Contains Nonbinding Recommendations

Surveying, Leveling, and Alignment Laser Products

Guidance for Industry and Food and Drug Administration Staff

Document issued on January 31, 2023.

The draft of this document was issued on May 5, 2014.

For questions regarding this document contact the Office of Health Technology 8 (OHT8): Office of Radiological Health at RadHealth@fda.hhs.gov.

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

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2014-D-0435. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 1764 and complete title of the guidance in the request.

Contains Nonbinding Recommendations

Table of Contents

Surveying, Leveling, and Alignment Laser Products

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 is intended for manufacturers of laser products and outlines the Food and Drug Administration's (FDA's or the Agency's) approach regarding the applicability of FDA's performance standard regulations to surveying, leveling, and alignment (SLA) laser products.

The topics that are addressed include:

- The definition of an SLA laser product
- Considerations for what is an SLA laser product
- Examples of SLA and non-SLA laser products
- SLA laser product class limits
- Requesting a variance or exemption from SLA laser product class limits

In general, FDA guidance documents 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 guidances means that something is suggested or recommended, but not required.

II. Background

FDA regulates radiation-emitting electronic products, including all types of lasers. The Agency sets radiation safety product performance standards that must be met by manufacturers in order for laser products to be legally sold in the U.S. market.

III. Scope

This guidance is intended to summarize FDA's current thinking on the applicability of FDA's performance standards for laser products to specific purpose SLA laser products. This guidance is not intended to serve as a replacement for the performance standards themselves.

IV. Questions and Answers

A. Question: What is an SLA laser product?

Answer: An SLA laser product is defined in 21 CFR 1040.10(b)(39) as "a laser product manufactured, designed, intended or promoted for one or more of the following uses:

(i) Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement.

(ii) Positioning or adjusting parts in proper relation to one another.

(iii) Defining a plane, level, elevation, or straight line."

SLA laser products are "designed to transmit laser radiation through open space for measuring and positioning purposes" and SLA laser product class limits at 21 CFR 1040.11(b) are intended to "impose appropriate upper limits on the accessible laser emission from such products consistent with their intended function and the generally unrestricted environments in which they are used."[1]

Be aware that promotion of a multi-use laser product for other, non-SLA laser product uses does not remove the product from the SLA laser product definition or class limits, or allow alternative class specific limits to be applied in lieu of the SLA laser product class limits, as long as the laser product is manufactured, designed, intended, or promoted for one or more SLA uses.

B. Question: What does FDA consider as transmission of laser radiation through open space?

Answer: SLA laser product class limits apply to products defined in 21 CFR 1040.10(b)(39),

[1] See 38 FR 34084, 34085 (December 10, 1973).

which are designed to transmit laser radiation through open space. FDA considers transmission through open space generally as transmission through any space where a person may be exposed directly or indirectly to the laser radiation. Transmission of laser radiation outside of a protective housing or optical fiber would be considered as transmission through open space.

C. Question: What design factors should manufacturers consider when determining whether their product is an SLA laser product?

Answer: Manufacturers should consider whether the product design can transmit laser radiation through open space for any of the purposes outlined in 21 CFR 1040.10(b)(39). Any laser product manufactured, designed, intended, or promoted to transmit laser radiation through open space outside a protective housing for a surveying, leveling, or alignment use would be considered an SLA laser product, regardless of the light characteristics of the laser beam (e.g., illumination, divergence, visibility, whether it is focused on a directed area). Thus, for example, a laser product designed to align the orientation of machinery or parts of a manufacturing process, or to define a straight line to a specific target would be an SLA laser product, regardless of the light characteristics of the laser beam. FDA would consider design features that allow the laser product to be portable (e.g., handheld, battery operated) and transmit through open space (e.g., lacking features for a protective housing or optical fiber connections) to be factors supporting that the product is manufactured, designed, or intended for SLA laser product purposes. See Question H for examples of SLA laser products.

D. Question: Do SLA laser product class limits apply to any laser product that is designed to transmit laser radiation through open space?

Answer: No. Not all laser products that are designed to transmit laser radiation through open space are considered to be SLA laser products. If the laser product is not manufactured, designed, intended, or promoted for one or more of the uses identified in 21 CFR 1040.10(b)(39), it would not be considered an SLA laser product and the SLA laser product class limits would not apply. Please see Question G for examples of products that FDA does not consider to be SLA laser products.

