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# **Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors (LIPs)**

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## **Guidance for Industry and Food and Drug Administration Staff**

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health**

**Office of In Vitro Diagnostics and Radiological Health (OIR)  
Division of Radiological Health**

# Preface

## Public Comment

You may submit comments and suggestions regarding this document within 60 days of publication in the Federal Register of the notice announcing the availability of the guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Identify all comments with the docket number listed in the notice of availability that publishes in the Federal Register.

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## **Guidance for Industry and Food and Drug Administration Staff**

*This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.*

### **I. Introduction**

This guidance describes FDA's policy with respect to certain laser illuminated projectors that comply with International Electrotechnical Commission (IEC) standards during laser product classification<sup>1</sup> under the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) that apply to electronic products.

For purposes of this guidance, the term "laser illuminated projector" (LIP) refers to a type of demonstration laser product<sup>2</sup> defined in 21 CFR 1040.10(b)(13) that is designed to project full-frame digital images. LIPs may be used in locations such as indoor or outdoor cinema theaters, laser shows, presentations at conventions, as image/data projectors in an office setting, or in a home.

Lasers are being used in LIPs as an alternative to conventional lamps in projectors. Although these LIPs emit laser light from extended sources and their uncollimated beams do not present

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<sup>1</sup> The requirements for classifying laser products are set forth in 21 CFR part 1040.

<sup>2</sup> The term "demonstration laser product" is defined under 21 CFR 1040.10(b)(13) to mean "any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition."

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the same hazards as other lasers, they are laser products that present risks and must undergo classification in accordance with 21 CFR 1040.10(c).

Under 21 CFR 1040.10(c), FDA recognizes four major hazard classes (I to IV) of lasers, including three subclasses (IIa, IIIa, and IIIb). Under this classification procedure, higher laser classes correspond to more powerful lasers and a higher potential to pose serious danger if used improperly.

As demonstration laser products, LIPs and applications for LIPs cannot exceed Class IIIa (which is comparable to IEC Class 3R) emission limits as specified in 21 CFR 1040.11(c) unless granted a variance by FDA under 21 CFR 1010.4. Many LIPs and applications for LIPs will exceed the Class IIIa (IEC Class 3R) limits and therefore require a variance to exceed those emission limits.

This guidance document describes FDA's intent with regard to the application of certain aspects of the performance standard requirements in 21 CFR 1040.11(c) for LIPs. The IEC standards used to evaluate lamps are applicable to characterizing ocular hazards in LIPs, because a laser retinal hazard is related to the radiance of the laser source and the radiant emission levels produced by LIPs are comparable to conventional lamps. Because the radiant emission levels produced by LIPs can scientifically be characterized by an alternative IEC standard, FDA does not intend to consider whether LIP manufacturers that conform to these standards under the situations outlined in sections III and IV of this guidance also comply with 21 CFR 1040.10(c) and 21 CFR 1040.11(c).

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). The Agency made this determination because the guidance presents a less burdensome policy that is consistent with the public health. Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance as appropriate.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

## **II. Background**

IEC is a global organization that prepares and publishes international standards for electrical, electronic, and related technologies, including laser products. FDA is aware that standard IEC 60825-1:2014 "Safety of laser products – Part 1: Equipment classification and requirements" (IEC 60825-1:2014) allows alternative classification procedures for certain laser products that produce extended source light emissions, such as LIPs. Under this alternative classification procedure, LIPs are categorized by optical safety "Risk Groups" specified in standard IEC 62471:2006 "Photobiological Safety of Lamps and Lamp Systems" (IEC 62471:2006). Under the IEC's classification procedure, LIPs are assigned a Risk Group (RG) of 0, 1, 2, or 3, where

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higher RGs correspond to higher radiation outputs and a higher potential to pose serious danger if used improperly.

FDA believes that, under certain circumstances set forth below, the relevant IEC standards adequately categorize the risks to health posed by qualified LIPs. Therefore, FDA does not intend to consider whether qualified LIPs that conform to certain IEC 62471:2006 RGs under the situations described in this guidance also comply with 21 CFR 1040.10(c) and 21 CFR 1040.11(c).

