# 04-163 czb FW: Request for information about laser pointer regulation

2 messages

**Ellsworth, Eva** <Eva.Ellsworth@fda.hhs.gov> Wed, Apr 10, 2013 at 5:19 PM
To: "patrickmurphy5@gmail.com" <patrickmurphy5@gmail.com>
Cc: "CDRH Small Manu. Assistance" <DSMA@cdrh.fda.gov>

Dear Mr. Murphy,

I apologize for the delay in responding to your email of April 4, 2013. The regulations pertaining to demonstration laser products are found in 21 CFR 1040.11(c), and defined in 21 CFR 1040.10(b)(13) as you indicated. You will notice that neither the definition for demonstration laser products nor the regulations in 1040.11(c) specify or necessarily limit which kinds of laser products can be demonstration laser products. The determination as to whether a laser product is a demonstration laser product depends on how the laser product is intended to be used. If a laser pointer is intended to be used and marketed as a demonstration laser product as per the definition of a demonstration laser product, then 1040.11(c) applies. This determination dates back to the final rule including the FDA laser performance standard found in 21 CFR Subchapter J.

With respect to laser pointers, an example of when a laser pointer might be determined to be a demonstration laser product is if a mounted laser pointer uses a "diffraction grating protective housing" which spreads the beam and makes interesting or entertaining patterns (e.g. stars, geometric shapes, letters, words, etc.) on surfaces. The most recent (1992) "Compliance Guide for Laser Products" (HHS Publication FDA 86-8260) contains the same information on demonstration laser products as the 1985 version, and includes examples of demonstration laser products such as:

1. Laser products promoted for classroom demonstration of optical phenomena
2. Artistic displays and their associated apparatus
3. Laser light show projectors
4. Laser light shows and displays, themselves

This compliance guide can be found at the following website: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095304.pdf

To review, the definition of a demonstration laser product in 1040.10(b)(13) is…"any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition." This definition goes on to state that 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."

This means that if a laser pointer is not intended or marketed to be a demonstration laser product, then it must comply with 1040.11(b) – the regulations for surveying, leveling, and alignment (SLA) laser products. Both 1040.11(b) and 1040.11(c) have the same accessible exposure limits (AEL); so, in the case of laser pointers, there is

little regulatory difference between using them as a demonstration or an SLA laser product.

A search of the Federal Register archives for the date when the sentinel FDA determination that a laser pointer may be used as a demonstration laser product was published resulted in the same results you discovered, even dating back to 1975. You are also correct that the answer to your question is not found among the FDA Laser Notice guidance documents. However, because of the way the regulations are stated, the FDA determined that a guidance document was not needed when making this determination.

There are other sources which may be useful to you. You may consider searching www.regulations.gov for a variance which describes a laser pointer being used as a demonstration laser product in a laser light show, for example. However, laser pointers are most often regulated as SLA laser products rather than demonstration laser products. Therefore, they may not be found under demonstration laser product variances for Class IIIb and Class IV laser pointers. Another place you may look for instances where laser pointers may have been considered demonstration lasers is within warning letters issued to laser manufacturers for laser products which were not compliant with the FDA performance standard. The FDA warning letters are found at the following web site: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm.

If you decide to pursue a Freedom of Information Act (FOIA) information request, you may find instructions at the following website: http://www.fda.gov/RegulatoryInformation/FOI/default.htm

I hope this answered your question. Feel free to contact DSMICA at DSMICA@fda.hhs,gov if you have further questions.

Best regards,

Eva Ellsworth

Eva Ellsworth, RAC

Consumer Safety Officer

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**From:** patrickmurphy5@gmail.com [mailto:patrickmurphy5@gmail.com] **On Behalf Of** Patrick Murphy
**Sent:** Thursday, April 04, 2013 12:09 PM
**To:** CDRH Small Manu. Assistance
**Subject:** Request for information about laser pointer regulation

Hi, I hope I am at the right place.

I need to find out when and how FDA/CDRH first determined that laser pointers are demonstration laser products under 21 CFR 1040.10 (b) (13).

Since pointers are not mentioned in 21 CFR 1040.10 or 1040.11 (which became active in August 1976), at some point this determination must have been made. However, I have looked through all the Laser Notices and have not seen any notice making this determination. I also searched the Federal Register online back through 1996 and have not seen this.

Therefore, could you point me to the right place to find this information? If I need to file a formal request such as FOIA in order to find this out, please let me know.

Thank you very much for your assistance,

Patrick Murphy

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**Patrick Murphy** <patrickmurphy5@gmail.com> Thu, Apr 11, 2013 at 11:50 AM
To: "Ellsworth, Eva" <Eva.Ellsworth@fda.hhs.gov>

Ms. Ellsworth --

Thank you very much for your detailed reply. I was impressed by the depth of your research -- it definitely gave me the answers I was looking for.

I want to commend you and any of your colleagues who may have assisted in the research. I know this could not have been easy or quick, so thank you VERY much again!

Sincerely,

Patrick Murphy

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