Contains Nonbinding Recommendations

Draft – Not for Implementation

Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57)

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Document issued on October 2, 2017.

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For questions about this document, contact the Division of Radiological Health at (301) 796-2121 or Patrick Hintz at (301) 796-6927 or via email at Patrick.Hintz@fda.hhs.gov.

When final, this guidance will supersede *Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors (LIPs)*, dated February 18, 2015.

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
Division of Radiological Health

Preface

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Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57)

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

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[1] 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[2] regulated under 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 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).

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[1] The requirements for classifying laser products are set forth in 21 CFR part 1040.

[2] 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."

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 emission limits as specified in 21 CFR 1040.11(c) (which is comparable to IEC 60825-1 Ed. 2.0 Class 3R) unless granted a variance by FDA under 21 CFR 1010.4. Some LIPs and applications for LIPs will exceed the Class IIIa limits and therefore require a variance to exceed those emission limits.

This guidance document describes FDA's intent to clarify the application of certain aspects of the performance standard requirements in 21 CFR 1040.11(c) for LIPs. Because the radiant emission levels produced by LIPs can be scientifically characterized by an alternative IEC standard, IEC 62471-5:Ed. 1.0, 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)(1) and 21 CFR 1040.11(c). For LIP manufacturers who choose not to conform to these standards under the situations outlined in sections III and IV of this guidance, such manufacturers should evaluate these laser products in accordance with FDA's guidance entitled "Laser Products – Conformance with IEC 60825-1 and IEC 60601-2-22 (Laser Notice No. 50); Guidance for Industry and FDA Staff" (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094361.htm) or must continue to comply with 21 CFR 1040.10(c) and 21 CFR 1040.11(c), among other applicable requirements.

FDA's guidance documents, including this draft 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 acknowledges that standard IEC 60825-1:Ed. 3 "Safety of laser products – Part 1: Equipment classification and requirements" (IEC 60825-1:Ed. 3) 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" (RGs) specified in standard IEC 62471-5:Ed. 1.0 "Photobiological Safety of Lamps and Lamp Systems, Part 5: Image Projectors" (IEC 62471-5:Ed. 1.0). Under the IEC's classification procedure, LIPs are assigned a Risk Group of 0, 1, 2, or 3, where higher Risk Groups correspond to higher radiation outputs and a higher potential to pose serious danger if used improperly. The laser standard, IEC

60825-1:Ed. 3 has an exemption Subclause 4.4 that, if satisfied, qualifies the laser product for the use of classification risk groups from the IEC series of lamp standards.

FDA recognizes the advantages of one set of worldwide standards for classifying laser products, including LIPs. Moreover, 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 62471-5:Ed. 1.0 RGs under the situations described in this guidance also comply with 21 CFR 1040.10(c)(1) and 21 CFR 1040.11(c).

III. Scope

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

(a) The projector is neither a children's toy laser product[3] nor a medical device.[4]

(b) The projector does not produce scanned laser radiation.[5]

(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[6] (see Subclause 4.4 of IEC 60825-1:Ed. 3) and Section IV(a)(iii) of this guidance.

(e) The emissions are only within the wavelength range of 400 nm to 1400nm. Infrared Accessible Emissions within the wavelength range 700 nm to 1400 nm should not exceed the Accessible Emission Limits for Laser Class 1.

(f) The unweighted, spatially-averaged peak radiance threshold (L_T) levels do not exceed 1 ($MW \cdot m^{-2} \cdot sr^{-1}/\alpha$ where α is the subtended plane angle[7] (angular subtense) of the source measured at 0.2 m from the closest distance of human access. Measured quantity

[3] *See* FDA's guidance entitled "Minimizing Risk for Children's Toy Laser Products" (https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm363731.pdf)

[4] The term "device" is defined in 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."

[5] 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."

[6] 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"

[7] Paul Quincey, "The range of options for handling plane angle and solid angle within a system of units", Metrologia 53 (2016) p. 840-845.

L_T is averaged over a 0.005 rad acceptance angle γ, see Subclause 4.4 of IEC 60825-1:Ed. 3 and its Interpretation Sheet I-SH 2.

