Friday, September 20, 2013

RE: Laser Products Proposed Amendment to Performance Standard
Docket No. FDA-2011-N-0070 and/or
Regulatory Information Number (RIN) 0910-AF87

Division of Docket Management (HFA-305)
Food and Drug Administration
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The Photonics Group, (Franklin, PA and West Chester, OH) has been providing compliance engineering and administration services in the Photonics industry since 1980.

We appreciate the opportunity to review and comment on the Notice of Proposed Rule (NPR), and submit suggestions which are based upon our experience working with regulatory officials, academia, and industry. Our specific comments follow:

COMMENTS SPECIFIC TO THE NPR

1. Proposed § 1002.1 (**21 CFR 1002.1**) revises the entries in table 1, for laser products, to reflect the hazard classification designations used in the IEC standards.
   We support this rule change, however, any harmonization should be with the latest version of the standard (EN60825-2013 to be issued later this year)

2. Proposed § 1010.1 (**21 CFR 1010.1**), Scope, is amended to update the reference to the legal authority for these regulations and amendments.
   We support this rule change

3. Proposed §§ 1010.2(d) and 1010.3(b) (**21 CFR 1010.2**(d) and 1010.3(b)) would authorize the Director, Center for Devices and Radiological Health (CDRH), or as delegated, on the Director's own initiative or upon written application by the manufacturer, to approve alternate means of providing certification and identification information.
   We support this rule change

4. Proposed § 1040.5 (**21 CFR 1040.5**) incorporates by reference into §§ 1040.10 and 1040.11 (**21 CFR 1040.10** and 1040.11) many of the provisions found in two amended IEC standards relating to laser products (i.e., IEC 60825-1:2007 and IEC 60601-2-22:2007) in order to bring the FDA standard up to date and achieve closer alignment with the IEC standards.
   We support this rule change, however, any harmonization should be with the latest version of the standard (EN60825-2013 to be issued later this year)

5. Proposed § 1040.10(a) retains the existing applicability stipulations and contains a note emphasizing that the standard is not being expanded to apply to light emitting diodes (LEDs) unless such products are also laser products as defined in § 1040.10(b)(4). LEDs do not typically meet the definition of laser product because they do not exhibit light amplification by controlled stimulated emission (capable of producing a high-intensity, long-distance hazard) and FDA does not want to apply unnecessarily-stringent requirements to LED manufacturers.
   We have a fundamental issue with not addressing LEDs simply due to their non-coherency characteristics- see GENERAL COMMENTS 1. below.

6. FDA is proposing to amend § 1040.10(a)(3) by adding a new paragraph (iii) as a means of addressing uncertified, unreported complete laser systems that are sold as components. FDA has observed that some manufacturers and distributors are marketing what are actually complete laser systems as components or original equipment manufacturer (OEM) parts...
   We have a fundamental issue how components and embedded devices are addressed- see GENERAL COMMENTS 2. below.

7. Proposed § 1040.10(b) incorporates by reference many of the numbered definitions in clause 3 of IEC 60825-1:2007 that apply to laser products, but excludes those aspects of the definition in clause 3 that are not applicable in the context of FDA's regulation because they pertain to the purchaser's use of the laser product, an aspect generally not regulated by FDA.
We support this rule change, however, any harmonization should be with the latest version of the standard (EN60825-2013 to be issued later this year)

8. Proposed § 1040.10(b)(2) provides a definition for children's toy laser products to distinguish between laser products provided for use as tools in professional or academic settings and those promoted for novelty use by children (Refs. 1, 2, and 3)...
We oppose this rule change. Internet proliferation and defining the age of a child is difficult, together, this presents a significant enforcement issue.

9. Proposed § 1040.10(b)(8) seeks to avoid confusion and clarifies that the terms must as used in §§ 1040.10 and 1040.11 and shall as used in §§ 1040.10 and 1040.11 and the IEC standards are equivalent in meaning and signify a requirement.
We support this rule change

10. Proposed § 1040.10(b)(9) would add two sentences to the definition at subclause 3.24 of IEC 60825-1:2007, which would be incorporated by reference by proposed § 1040.10(b)(1). This language would clarify the definition of the term “collateral radiation” consistent with current and proposed requirements as well as longstanding FDA policy...
We are not sure this proposed rule change is an issue due to most enclosures provide enough basic protection to the user against the level of x-rays emitted (except in the case of R&D)

11. Proposed § 1040.10(c) incorporates by reference the hazard classifications of the IEC standard IEC 60825-1:2007.
We support this rule change, however, any harmonization should be with the latest version of the standard (EN60825-2013 to be issued later this year)

12. Proposed § 1040.10(d) incorporates by reference tables of accessible emission limits (AELs) for the classes of laser products identified in IEC 60825-1:2007. FDA acknowledges that the AELs of the IEC are more up to date and better represent current understanding of the biological hazards of laser radiation...
We support this rule change, however, any harmonization should be with the latest version of the standard (EN60825-2013 to be issued later this year)