E. Question: What intended use and promotion factors should manufacturers consider when determining whether their product is an SLA laser product?

Answer: The design of a laser product should support its intended use. The intended use is determined, for example, based on the manufacturer's written or oral expressions, including, but not limited to, the content of the product labels and product description contained in the user or service instructions as well as any promotional materials, product catalogues, specification sheets, product websites or demonstrations of how the product should be used and for what purposes.

Promotion of a product that meets the definition of an SLA laser product for non-SLA general or research purposes, or promotion for sale only to certain types of purchasers does not relieve the manufacturer from complying with the SLA laser product class limits or obtaining a

variance from FDA if the product exceeds the SLA laser product class limits.

Manufacturers of SLA laser products are responsible for complying with the applicable class limits and cannot avoid that responsibility by issuing a disclaimer. If the manufacture, design, intended use, or promotion of a laser product causes it to meet the definition of an SLA laser product, then a disclaimer would not be considered sufficient to comply with the regulations or protect the public from a laser exposure that exceeds the SLA laser product class limits.

F. Question: Are general purpose laser products or laser products for laboratory research considered to be SLA laser products?

Answer: Laser products that are manufactured, designed, intended, and promoted only as general purpose laser light sources or for laboratory research purposes such as fluorescence-based applications, flow cytometry, confocal microscopy, and multi-array readers, or for bench research purposes (e.g., laser sources for an optical physics laboratory) are not considered to be SLA laser products.

By design, these products typically utilize power solely from a corded, hard-wired electrical source that terminates in a connector or plugs into to a non-battery power source. The design typically facilitates fixture onto an optical bench or protective housing. Such laser products may be of a size which could lend themselves to be used for, e.g., pointing or alignment purposes; however, FDA would not consider the laser to be an SLA product if other aspects, such as whether it transmits laser radiation through open space, do not suggest it is manufactured, designed, intended, or promoted for an SLA laser product purpose.

G. Question: What are examples of products that are <u>not</u> SLA laser products?

Answer:

(1) **Laser guide star** – is artificially created by transmitting laser radiation through open space into the atmosphere. The purpose is to interact with sodium atoms creating a glow in the upper atmosphere or to produce molecular light scatter in lower regions of the atmosphere. This scatter serves as a wavefront reference for adaptive optics used on ground-based space telescopes to compensate for atmospheric distortion of light. It is manufactured, designed, intended, and promoted to provide data for adaptive optics, not for an SLA laser product purpose. Although the laser radiation is being transmitted through open space, the product generally would not be manufactured, designed, intended, or promoted for an SLA use if, as would normally be the case for this type of laser, the laser radiation and product cannot be used in determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement, positioning or adjusting parts in proper relation to one another, or defining a plane, level, elevation, or straight line.

(2) **Remote-sensing lasers** – transmit laser radiation through open spaces and do not have a surveying, leveling, or alignment use. These laser products may measure gases from a distant location, such as from ground positions or airborne platforms through analysis of reflected signals following emission of laser light at specific wavelengths. Although the

laser radiation is being transmitted through open space, the product generally would not be manufactured, designed, intended, or promoted for an SLA use if, as would normally be the case for this type of laser, the laser radiation and product cannot be used in determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement, positioning or adjusting parts in proper relation to one another, or defining a plane, level, elevation, or straight line.

(3) **Communication or Energy transmission lasers** – transmit laser radiation for the purpose of sending and receiving data or power through open space rather than through fiber optics or another solid medium. These are considered to be outside the scope of SLA uses. The transmission of the laser light would be controlled based on the input signal (e.g., communications cable), and not include other functionality that would constitute an SLA use. Although the laser radiation is being transmitted through open space, the product generally would not be manufactured, designed, intended, or promoted for an SLA use if, as would normally be the case for this type of laser, the laser radiation and product cannot be used in determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement, positioning or adjusting parts in proper relation to one another, or defining a plane, level, elevation, or straight line.