(g) The angular subtense of the LIPs exit pupil is ≥ 11 mrad when measured at 1 m. Projectors with smaller exit pupils should be evaluated to IEC 60825-1 Ed. 2. This source size limit is imposed because the injury model used for the projector standard assumes a conservatively estimated smallest exit pupil of 11 mrad.[8]

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)(1) and 21 CFR 1040.11(c). For 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) Provided that the LIPs meet the descriptions in Section III, 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 and any other light sources emitted from the projector lens. Hybrid light sources combine laser light with LED and both types of light are emitted from the projector's lens aperture to form an image. LEDs are technologically necessary for the operation of hybrid LIPs laser products because their design uses LED-produced radiation along with the laser's stimulated-emission radiation to accurately reproduce a full spectrum of colors. See Appendix A for more information.

(ii) 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 for projectors with 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 ratio

[8] Karl Schulmeister and Jan Daem, "Biophysical data in support of the classification distance for image projectors under IEC 62471-5", Proc. ILSC, March 23-26 2015, P. 96-105 and available from the authors as pdf reprint.

Accessible Emission to Accessible Emission Limits (see Subclause 5.2.1 of IEC 62471-5:Ed. 1.0; the last sentence in Subclause 5.2.1 is not applicable).

(iii) Evaluate the optical profile of the beam at a distance of 200 mm from the closest point of human access to determine the subtended plane angle α (angular subtense) of the projected beam. Using a detector plane angle of acceptance γ (angular field of view) of 0.0015 rad or smaller, profile the beam to determine the maximum radiance (hotspot). Determine the 50% level with respect to the maximum radiance to define the outer edges of the source profile. Compute and limit α to a maximum of 0.1 rad and a minimum of 0.005 rad. See Subclause 5.3 of IEC 62471-5:Ed. 1.0 for determining the plane angular subtense of an elliptical or oblong source. The raw profiles or camera image of the exit pupil are useful for the evaluation of hotspots and should be included in the LIPs product report (21 CFR 1002.10).

(iv) Determine the unweighted, spatially-averaged peak radiance threshold (L_T) for the qualifying criterion of paragraph III(f) in this guidance using an acceptance angle γ of 0.005 rad measured at 200 mm from the closest point of human access. If the projector beam has a diameter of less than 7 mm at the 200 mm distance, use an aperture stop of 1 mm for radiance determination. Consider maximum emissions during normal operations and maintenance as well as all reasonably foreseeable single fault conditions. The L_T measurement should be included in the LIPs product report (21 CFR 1002.10).

(b) Provided that the LIPs meet the descriptions in Section III and are measured according to the procedures in paragraph (a), manufacturers should then classify the LIPs in RGs and laser classes and certify their product as follows:

(i) Classify the projector to a risk group according to IEC 62471-5:Ed. 1.0 "Photobiological Safety of Lamps and Lamp Systems, Part 5: Image Projectors".

(ii) The informative Annex B in IEC 62471-5:Ed. 1.0 is not applicable.

(iii) Average the integrated spectral radiance L_λ for the retinal thermal exposure over an acceptance angle γ of not less than 0.011 rad, and not more than 0.1 rad.

(iv) Average the integrated spectral radiance L_B for the retinal blue light exposure over an acceptance angle as specified in Tables 1 and 2 of IEC 62471-5:Ed. 1.0.

(v) If the LIPs output exceeds RG2 at any point between the 1 m measurement distance and the 200 mm distance to closest human access, include the following special warning labeling and user instructions in addition to other applicable labeling. This condition may be approximated by using the limit factor $(4/7)^2$ times the RG2 exposure limit or 9143 $(W \cdot m^{-2} \cdot sr^{-1})/\alpha$ measured at 1 m. Special

handling is justified for RG2 LIPs whose radiance exceeds the limit value to prevent exposures.

a. An additional Product Warning label should be placed near the symbol of Figure 8 in IEC 62471-5:Ed. 1.0 (staring prohibited): "WARNING: AVOID DIRECT EYE EXPOSURE CLOSER THAN 1.0 m (39 in)." Text and border of the label should be black on an orange background. The warning statement may also be combined with the staring prohibited label if the warning text has an orange background or orange header for the signal word, "WARNING".

b. The User's Manual Installation Instructions should additionally state: "WARNING: AVOID DIRECT EYE EXPOSURE CLOSER THAN 1.0 m (39 in). The use of a ceiling mount is recommended to place this product above the reach of children."