13. Proposed § 1040.10(e) incorporates by reference the measurement conditions set forth in IEC 60825-1:2007 for use in determining the hazard classification of the laser product. However, FDA retains its requirement that tests under this section be part of the basis of the required certification of the product...
We support this rule change, however, any harmonization should be with the latest version of the standard (EN60825-2013 to be issued later this year)

14. Proposed § 1040.10(f) incorporates by reference the engineering specifications provisions of clause 4 of IEC 60825-1:2007 with certain exceptions. The exceptions include retention of the existing authority in current § 1040.10(f)(6) for CDRH to approve alternate means of safety in lieu of a beam attenuator. Proposed § 1040.10(f)(4) is intended to allow more flexibility to manufacturers in providing means to preclude unintended or unauthorized use of Class 3B or 4 laser systems...
We support this rule change, however, any harmonization should be with the latest version of the standard (EN60825-2013 to be issued later this year)

15. Proposed § 1040.10(f)(12) relating to collateral radiation would not incorporate subclause 4.14.2 of IEC 60825-1:2007, but instead require that the protective housing of laser products must prevent human access to collateral radiation that exceeds the limits for collateral radiation as specified in proposed § 1040.10(d)(2).
We support this rule change, however, any harmonization should be with the latest version of the standard (EN60825-2013 to be issued later this year)

16. Proposed § 1040.10(g) incorporates by reference the labeling provisions of IEC 60825-1:2007 but allows labeling in the format specified in the American National Standards Institute (ANSI) 535 series for labels. Under this provision, either type of labeling could comply with the regulations.
We do not support this rule change- see GENERAL COMMENTS 3. below (and any harmonization should be with the latest version of the standard (EN60825-2013 to be issued later this year)

17. Proposed § 1040.10(h)(1) includes minor conforming changes. Proposed § 1040.10(h)(2)(ii) reorganizes and clarifies what service information must be made available by manufacturers. In particular, the service information addresses procedures or adjustments which may affect any aspect of the products performance...
We support this rule change with a minor difference in approach see GENERAL COMMENTS 7.

18. Proposed § 1040.11(a), which applies to medical laser products, would incorporate by reference certain pertinent clauses and subclauses from the IEC standard IEC 60601-2-22:2007 including instructions for use (subclause 201.7.9.2) and laser radiation (clause 201.10)...
We support this rule change

19. FDA is proposing to amend § 1040.11(b) and (c) to change the highest allowed class designation from Class IIIa to Class 3R. This change is necessitated by the incorporation of the IEC classifications and measurements for classification by reference into § 1040.10(d) and (e).
We support this rule change

20. FDA is also proposing to amend § 1040.11 by adding a new paragraph (d). Proposed § 1040.11(d) would restrict to Class 1 under any conditions of operation, maintenance, service, or failure, any laser products that are made or promoted as children's toys.
We do not support this rule change. The mission is important but as written, can be a source of abuse and rule undermining.

21. FDA, in response to a specific request from the U.S. Department of Defense (DOD), is proposing a new § 1040.11(e) that codifies an exemption from the standard granted for the DOD in 1976 for laser products that are intended for use in combat, combat training, or that are classified in the interest of national security.
We support this rule change

GENERAL COMMENTS

1. LEDs

The LED industry is advancing commercially at the same rate (if not faster in specific segments), than lasers. As the FDA/CDRH protects the public's radiological health, LEDs cannot be left out of the discussion. LEDs (specifically Super Radiant LEDs or "SLEDs") are producing increasingly hazardous levels of radiation and they are ubiquitous. We suggest the investigation of the inclusion of LEDs into the code of those devices characterized as Risk Group 2 or 3 (non-exempt) as per EN62471.

2. Compliance Lineage

The current state of compliance lineage is confusing. In order for a manufacturer to complete product development and manufacturing, the best position for product liability, is to ensure all subsystems contained comply with applicable standards and regulations. Consider the following:

REFERENCE (21CFR1040.10)
(a)*Applicability.* The provisions of this section and 1040.11, as amended, are applicable as specified to all laser products manufactured or assembled after August 1, 1976, **except** when:
(1) Such a laser product is either sold to a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, or
(2) Sold by or for a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, provided that such laser product:
(i) Is accompanied by a general warning notice that adequate instructions for the safe installation of the laser product are provided in servicing information available from the complete laser product manufacturer under paragraph (h)(2)(ii) of this section, and should be followed,
(ii) Is labeled with a statement that it is designated for use solely as a component of such electronic product and therefore does not comply with the appropriate requirements of this section and 1040.11 for complete laser products, and
(iii) Is not a removable laser system as described in paragraph (c)(2) of this section; and
(3) The manufacturer of such a laser product, if manufactured after August 20, 1986:
(i) Registers, and provides a listing by type of such laser products manufactured that includes the product name, model number and laser medium or emitted wavelength(s), and the name and address of the manufacturer. The manufacturer must submit the registration and listing to the Food and Drug Administration, Center for Devices and Radiological Health, Director, Office of Compliance, 10903 New

Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993-0002.
(ii) Maintains and allows access to any sales, shipping, or distribution records that identify the purchaser of such a laser product by name and address, the product by type, the number of units sold, and the date of sale (shipment). These records shall be maintained and made available as specified in 1002.31.

