",[58] McCollough supported the proposal: "Now, if push came to shove, would I rather have improved protection and safety for people in the air? Absolutely, rather than have my green laser pointer the next time I talk, especially since so many presentations have gone electronic and you can move your mouse around. So if that were the direction it went, I would actually be fine with that, though I think it is a bit of a feel-good step that we're doing something that may not actually reduce, just because there's so many out there."[59]

Similarly, TEPRSSC member Patrick Murphy (a co-author of this paper) of the International Laser Display Association initially was skeptical. He pointed out that if FDA simply reduced the allowed laser pointer powers to 1 mW, as is done in most other countries with laser pointer restrictions, this would reduce glare effects more than the FDA's proposal of allowing 610 nm lasers at 5 mW.[60]

FDA presenter CAPT Dan Hewett (the other paper co-author) replied that the advantage was "immediately recognizing that someone has a blue laser in their hand or a green laser in their hand and be able to say that this particular product, due to its color alone, is a hazard versus stopping someone and saying I've got to take your green laser and I've got to measure it to determine if it's a 1 mW laser or not. And other countries, I think, are not able to do that level of enforcement so -- I mean while it sounds like a good idea, I think we have to fold in the practicality."[61]

After further discussion, Murphy called the FDA proposal "very interesting for a number of reasons" but did suggest that FDA "prepare a Plan B if, when that comment comes up, a lot of people don't go for [the proposal] for whatever reason."[62]

Next steps

FDA will take TEPRSSC's comments and advice into consideration, to decide whether to make any changes to the many proposals (most non-laser related) FDA made to the committee.

For the laser amendments, when FDA is ready they would go through standard rule-making procedures. For the public, this starts with the proposed amendments being published in the Federal Register. There would be a time period for public comments which could vary from 30 to 180 days.[63]

The comments give input to the FDA: "the agency must base its reasoning and conclusions on the rulemaking record, consisting of the comments, scientific data, expert opinions, and facts accumulated during the pre-rule [example: TEPRSSC] and proposed rule stages."[64]

After these processes, FDA has these options: "If the rulemaking record contains persuasive new data or policy arguments, or poses difficult questions or criticisms, the agency may decide to terminate the rulemaking. Or, the agency may decide to continue the rulemaking but change aspects of the rule to reflect these new issues. If the changes are major, the agency may publish a supplemental proposed rule. If the changes are minor, or a logical outgrowth of the issues and solutions discussed in the proposed rules, the agency may proceed with a final rule."[65]

Summary

Misuse of laser pointers by the general public, by pointing them at aircraft in flight, continues to be a concern. In the U.S. the number of incidents almost doubled in 2015 and 2016, compared to the previous four years. Currently, there is an average of over 20 incidents each night reported to FAA. Although thus far there has not been a serious accident, the risk of a pilot being distracted, startled or flash blinded is clear.

One way to help reduce the number and severity of incidents is to reduce the availability of laser pointers, especially green and blue ones which represent 95% of all FAA-reported incidents.

The FDA has made a first-in-the-world proposal to allow manufacture only of red pointers (610-710 nm). By designating all others (400-609 nm) as "defective", this would give the agency additional regulatory authority which makes it much easier for authorities to determine which laser pointers may be imported, manufactured or (depending on state and local laws) sold, owned or used.

An FDA advisory committee appeared to support this proposal.[66] The next step is for FDA to submit this proposal to the Federal Register for public comments, likely as part of a package of overall laser regulation amendments.

If the laser pointer wavelength proposal eventually becomes an FDA regulation, it will only affect manufacturers and importation. There still may be a public safety need for states and localities to build upon the "defective" designation, with additional restrictions as needed for sale, possession and/or use.

Authors' Note

Patrick Murphy is executive director of the International Laser Display Association, editor of LaserPointerSafety.com, and a member of SAE and ANSI committees involved with laser safety.

CAPT Daniel Hewett served as a Regulatory Officer at FDA from October 2007 through December 2016. He is currently an Industrial Hygienist and Safety Officer at FDA.