(vi) With respect to the embedded laser(s), certify the LIP (1) as a Class I laser product according to applicable requirements of 21 CFR 1010, 1040.10, and 1040.11, or (2) as an IEC Class 1 laser product using the process discussed in Laser Notice No. 50.[9] 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 and classified according to the procedures in paragraphs (a) and (b) of this section, manufacturers should:

(i) Use the following modified statements of compliance on the certification label, as applicable:

a. "Complies with FDA performance standards in 21 CFR 1040.10 and 1040.11 as Risk Group (0, 1 or 2 – Select appropriate RG) LIP as defined in IEC 62471-1:Ed. 1.0"; 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 62471-1:Ed. 1.0 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 Risk Group (0, 1, or 2 – Select appropriate RG) LIP as defined in IEC 62471-1:Ed. 1.0

[9] 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:Ed. 2 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.

except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007."

(ii) Conform to all labeling specifications as provided in IEC 62471-5:Ed. 1.0 with the following exceptions/additions:

a. With regard to RG0 LIPs, the second sentence in Subclause 6.5.2 of IEC 62471-5:Ed. 1.0 is not applicable.

b. Always include the label for RG1 LIPs as provided in Subclause 6.5.3 of IEC 62471-5:Ed. 1.0. The statement in Subclause 6.5.3 of IEC 62471-5:Ed. 1.0 that the label for RG1 LIPs is optional is not applicable.

(iii) Conform to requirements applicable to the Operation Manual as specified in Subclause 6.6.3 of IEC 62471-5:Ed. 1.0 with the following additions:

a. Notice should be given to supervise children and to never allow them to stare into the projector beam at any distance from the projector.

b. Notice should be given to use caution when using the remote control for starting the projector while in front of the projection lens.

c. Notice should be given to the user to avoid the use of optical aids such as binoculars or telescopes inside the beam.

(iv) 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, 21 CFR 1040.10, and 21 CFR 1040.11. The manufacturer may use Form FDA 3632 "Guide for Preparing Product Reports for Lasers and Products Containing Lasers" (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081592.pdf) to submit these reports.

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

(d) The following situations should apply to LIPs that are in RG3 meet the descriptions in Section III and are measured, classified and certified according to the procedures in paragraphs (a) and (b) of this section:

(i) CDRH considers LIPs that are in RG3 to be demonstration laser products equivalent to Laser Classes IIIb or IV (IEC 60825-1 Ed. 2.0 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). When demonstration laser products are Class IIIb or IV, a variance approval by FDA is required under 21 CFR 1010.4 that permits the laser product to exceed the demonstration laser product class limit of IIIa. For variance approvals under 21 CFR 1010.4 of such RG3 LIPs products, FDA generally makes the approvals conditional on the laser products being sold only to manufacturers of laser light shows currently holding a valid variance or to cinema theater operators.

(ii) FDA also generally makes variance approvals under 21 CFR 1010.4 for RG3 LIPs conditional on the display of the warning specified in IEC 62471-5:Ed. 1.0. "No direct exposure to beam shall be permitted" on RG 3 LIPs product's RG label and a symbol representing or a label stating "Not for household use."

(iii) FDA will also generally make approvals of variances for RG3 LIPs subject to the condition that user information 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. For Class IIIb or IV LIPs, submit a variance request in accordance with 21 CFR 1010.4. The variance application must provide the submission information requirements specified in 21 CFR 1010.4(b).

(iv) Submit product reports and annual reports and comply with all other reporting and recordkeeping requirements under 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, 21 CFR 1040.10, and 21 CFR 1040.11. The manufacturer may use Form FDA 3632 "Guide for Preparing Product Reports for Lasers and Products Containing Lasers" (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081592.pdf) to submit these reports.