(4) **General purpose laser products or laser products for laboratory research as indicated in Question F.**

For non-SLA laser products that utilize laser emissions in open space environments, we note that, among other requirements, 21 CFR 1040.10(f)(1) requires manufacturers to "have a protective housing that prevents human access during operation to laser and collateral radiation that exceed the limits of Class I and table VI, respectively, wherever and whenever such human access is not necessary for the product to perform its intended function. Wherever and whenever levels that exceed these limits are necessary, these levels shall not exceed the limits of the lowest class necessary to perform the intended function(s) of the product."

H. Question: What are examples of SLA laser products?

Answer: Examples of products that FDA is aware of that are manufactured, designed, intended, or promoted for one or more of the uses listed in 21 CFR 1040.10(b)(39) include but are not limited to the following products, all of which are designed to transmit laser radiation through open space:

(1) **Laser pointers**[2] – ergonomically hand-held, portable, battery powered laser products that are designed for transmitting laser radiation in a straight line. These products may be promoted for a variety of purposes such as high intensity focus and heating, avian control, and as pet toys. By the way they are designed, they are considered SLA products.

(2) **Levels and tools that incorporate laser guides** – typically portable, battery powered laser products manufactured, designed, intended, or promoted for positioning parts in relation to each other, or defining a plane, level, elevation, or straight line in construction trades or for home use; they are also sometimes integrated into other tools, such as power

[2] Some laser pointers may be demonstration laser products, as defined in 21 CFR 1040.10(b)(13), if they are manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition. Laser pointers are subject to the same class limits regardless of whether they are classified as SLA laser products or demonstration laser products. See 21 CFR 1040.11(b) and (c).

tools that define a plane, line, or point to guide cutting or drilling.

(3) **Machine vision structured light lasers** – generate lines, point, or bar patterns to determine data based on known angles and apply trigonometry on a point-by-point basis to generate a three-dimensional data set or point-cloud of a form or object. These are used to measure contours and delineate the form, extent, or shapes of objects or people by taking an angular measurement.

(4) **Gun sights** – portable, battery powered laser products mounted on various guns for transmitting laser radiation in a straight line for aligning the path of a ballistic projectile toward a target.

(5) **Target designators** – may be ergonomically hand-held or mounted, portable, battery powered laser products or integrated into a targeting system that fires ordinances. These products are for identifying a target or for aiming a projectile or ordinance at a target by defining a straight line.

(6) **Night vision illuminators** – products that are designed for aiming or targeting at night by transmitting laser radiation in a straight line that is visible using night vision goggles. These products are typically promoted for these purposes and may be a standalone unit, a unit mounted onto another product, or integrated into another product such as a weapon, optics such as binoculars or telescopes, surveillance cameras, or other surveillance/target designator systems.

(7) **Visual disruptors** – may be portable handheld or fixed designs. These products may be manufactured, designed, intended, or promoted for illumination of a human target at a defined position in a straight line from the laser to a person to disrupt vision. FDA considers a visual disruptor to be an SLA laser to the extent it could be used for aiming a beam, projectile, or ordinance at a target by defining a straight line (e.g., laser-based target designators, laser night vision illuminators, laser-based gun sights), akin to a gunsight or target designator. Some disruptors have settings for adjustment of beam characteristics allowing use in different applications. If the disruptor can be utilized as an SLA laser under any of its settings, then the disruptor would meet the definition of an SLA laser product.

(8) **Alignment lasers** – are manufactured, designed, intended, or promoted to align or position laser light, moving/fixed objects or structures in relation to each other, or take a measurement by angular positioning. These products may also be used to determine when a particular group of objects or structures are out of a specified position.

(9) **LIDAR (Light Detection and Ranging) lasers** – These products may emit laser radiation specifically to perform distance measurement and survey or map areas by taking angular measurements. The products would be utilized for an SLA purpose when surveying or mapping, such as by taking angular and distance measurements of multiple points to delineate the form or extent of a region. Accordingly, LIDAR products may be considered SLA laser products. However, the preamble to the performance standard in the Federal Register states "[i]mposition of the requirements of §1040.11(b) on distance measurement laser products is not appropriate since substantially higher powers and different beam configurations are required for ranging purposes."[3] A laser that is solely manufactured, designed, intended and promoted as a LIDAR laser for distance measurement for ranging purposes is not class limited under 21 CFR 1040.11(b). Regarding the safety of LIDAR laser products, they remain subject to the requirements of 21 CFR 1040.10, including that the scanned portion of the laser emission from a LIDAR

[3] See 39 FR 32098 (September 4, 1974).

is subject to the scanning safeguard provision of the performance standard under 21 CFR 1040.10(f)(9). Any non-scanned radiation from a LIDAR or rangefinder should be as low as reasonably achievable to prevent inadvertent hazardous exposures or cause the disruption of vision.