This paper has been reviewed by FDA for accuracy. It represents the authors' views and does not necessarily reflect the views of FDA, ILDA or any other group or organization.

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[1] From the Jan. 9, 2017 FAA Laser Report, for data Jan. 1 – Dec. 31, 2016. Of 7,439 illumination events where a color was specified, 6,766 or 91% had "Green" as the sole color listed and 213 events had "Blue" as the sole color listed. There were 101 events listing green or blue along with other colors. This is a total of 7,080 events with green and/or blue which represents 95% of total 2016 events. For comparison, there were 103 events with just "Red" plus 55 events listing red along with other colors. This is a total of 158 events with red which represents 2.1% of total 2016 events.

[2] Based on the weekly FAA Laser report. An example of the 2010-2014 data is at https://www.faa.gov/about/initiatives/lasers/laws/media/laser_incidents_2010-2014.xls

[3] Murphy, Patrick, "Lasers and Aviation Safety," ILSC 2009 Conference Proceedings, p. 41.

[4] McLin, Leon, "Dazzling and High-Powered Laser Pointers," ILSC 2011 Conference Proceedings, p. 52

[5] Makhov, Greg and Murphy, Patrick, "Better Informing the Public of Laser Exposure Injury Potential," ILSC 2013 Conference Proceedings, page 288 (one-paragraph abstract only -- no paper available in the Proceedings).

[6] Murphy, Patrick, "Laser Safety Concepts for Aviation", ILSC 2015 Conference Proceedings, p. 214.

[7] See SAE ARP5293, "Safety Considerations for Lasers Projected in the Navigable Airspace", p. 24 and especially SAE ARP6378 "Guidance on Mitigation Strategies for Laser Illumination Hazards" (in draft).

[8] There is also concern over drivers of land and water vehicles. There is at least one documented case of a 3-car crash caused by one driver aiming a laser at another. (The vehicles were damaged but no one was injured by the laser or in the crash, which occurred October 2016 in Oregon). However, the primary concern for vehicle operations is for aircraft pilots, both fixed-wing and helicopter. This is due to the potential for a catastrophic accident involving both lives on the aircraft and on the ground below.

[9] A list of 37 (as of January 2017) news items about missions being aborted due to laser illuminations: http://www.laserpointersafety.com/news/news/aviation-incidents_files/category-interrupting-mission.php#on

[10] Selected Coast Guard mission cases are here: http://www.laserpointersafety.com/news/news/aviation-incidents_files/tag-coast-guard.php#on

[11] Just as the skin can heal from scratches or small burns, so too the retina can heal from minor injuries.

[12] Marshall, John; O'Hagan, John and Tyrer, John, "Eye hazards of laser 'pointers' in perspective", editorial in the British Journal of Ophthalmology, published Online First April 19 2016, http://bjo.bmj.com/content/early/2016/04/18/bjophthalmol-2016-308798.full

[13] U.S. 2004-2016: 36,736. U.K. 2009-2014: 8,565. Australia 2007-2015: 3,713. Italy 2010-2014: 3,124. Canada 2008-2015: 2,585. Total: 54,723. Data and links to original sources at http://www.laserpointersafety.com/latest-stats/latest-stats.html

[14] Some persons have asserted that civilian pilots have suffered permanent eye injuries. As far as can be determined, there has been no proven or demonstrated permanent eye injury as of mid-January 2017. A few well-publicized cases such as Kapitan Man in 1997 and a British Airways pilot in spring 2015 are suspect according to laser eye injury experts. On March 19 2015, an FAA spokeswoman said "The FAA is unaware of any U.S. commercial pilot who has suffered permanent eye damage as a result of exposure to laser light when in the cockpit." Note that there may be classified reports of injuries to military pilots in war zones; these would not be known to the authors and would not be relevant to consumer misuse of pointers and handheld lasers. For details, see http://www.laserpointersafety.com/media/media.html

[15] Radio New Zealand, "Pilots call for total ban on high-power lasers", January 3 2017, http://www.radionz.co.nz/news/national/321656/pilots-call-for-total-ban-on-high-power-lasers