SUMMATION
In order for a laser diode (component) to be exempt from filing compliance, the diode/device:
1. (as per (1)(2)(i))
must be accompanied by a general warning notice that adequate instructions for the safe installation of the laser product are provided in servicing information available from the complete laser product manufacturer under paragraph (h)(2)(ii) of this section, and should be followed;
2. (as per (1)(2)(ii))
is labeled with a statement that it is designated for use solely as a component of such electronic product and therefore does not comply with the appropriate requirements of this section and 1040.11 for complete laser products;
3. (as per (1)(2)(iii))
is not a removable laser system as described in paragraph c(2) of this section;
4. (as per (3)(i))
registers, and provides a listing by type of such laser products manufactured that includes the product name, model number and laser medium or emitted wavelength(s), and the name and address of the manufacturer. The manufacturer must submit the registration and listing to the Food and Drug Administration, Center for Devices and Radiological Health, Director, Office of Compliance, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993-0002;
5. (as per (3)(ii))
maintains and allows access to any sales, shipping, or distribution records that identify the purchaser of such a laser product by name and address, the product by type, the number of units sold, and the date of sale (shipment). These records shall be maintained and made available as specified in 1002.31.

REFERENCE (IEC60825-1-2007)
Laser products that are sold to other manufacturers for use as components of any system for subsequent sale are not subject to IEC 60825-1, since the final product will itself be subject to this standard. However, if the laser system within the laser product is operable when removed from the equipment, the requirements of this Part 1 apply to the removable unit.
NOTE 1 Operable equipment does not require a tool to prepare for operation. Any laser product is exempt from all further requirements of this Part 1 if classification by the manufacturer of that product according to Clauses 3, 8 and 9 shows that the emission level does not exceed the AEL (accessible emission limit) of Class 1 under all conditions of operation, maintenance, service and failure.
NOTE 2 The above exemption is to ensure that inherently safe laser products are not unnecessarily subject to the standard.

SUMMATION
Laser products within laser products are not subject to IEC 60825-1 unless it is removable.

3. Labeling Colors

The US system (both FDA/CDRH and OSHA) have a long history of connoting the coloring of signs and warning logos to actions:

Blue/green is meant for notice;
Yellow is caution/to take notice, and;
Red is Danger or important safety information.

The IEC scheme does not distinguish but instead chooses Yellow for all labeling with respect to lasers (and fiberoptic) product safety. Considering the aging US worker base, this causes confusion where there shouldn't be. Safety labels and signage are critical informational pieces to inform and alert workers. We are suggesting a standing alternative labeling scheme using the Blue/Yellow/Red colors as long as the proper performance/exposure details are maintained.

4. Fiberoptics

There are laser systems (that are not telecommunications systems) which distribute high optical power and/or energy over fiberoptics. Currently there are no labeling requirements for such fiberoptic cables in the code. We suggest adopting the OFCS language stipulated in 60825-2.

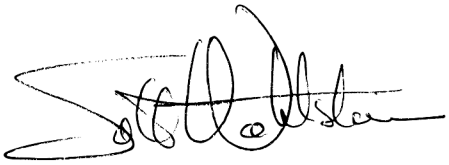
5. **Internet**
   The growth of the internet has been phenomenal, and with it, sellers of laser products online. A number of these companies are prolific in their marketing methods, and children (and the parents of children) are buying Class III and IV products without the required documentation (to any system) completely unaware of the hazards. We strongly suggest the strengthening of labeling requirements of any/all advertising of laser products > Class I/1.

6. **Growth of Technology**
   The Photonics technological landscape continues to evolve. We suggest reviewing the language which defines a laser to include those devices which can produce harmful levels of Photons regardless of coherency to ensure generations are protected from potentially hazardous light sources.

7. **Definition of Maintenance and Service**
   For decades the industry has used the analogy that if a laser system is a copier: Normal operation is making copies, Maintenance is loading paper and changing the toner, and Service is changing lamps and belts. This analogy no longer applies, in fact, we have rarely seen that scenario successfully employed. Anytime a laser system undergoes anything other than Normal operation, there is a risk of exposure. We suggest engineering controls to physically lock out Service mode of operation while allowing Maintenance modes to be at the discretion of the user.

Respectfully,

for The Photonics Group



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