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

Guidance for Industry and Food and Drug Administration Staff

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This document supersedes Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors (LIPs), dated February 18, 2015.

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

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Preface

Public Comment

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

Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 a display image without the use of raster-scanned collimated laser beams. 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).

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

[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."

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. 3.0[3] 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 enforce the requirements under 21 CFR 1040.10(c)(1) and 21 CFR 1040.11(c) when LIP manufacturers conform to these standards under the situations outlined in sections III and IV of this guidance. For LIP manufacturers that do not conform with the situations outlined in sections III and IV of this guidance, FDA intends to consider whether those manufacturers' laser products comply with 21 CFR 1040.10(c)(1) and 21 CFR 1040.11(c), among other applicable requirements. Such manufacturers may elect to evaluate their laser products in accordance with FDA's guidance entitled "Laser Products – Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56); Guidance for Industry and FDA Staff"[4] however, sub-clause 4.4 of IEC 60825-1 Ed. 3 would not apply to these products.

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 acknowledges that standard 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*. 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

[3] International Electrotechnical Commission (IEC) 60825-1 Ed. 3.0: *Safety of laser products - Part 1: Equipment classification, and requirements*

[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-products-conformance-iec-60825-1-ed-3-and-iec-60601-2-22-ed-31-laser-notice-no-56

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 enforce the requirements in 21 CFR 1040.10(c)(1) and 21 CFR 1040.11(c) for qualified LIPs that conform to certain IEC 62471-5:Ed. 1 RGs under the situations described in this guidance.

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[5] nor a medical device.[6]

(b) The projector does not produce scanned laser radiation.[7]

(c) The projector's laser illumination system is an alternative to a conventional projector light source.

(d) The projector passes the IEC 60825-1:Ed. 3 radiance limit threshold (L_T), subclause 4.4 of IEC 60825-1:Ed. 3 using the measurement conditions discussed in IEC 60825-1:Ed. 3 Information Sheet ISH2.

(e) Applicability of RG2 LIPs is limited to Table 1 (below) using source angular extent α and emissions expressed as a fraction of the RG2 accessible emission limit (AEL) after classifying the LIP to IEC 62471-5:Ed. 1. RG1 and RG0 LIPs have no applicability restrictions.

[5] *See* FDA's guidance entitled "Minimizing Risk for Children's Toy Laser Products" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/minimizing-risk-childrens-toy-laser-products).

[6] 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."

[7] 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."

Table 1 – Applicable RG2 LIPs

Source α (milliradians) measured at 1 m	Limit Threshold Fraction of RG2 AEL
≥ 11	1.0
10	0.92
9	0.83
8	0.73
7	0.64
6	0.55
5	0.45

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)(1) and 21 CFR 1040.11(c) for those LIPs. Non-applicable LIPs may be considered individually in a variance submitted to FDA under 21 CFR 1010.4.

IV. Policy

FDA does not intend to enforce the requirements in 21 CFR 1040.10(c)(1) and 21 CFR 1040.11(c) for manufacturers of LIPs within the scope of this guidance (see Section III above) that fall within all of the situations described in paragraphs (a), (b), and (c) set forth below. 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 first conduct measurements for classifying LIPs. Normative standard IEC 62471: Ed. 1 Subclause 5.2.2 supplies important information for optical measurement conditions. The classification measurements and analysis include all exit pupil radiation from lasers, phosphors and LEDs. As provided in paragraph (c)(iv) below, conformance to subclause 5.2.2 is noted in reports to FDA and supporting records are kept in accordance with 21 CFR 1002.30.

(b) Provided that the LIPs meet the descriptions in Section III and are measured as described in paragraph (a), manufacturers 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 "Photobiological Safety of Lamps and Lamp Systems, Part 5: Image Projectors".

(ii) Determine that the informative Annex B in IEC 62471-5:Ed. 1 is not applicable to the projector.

(iii) If the LIP output exceeds a fraction of 0.6 (60%) of the RG2 AEL, supply special labeling and user information to reduce exposure risks to children:

a. An additional Product Warning label is placed near the symbol of Figure 8 in IEC 62471-5:Ed. 1 (staring prohibited): "WARNING: MOUNT ABOVE THE HEADS OF CHILDREN" Text and border of the label is 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 additionally state: "WARNING: MOUNT ABOVE THE HEADS OF CHILDREN. The use of a ceiling mount is recommended with this product to place it above the eyes of children."

(iv) With respect to the embedded phosphor-pump 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. 56.[8] Conform to the accessible laser class requirements during procedures of "Maintenance" and "Service", as applicable, in accordance with 21 CFR Part 1040. For LIPs with embedded alignment laser(s) that are visible only during Maintenance or Service, certify the LIP as applicable to Laser Class I, II or IIIa or as IEC Class 1, 2 or 3R for the visible alignment laser emissions.

(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:

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

a. "Complies with 21 CFR 1040.10 and 1040.11 except for conformance as a Risk Group [0, 1 or 2 – Select appropriate RG] LIP as defined in IEC 62471-5:Ed. 1.0. For more information see Laser Notice No. 57, dated May 8, 2019."; or,

b. "Complies with FDA performance standards for laser products except for conformance as a Risk Group [0, 1, or 2 – Select appropriate RG] LIP as defined in IEC 62471-5:Ed. 1.0. For more information see Laser Notice No. 57, dated May 8, 2019." or,

c. "Complies with 21 CFR 1040.10 and 1040.11 except for conformance as a Risk Group (0, 1, or 2 – Select appropriate RG) LIP as defined in IEC 62471-

[8] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-products-conformance-iec-60825-1-ed-3-and-iec-60601-2-22-ed-31-laser-notice-no-56

5:Ed. 1.0. For more information see Laser Notice No. 57, dated May 8, 2019."

(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 is not applicable.

b. Always include the label for RG1 LIPs as provided in Subclause 6.5.3 of IEC 62471-5:Ed. 1. The statement in Subclause 6.5.3 of IEC 62471-5:Ed. 1 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 with the following additions:

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

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

c. Notice is 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"[9] 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 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. 3 Class 3B or 4) that are

[9] https://www.fda.gov/media/72593/download

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. "No direct exposure to beam shall be permitted" on RG 3 LIPs products' 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"[10] 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 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. The Hazard Zone encompasses a region of space that is considered RG3.

[10] https://www.fda.gov/media/72593/download

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 (6.4.2)) will not require a variance application.

(vii) RG3 LIPs may be distributed to laser light show manufacturers possessing a variance approval to produce laser light shows (LLS). The conditions of approval for using LIPs in LLSs are provided in LLS variance-granting letters.

Summary of exceptions or additions to IEC 62471-5:Ed. 1:

IEC 62471-5 Subclause	**Description**	**Exception or Addition and 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.

FDA's concerns over the Risk Group Classification system used for LIPs:
Both IEC 62471:First edition and IEC 62471-5:Ed. 1 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).[11] 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 "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.

[11] http://wayback.archive-it.org/7993/20170722040812/https:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm478707.htm