[16] BALPA Press Release "Pilots call for greater safety in the skies at TUC", http://www.balpa.org/Media-Centre/Press-Releases/Pilots-call-for-greater-safety-in-the-skies-at-TUC

[17] Daily Mail, "Aviation regulator calls for people found carrying laser pointers to be arrested", August 24 2016, http://www.dailymail.co.uk/wires/pa/article-3755572/Aviation-regulator-calls-people-carrying-laser-pointers-arrested.html

[18] Ottawa Citizen, "Pilots' group seeks criminal punishment for laser pointing," February 13 2014. No longer available on the internet, but a story summarizing this is at http://www.laserpointersafety.com/news/news/other-news_files/466061ecc17778ae62688a62c14881d7-382.php#on

[19] Newsday, "Sen. Chuck Schumer renews push to ban laser pointers", February 4 2016. http://www.newsday.com/long-island/transportation/sen-chuck-schumer-renews-push-for-fda-ban-on-sale-of-green-laser-pointers-1.11430323. Note that although Califf's nomination as Commissioner had not been approved by the Senate at the time of the Schumer meeting, he was approved later that month and took his position.

[20] Some material in this section is from FDA's "Important Information for Laser Pointer Manufacturers", http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116373.htm. A broad overview of the agency's laser regulations is on the "Laser Products and Instruments" webpage, http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/default.htm

[21] https://www.gpo.gov/fdsys/pkg/CFR-2000-title21-vol8/pdf/CFR-2000-title21-vol8-sec1040-10.pdf

[22] https://www.gpo.gov/fdsys/pkg/CFR-2000-title21-vol8/pdf/CFR-2000-title21-vol8-sec1040-11.pdf

[23] From 21 CFR 1040.10(b)(13): "Demonstration laser product means any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition. The term 'demonstration laser product' does not apply to laser products which are not manufactured, designed, intended, or promoted for such purposes, even though they may be used for those purposes or are intended to demonstrate other applications."

[24] From 21 CFR 1040.10(b)(39): "Surveying, leveling, or alignment laser product means a laser product manufactured, designed, intended or promoted for one or more of the following uses:

(i) Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement.

(ii) Positioning or adjusting parts in proper relation to one another.

(iii) Defining a plane, level, elevation, or straight line."

[25] Email sent January 13 2017 from former FDA/CDRH official Jerome Dennis to Patrick Murphy.

[26] From a November 29 2012 warning letter sent by FDA to a laser manufacturer, http://www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm341876.htm

[27] Jerome Dennis email, *op. cit.*: "As later products came along, as those that projected cute patterns or those promoted as toys, they also were considered to be demonstration laser products."

[28] Email sent December 7 2012 from FDA's Dan Hewett to Patrick Murphy.

[29] Personal observation by Murphy based on viewing laser pointer labels online and in person.

[30] TEPRSSC charter: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/ucm124730.htm

[31] TEPRSSC day 1 meeting transcript, pp 10-11. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/UCM528629.pdf

[32] TEPRSSC charter, *op. cit.*

[33] Search result looking for all TEPRSSC meetings: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/results.cfm?panel=27&searchtype=1&month=0&year=&maxrows=30

[34] Brief Summary of the TEPRSSC Meeting October 25-26 2016: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/UCM527242.pdf

[35] Brief Summary of the TEPRSSC Meeting, *op. cit.*

[36] TEPRSSC day 1 meeting transcript, p. 86.

[37] *Ibid*.

[38] CAPT Daniel Hewett, a co-author of this paper, was the primary presenter for FDA regarding changes to the laser performance standard. Most quotes in this paper from FDA during the TEPRSSC meeting were made by CAPT Hewett.

[39] TEPRSSC day 1 meeting transcript, p. 97.

[40] TEPRSSC day 1 meeting transcript, p. 88.

[41] TEPRSSC day 1 meeting transcript, p. 104.

[42] *Ibid*.

[43] TEPRSSC day 1 meeting transcript, p. 106.

[44] Emphasis added by FDA in TEPRSSC meeting slide presentation, "Laser LiDAR, Remotely Controlled Mobile Laser Products, and Laser Pointers", slide 33, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/UCM526255.pdf

[45] TEPRSSC day 1 meeting transcript, p. 109.