The above-described laser products have design and manufacturing features that allow them to transmit laser radiation through open spaces for SLA laser purposes, such as to delineate a point or form by taking an angular measurement, position parts in relation to one another, or define a plane, level, elevation, or straight line.

To the extent that an SLA laser product exceeds the class limits, such product manufacturers should determine whether the SLA laser product cannot achieve its purpose without emitting laser radiation that exceeds the SLA laser product class limit. If this is the case, the manufacturer should submit a variance application to FDA under 21 CFR 1010.4 that explains how an alternative suitable means of protection will be provided. For more information about variances, please see Question L.

I. Question: Do SLA laser product class limits apply to laser products intended for use as components?

Answer: If laser products that are intended for use as components (LPAC) of electronic products meet the criteria for exception from the performance standard at 21 CFR 1040.10(a), then SLA laser product class limits do not apply. The finished laser product manufacturer will be responsible for compliance with the performance standard, including SLA laser product class limits as applicable. LPACs subject to the performance standard must be certified. *See* 21 CFR 1010.2.

If an SLA laser product is sold in a kit form, as a collection of parts, part bundles, labels, and assembly and user instructions, then the laser performance standard requirements apply when the laser is properly assembled, including instructions for assembly and use and labels. *See* the guidance "Manufacture and Certification of Laser Kits, 21 CFR 1040.10 and 1010.2 (Laser Notice 13)."[4]

J. Question: What are the SLA laser product class limits?

Answer: 21 CFR 1040.11(b) states that SLA laser products must comply with all applicable requirements of 21 CFR 1040.10 for a Class I, IIa, II, or IIIa laser product, and are not allowed to permit human access to laser radiation in excess of the accessible emission limits of Class IIIa. As a result, this regulation establishes an upper class limit of Class IIIa, which has an accessible emission limit of 5 milliwatts, for visible wavelengths. SLA laser products that emit invisible radiation (wavelengths up to and including 400 nanometers and wavelengths higher than 710 nanometers) may not exceed the accessible emission limits for Class I, because Classes IIa, II, and IIIa do not include wavelengths outside the visible range.

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/manufacture-and-certification-laser-kits-laser-notice-13.

FDA does not intend to object to SLA laser product emissions that are within the accessible emission limits for Classes 1, 2, and 3R in the International Electrotechnical Commission (IEC) International Standard 60825-1, "Safety of laser Products – Part 1: Equipment classification and requirements," Ed. 1.2, 2.0, or 3.0 (IEC 60825-1). This is because FDA considers the IEC limits to be sufficiently comparable to the class limits for SLA laser products in FDA regulations to adequately assure safety. FDA does not consider conformance to the parameters for IEC Classes 1M or 2M to be equivalent to FDA performance standards because IEC Classes 1M and 2M do not have comparable analogs in FDA's classification system.

The properties of laser light make its emission highly directional. Collimated laser light maintains its power density over long distances. These properties are highly suitable for SLA laser product uses, but also present hazards to the public when transmitted through open space in unrestricted environments.

The SLA laser product class limits at 21 CFR 1040.11(b) are intended to impose appropriate upper limits on the accessible laser emissions from such products consistent with their intended function and the generally unrestricted environments in which they often are intended to be used. The SLA laser product class limits consider the normal human aversion reflex (blinking or turning away) that would occur and reduce the hazard from accidental exposure to visible laser light. The SLA laser product class limits also reduce the hazard from exposure to invisible laser light, when the aversion reflex is not effective.

K. Question: Would an SLA laser product that exceeds the SLA laser product class limits be considered compliant if a manufacturer incorporates the Class IIIb or IV laser performance requirements?

Answer: No. SLA class limits under 21 CFR 1040.11(b) apply to SLA products, unless an exception in 21 CFR 1040.10(a) applies, or FDA has approved a variance under 21 CFR 1010.4 or an exemption under 21 CFR 1010.5 that permits the class limits to be exceeded under certain conditions.