(v) Cinema theaters in which RG3 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.

(vi) Subclause 3.14 of IEC 62471-5:Ed. 1.0 defines a Hazard Distance that is collinear to the optical projection axis. The optical projection axis may be tilted with respect to the optical axis of the projection lens. The Hazard Distance alone does not sufficiently describe a 3-dimensional Hazard Zone. A Hazard Zone is the region of space bounded by a plane intersecting the light cone and perpendicular

to the Hazard Distance line and the point of closest human access. The Hazard Zone encompasses a region of space that is considered RG3.

a. RG3 LIPs for fixed installation at locations other than cinema theaters should be installed at a height not lower than 3 m vertically. The lowest tip of the Hazard Zone should be no lower than 3 m measured vertically above the floor. Horizontal clearance to the Hazard Zone should be 2.5 m measured horizontally. Any human access to the Hazard Zone, if applicable, is to be restricted by barriers. Manufacturers of RG3 LIPs should assure that the fixed installation is performed by authorized installers, who are trained to perform installations in accordance with the manufacturer's instructions.

b. RG3 LIPs that prevent human access to the Hazard Zone (v) by use of a engineering controls (see IEC 62471-5:Ed. 1.0 (6.4.2)) will not require a variance application.

Summary of exceptions or additions to IEC 62471-5:Ed. 1.0:

IEC 62471-5 Clause	**Description**	**Reason**
4.1	RG2 projector application	Exception as FDA does not consider safe in **all** applications
5.2.1	Measurement throw ratio	Not applicable
6.5.2	RG0 label	Label required
6.5.3	RG1 label	Label required, not optional
6.5.4	RG2 additional label	Additional warning against eye exposure for close exposures less than 1 m
6.6.3.1	General user information	Additional instructions to supervise children, no staring, and not use optical aids
6.6.3.4	User warnings specific to brightest RG2 projectors	Additional instructions to install above the reach of children

Appendix A.

LED radiation in hybrid light source LIPs meets the definition of laser radiation:
21 CFR 1040.10 (b)(22) "Laser radiation means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph (b)(19) of this section that is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the appropriate aperture stop and within the appropriate solid angle of acceptance, as specified in paragraph (e) of this section." The LED radiation exits the projector lens aperture stop along with the laser radiation so it is included in the definition of laser radiation. IEC 60825-1:Ed. 3 Interpretation Sheet I-SH 2, condition #4 also supports inclusion of LED radiation for hybrid LED and laser LIPs.

Appendix B.

FDA's concerns over the Risk Group Classification system used for LIPs:
Both IEC 62471-1:2006 and IEC 62471-5:Ed. 1.0 define a hazard-based risk classification system that is equivalent to that of 21 CFR 1040.10. The laser risk Class IIIa (21 CFR 1040.10(b)(8)) has served as a transitional risk-based hazard class to the more hazardous Classes IIIb and IV. Class III (both IIIa and IIIb) accessible radiation levels can produce biological damage to human tissue resulting from accidental exposure. Laser Class IIIa radiation is an acceptable risk for many products but has not been recognized by FDA as safe for use by children (*see* Risk of Eye and Skin Injuries from Hand-held Lasers: FDA Safety Communication, Dec. 22, 2015). The brightest RG2 products require additional warnings and installation instructions to protect children from reasonably foreseeable exposures that could occur if the products were installed on tabletops or mobile carts. FDA recommends against installing the brightest (see Section (IV)(b)(v) of this guidance) RG2 projectors on tabletops or carts because such locations place the projection lens near eye-heights for children. FDA notes that Subclause 6.4.2 of IEC 62471-5:Ed. 1.0 "Power reduction by sensor system" can be considered effective for reducing the risk of hazardous light exposure and may enhance projector safety. FDA does not object to the use of power-reduction sensors in place of warning labels and user instructions specified in Section (IV)(b)(v) of this guidance for RG2 projectors.