[46] TEPRSSC day 1 meeting transcript, p. 110.

[47] A selected list which includes some U.S. state or local laws regulating individual possession or use is at http://www.laserpointersafety.com/rules-general/uslaws/uslaws.html

[48] TEPRSSC day 1 meeting transcript, p. 109; see also a similar comment on p. 178

[49] TEPRSSC day 1 meeting transcript, p. 105: "But our specific concerns with laser pointers as they exist now are that they emit visible wavelengths in the 400 nm to less than 610 nm that are a significant safety hazard to operators of marine vessels, aircraft, and motor vehicles…. These illuminations cause startle, distraction, glare, flash blindness, and a persistent afterimage of a reverse contrast shadow in the visual field, lasting minutes."

[50] It may be that FDA's other laser pointer-related proposals are intended to help reduce consumer eye injuries. For example, proposals regarding children's toy laser products, or adding the following language to the definition of laser pointer: "Laser products are not excluded as laser pointers when used for visual entertainment, vision disruption, to startle, or novelty purposes." However, the background materials and TEPRSSC presentations focused on the green/blue exclusion proposal as it related to startle and flash blinding hazards. Only one question asked by FDA to the committee members was about laser pointers in general: "What do you think of the laser pointer definition", from the Background Materials page 31, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/UCM526014.pdf.

[51] TEPRSSC day 1 meeting transcript, p. 197.

[52] TEPRSSC day 1 meeting transcript, p. 106: "Colors at 615 nm and longer, viewed with night-adapted vision, appear only 1.4% as bright as green at the commonly manufactured 532."

[53] There appears to be a discrepancy between FDA's photopic visual efficacy curve as presented to TEPRSSC, and FAA's Visual Correction Factor as found in Advisory Circular 70-1, Table 5. FAA's table shows 555 nm green as having a Visual Correction Factor of 1.0, 532 nm green with a VCF of 0.88016, and 615 nm red-orange with a VCF of 0.44210. Thus, according to the curve FAA uses, colors at 615 nm appear 50% as bright as at 532 nm green. But according to FDA's curve, colors at 615 nm appear only 1.4% as bright as at 532 nm. The discrepancy is probably due to FAA adopting a curve based on pilot vision at night not being fully dark adapted – there are lights in the cockpit as well as city and airport lights outside the windscreen.

[54] Some laser glare protection eyewear may also protect against additional wavelengths as well. Almost always, 532 nm is the primary wavelength that is desired to be attenuated.

[55] This information is based on author PM's private conversations with FDA officials in October 2016.

[56] TEPRSSC day 1 meeting transcript, p. 189.

[57] TEPRSSC day 1 meeting transcript, p. 186.

[58] TEPRSSC day 1 meeting transcript, p. 187.

[59] *Ibid*.

[60] TEPRSSC day 1 meeting transcript, p. 181. Specifically, defining glare as being within the FDA's Critical Flight Zone Exposure Distance, a 5 mW 610 nm beam with 1 mrad divergence would cause glare at 829 feet. In contrast, a 1 mW 555 nm beam with 1 mrad divergence would cause glare at only 523 feet. This means that the brightest-appearing beam (610 nm) under FDA's TEPRSSC proposal would cause glare at a longer distance (more hazardous), than if FDA allowed any color laser pointer but reduced the maximum power to 1 mW. Note that these calculations use the FAA's Visual Correction Factor found in Advisory Circular 70-1, Table 5 which may differ from the photopic response curve presented by FDA in this paper's Figure 3.

[61] TEPRSSC day 1 meeting transcript, p. 181.

[62] TEPRSSC day 2 meeting transcript, p. 372, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/UCM528632.pdf

[63] "A Guide to the Rulemaking Process, Prepared by the Office of the Federal Register", https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf

[64] *Ibid*.

[65] *Ibid*.

[66] There was no formal TEPRSSC vote. But as the FDA Brief Summary document (*op. cit.*) stated, "Members of the committee generally agreed with FDA's proposals, while also raising concerns that FDA should note for further consideration."