For SLA laser products that exceed SLA class limits, even when other class-specific performance requirements in the laser performance standard are met, manufacturers must still apply for a variance or exemption from the applicable class limits in 21 CFR 1040.11(b). Class-specific performance standard requirements found in 21 CFR 1040.10(f-h) are insufficiently effective in reducing the hazard of unexpected exposure to laser radiation in open space above laser class IIIa levels. For these reasons, class-specific performance standards are seldom a condition of a variance or exemption approval.

L. Question: What should a manufacturer do if their product needs to exceed the SLA laser class limits in 21 CFR 1040.11(b) to achieve its intended purpose?

Answer: If a manufacturer wishes to enter commerce with an SLA laser product that needs to exceed the class limits in 21 CFR 1040.11(b) to achieve its intended purpose, then the manufacturer should review the criteria for qualifying for issuance of a variance as described in 21 CFR 1010.4(a) and the information required to be included in a variance application (*see* 21

CFR 1010.4(b)). FDA may issue a variance if these criteria are met, including an FDA determination that:

i. "The product utilizes an alternate means for providing radiation safety or protection equal to or greater than that provided by products meeting all requirements of the applicable standard, or

ii. The product performs a function or is intended for a purpose which could not be performed or accomplished if required to meet the applicable standards, and suitable means for assuring radiation safety or protection are provided, or

iii. One or more requirements of the applicable standard are not appropriate, and suitable means for assuring radiation safety or protection are provided."[5]

As described in 21 CFR 1010.5, if an SLA laser product is intended for United States Government use, either the manufacturer or the U.S. department or agency may apply for an exemption from portions of the performance standard; a manufacturer may distribute directly to a U.S. department or agency that currently holds an exemption with conditions allowing the distribution.[6]

M. Question: What are the typical requirements and conditions of an approved variance or exemption for SLA laser products that exceed the SLA laser class limits?

Answer: The requirements and conditions that would be needed for an individual variance or exemption are established on a case-by-case basis and tailored to provide appropriate levels of radiation safety protection based on the specific product design and intended use.

We encourage manufacturers to contact FDA with a proposed set of suitable alternative means of assuring radiation safety or protection prior to submitting an application for a variance or exemption. FDA will review the application to determine what design, installation, and/or other controls would be suitable. While FDA considers both engineering controls and administrative controls in variance applications, we recommend manufacturers use engineering controls as the primary form of emission control whenever possible.

Examples of engineering controls may include, but are not limited to:

- Use of interlock connections utilizing altitude monitoring and ground sensing systems for aircraft to limit unsafe levels of exposure to an unprotected person at ground level;
- Use of range-finding sensors or other instruments to monitor distances from the laser

[5] *See* 21 CFR 1010.4(a)(2).

[6] On July 29, 1976, FDA exempted "laser products that are used exclusively by Department of Defense components and that are designed for actual combat or combat training operations or are classified in the interest of national security" from the requirements of 21 CFR 1040.10 and 1040.11. This exemption can be viewed on pages 30-32 of the document "EXEMPTIONS From Electronic Product Regulations: A Compilation of Exemptions for Electronic Products Found in 21 CFR Chapter I, Sub-Chapter J --Radiological Health Parts 1000 – 1050" (https://www.fda.gov/media/78277/download). Clarification on the exemption was provided in FDA guidance "Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-department-defense-exemption-fda-performance-standard-laser-products).

to a potential individual; and/or
- Derating the laser's power or cutting its power when individuals approach the nominal ocular hazard distance of the laser.

Examples of administrative controls include, but are not limited to:

- Restriction of sales to certain types of purchasers, such as restricting sales only to federal, state, and local law enforcement or other agencies;
- Training users on how to safely use the product, using log books or other means to document the training, and
- Limiting use of the product to restricted environments, solely where the product's emission cannot be publicly accessible.

FDA considers a generally unrestricted environment to be any environment where a person untrained or unprotected from laser emissions could be present. Examples of generally unrestricted environments include:

- Any type of residence or residential property;
- Public areas within a commercial building;
- Any area of a workplace where employees are unprotected from unsafe exposure to laser emissions; or
- Any public place where people could be expected to purposely or accidently be exposed to the laser emission.