### **III. Scope**

This guidance only applies to LIPs with extended source emissions that meet all of the following criteria:

- (a) The projector is neither a children's toy laser product<sup>3</sup> nor a medical device.<sup>4</sup>
- (b) The projector does not produce scanned laser radiation.<sup>5</sup>
- (c) The projector's laser illumination system is an alternative to a conventional projector light source.
- (d) The apparent light source subtends an angle greater than or equal to 0.005 radians (rad), when determined at a distance of 0.2 meter from the nearest point of human access<sup>6</sup> (see Par. 6 of IEC 62471:2006).
- (e) The emissions are only within the visible wavelength range of 400 nm to 700 nm.
- (f) The unweighted peak radiance levels do not exceed  $1 \text{ MW} * \text{m}^{-2} \text{ sr}^{-1} / \alpha$  where  $\alpha$  is the angular subtense of the source at 0.2 m from the closest distance of human

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<sup>3</sup> FDA published a proposed rule that includes a new section to specifically identify what constitutes children's toy laser products. See 78 FR 37723, 37741 (June 24, 2013). This new section, as proposed, includes the definition of a children's toy laser product and requires that the emissions of children's toy laser products not exceed the IEC Class 1 limit. Consistent with the proposed rule, and for purposes of this guidance, "children's toy laser product" means a product primarily used as a toy that is manufactured, designed, intended or promoted for novelty or visual entertainment use by children under 14 years of age. This definition is intended to exclude laser products that are used in professional or academic settings that may be used by children (for example, laser printers, CD players, educational and science kits). Some examples of children's toy laser products include: (a) lasers mounted on toy guns that can be used for "aiming"; (b) spinning tops that project laser beams while they spin; and (c) hand-held lasers used during play as "light sabers." See 78 FR 37723, 37725, 37727, and 37737.

<sup>4</sup> The term "device" is defined in Section 201(h) of the FD&C Act to include an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . . or intended to affect the structure or any function of the body of man."

<sup>5</sup> The term "scanned laser radiation" is defined under 21 CFR 1040.10(b)(37) to mean "laser radiation having a time-varying direction, origin or pattern of propagation with respect to a stationary frame of reference."

<sup>6</sup> The term "human access" is defined under 21 CFR 1040.10(b)(15) to mean "the capacity to intercept laser or collateral radiation by any part of the human body."

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access and the radiance is averaged over a 0.0017 rad acceptance angle (see Par. 4.2.2 of IEC 62471:2006).

LIPs that do not meet all these factors are outside the scope of this guidance and FDA will continue to consider the requirements found at 21 CFR 1040.10(c) and 21 CFR 1040.11(c) for those LIPs.

## **IV. Policy**

FDA does not intend to consider whether manufacturers of LIPs within the scope of this guidance (see Section III above) that fall within the situations described in paragraphs (a),(b), and (c) set forth below also comply with 21 CFR 1040.10(c) and 21 CFR 1040.11(c). For those LIPs within the scope of this guidance that do not fall within the situations described in paragraphs (a), (b), and (c) below, FDA discusses some unique aspects to how it expects to regulate them in paragraph (d) below.

- (a) Manufacturers should first follow the following procedures in conducting measurements for classifying LIPs:
  - (i) Include laser radiation as defined at 21 CFR 1040.10(b)(22) in the RG classification analysis, which includes all radiation emitted by these electronic products as a result of controlled stimulated emission or that is detectable with radiation so produced.
  - (ii) Measure the accessible emissions at a distance of 1.0 meter (m) from the closest point of human access for qualifying LIPs intended for commercial movie theaters; and at the distance of 0.2 m from the closest point of human access for all other such LIPs (see Par. 6 of IEC 62471:2006).
  - (iii) Average the integrated spectral radiance  $L_{\lambda}$  for the retinal thermal exposure over an acceptance angle of not less than 0.0017 rad, and not more than 0.1 rad included angle (see Par. 4.3.5 of IEC 62471:2006).
  - (iv) Average the integrated spectral radiance  $L_B$  for the retinal blue light exposure over an acceptance angle of not less than 0.0017 rad, and not more than 0.1 rad included angle (see Par. 4.3.5 of IEC 62471:2006.)

In accordance with clause 8.3.f) of IEC 60825-1:2007, determine the most restrictive of conditions 1), 2) and 3)a) as applicable for the integrated spectral radiance emissions for all single pulses and pulse groups less than or equal to 0.25 s for the retinal thermal hazard and a time-averaged integrated spectral radiance for 0.25 s for the retinal photochemical (blue light) hazard. Note that clause. 8.3.f) in its second paragraph explicitly excludes the necessity for application of condition 3) for comparisons with photochemical limits such as the blue light hazard. Determine the Risk Group classification for pulsed emissions by comparing to the corresponding Emission Limits (EL) for the retinal thermal hazard and the blue light hazard as specified in IEC 62471:2006 with a value T set to 0.25 s.

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- (v) Evaluate the accessible emissions in the worst case configuration of the design that produces the highest emissions. For projectors with a fixed focal length with no adjustable zoom this means adjusting the output control settings and focus to maximize the emissions. For projectors with a variable throw ratio (zoom) lens that is non-interchangeable or interchangeable lenses for different throw ratios, this means adjusting the output controls as above and also adjusting the zoom or using the lens for that throw ratio that maximizes the emissions.
  - (vi) Determine the un-weighted peak radiance for the qualifying criterion of paragraph III(f) in this guidance and the RG assignment under every reasonably foreseeable single fault condition.
- (b) Manufacturers should then classify the LIPs in RGs and laser classes and certify their product as follows:
- (i) Classify the product in an RG according to IEC 62471:2006 “Photobiological Safety of Lamps and Lamp Systems.”
  - (ii) With respect to the embedded laser, certify the LIP (1) as a Class I laser product according to requirements of 21 CFR 1010 and 1040.10 or (2) as an IEC Class 1 laser product using the process discussed in the guidance entitled “Laser Products – Conformance with IEC 60825-1 and IEC 60601-2-22; Guidance for Industry and FDA Staff (Laser Notice No. 50)”<sup>7</sup> (<http://www.fda.gov/downloads/Medical%20Devices/.../ucm094366.pdf>). Conform to the accessible laser class during procedures of “Maintenance” and “Service”, as applicable, in accordance with 21 CFR Part 1040.
- (c) For LIPs that are in RG 0, 1, or 2, meet the descriptions in Section III, and are measured, classified, and certified according to the procedures in paragraphs (a) and (b) of this section, manufacturers should:
- (i) Include, in the user information accompanying the product, data regarding emissions, RG, numerical hazard distance(s), installation and use requirements as well as reproductions of all labels specified by this guidance; and
  - (ii) Use the following modified statements of compliance on the certification label, as applicable:

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<sup>7</sup> Laser Notice No. 50 excludes demonstration lasers from its scope. However, for LIPs that meet the descriptions in Section III and are measured according to paragraph (a) of Section IV of this guidance, FDA will not object to compliance with the IEC 60825-1:2014 and IEC 62471:2006 standards and certification of that compliance per Laser Notice No. 50. To that end, this guidance supersedes in part the policy set forth in Laser Notice No. 50.



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- a. “Complies with FDA performance standards in 21 CFR 1040.10 and 1040.11 as a Risk Group (0, 1, or 2 – Select appropriate RG) LIP as defined in IEC 62471:2006.”; or,
  - b. “Complies with FDA performance standards for laser products as a Risk Group (0, 1, or 2 – Select appropriate RG) LIP as defined in IEC 62471:2006 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.”; or,
  - c. “Complies with 21 CFR 1040.10 and 1040.11 as a Risk Group (0, 1, or 2 – Select appropriate RG) LIP as defined in IEC 62471:2006 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.”
- (iii) Submit product reports and annual reports and comply with all other reporting and recordkeeping requirements as required by 21 CFR 1002. Product reports for LIPs will document how the product meets the descriptions in Section III, was measured, classified, and certified according to the procedures in paragraphs (a) and (b) of this section, and complies with the requirements of 21 CFR 1010 and 21 CFR 1040.10. The manufacturer may use Form FDA 3632 “Guide for Preparing Product Reports for Lasers and Products Containing Lasers” (<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081592.pdf>) and FDA Form 3636 “Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products” (<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081603.pdf>) to submit these reports.

For manufacturers that follow the steps described in this paragraph, FDA will not object to the manufacturers selling these LIPs to the general public without obtaining a variance approval from the FDA.

- (d) CDRH considers LIPs that are in RG 3 to be equivalent to demonstration laser products in Laser Classes IIIb or IV (IEC Class 3B or 4) that are defined under 21 CFR 1040.10(b)(9)-(11). Laser products in these classes exceed the Class IIIa limit for demonstration laser products in 21 CFR 1040.11(c). For RG 3 and Class IIIb or IV (IEC Class 3B or 4) LIPs, manufacturers should:
- (i) Submit product reports and annual reports (see Section IV(c)(ii) above) and comply with all other reporting and recordkeeping requirements under 21 CFR 1002; and
  - (ii) Submit a variance application to exceed the demonstration laser product class limit of IIIa in 21 CFR 1040.11(c) (or IEC Class 3R). The variance application must provide the information specified in 21 CFR 1010.4(b). For these

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applications, FDA generally makes the approvals with the following conditions:

- a. The LIP may be sold only to manufacturers of laser light shows or to cinema theater operators;
- b. The label must display the warning “No direct exposure to beam shall be permitted”;
- c. The LIP must include a label stating “Not for household use”; and
- d. The user information must include installation instructions that include directions that specify mounting the projector high enough to provide clearance for people who may walk beneath the beam path or establishing a restricted access area that extends beyond the beam hazard distance.

Cinema theaters in which RG 3 LIPs are in use do not need to have a variance approval to use the projector because the LIP manufacturer’s variance has a condition of approval under 21 CFR 1010.4 that adequate instructions for the cinema theater to implement a safe installation under any reasonably foreseeable uses be provided.