DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Enclosed is a package of material for laser product manufacturers that can help familiarize them with the Federal performance standard and reporting requirements. This letter provides a brief summary of the regulatory requirements. For more details, the first document that you should review is the "Compliance Guide for Laser Products". This document provides an overview of the responsibilities of a manufacturer and an introduction to the Federal performance standard for laser products.

A manufacturer of a laser product is any person who manufacturers, imports or assembles a product which incorporates or is intended to incorporate a laser whether or not the person manufacturers the laser. Manufacturers or importers of lasers and laser products are required to submit reports to the Food and Drug Administration (FDA), maintain records, and comply with the regulations and performance standards issued under the provisions of the Federal Food, Drug and Cosmetic Act (the Act), Chapter V, Subchapter C, Electronic Product Radiation Control , formerly the Radiation Control for Health and Safety Act of 1968.

All laser products manufactured on or after August 2, 1976, except as noted in the standard, must be certified by their manufacturers as being in compliance with the standard which is described in the Code of Federal Regulations (CFR) Title 21, Part 1040.10 and 1040.11. Failure to certify products as required by Part 1010 or to provide reports or maintain required records are violations of Section 538 of the Act and may result in penalties as specified in Section 539.

Under 21 CFR Part 1002, Records and Reports, manufacturers, importers and assemblers of lasers or products containing lasers are required to submit:

I. An Initial Report (see 1002.10) for each laser product family which:

   a. Identifies models within the reported model family and their intended uses,

   b. Describes the nature of radiation emissions associated with those products and the performance and safety characteristics affecting such emissions, and

   c. Details manufacturers design, quality control, and testing standards and procedures with respect to product radiation safety.

II. Model change reports (see 1002.12) for each new or different model or model family.

III. Annual reports which summarize the contents of records maintained by the manufacturer [See 1002.11 and 1002.3(a)].

IV. Reports of accidental radiation occurrences (see 1002.20).

Initial and model change reports are required to be submitted prior to the introduction of a laser product into commerce. These reports are to include sufficient information to enable the determination of whether a manufacturer has correctly certified their products as being in compliance with the performance standard. Annual reports should be submitted by September 1 of each year and should cover the 12-month period, beginning on July 1 of the previous year, and ending June 30 of that year. Reports of accidental radiation occurrences must be submitted as soon as the manufacturer suspects that an incident has occurred.

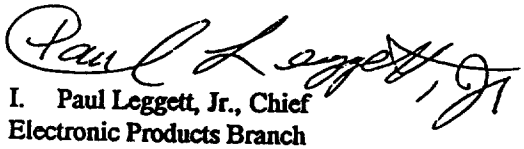
For aid in submitting the information required in the initial reports and model change reports consult the enclosed documents "Compliance Guide for Laser Products" and "Guide for Preparing Initial Reports and Model Change Reports on Lasers and Products Containing Lasers." The use of the enclosed reporting guide is mandatory.

For aid in submitting the information required in the annual report, consult the "Guide for Preparing Annual Reports on Radiation Safety Testing of Lasers and Laser Light Show Products." If you are producing Class IIIb or IV laser light shows or projection devices, you should complete the "Application for Variance from 21 CFR 1040.11© for a Laser Light Show, Display or Device" and a "Reporting Guide for Laser Light Show Products."

If your laser is a medical device, it is also subject to premarket notification requirements under the Act. Prior to introduction of a new medical device into commerce, you must file a 510(k) premarket notification with the FDA. Specific questions on medical devices should be addressed to the Division of Small Manufacturers Assistance, Office of Health and Industry Programs, 1350 Piccard Drive, Rockville, Maryland 20850 or you may call 1-800-638-2041 or fax 1-301-443-8818.

If you have any questions on the requirement, please call us at 1-301-594-4654 or fax 1-301-594-4672.

Sincerely yours,



I. Paul Leggett, Jr., Chief
Electronic Products Branch
Division of Enforcement III
Office of Compliance
Center for Devices and
Radiological Health

Enclosures

OFFICE OF COMPLIANCE
NOTICES TO THE LASER INDUSTRY

DATE & No.	SUBJECT	21 CFR CROSS REFERENCE
November 21, 1975 (2)	Laser Energy Source	1040.10(b)(17)
November 21, 1975 (3)	Emission Indicators on Energy Source	1040.10(f)(5)(iii)
November 21, 1975 (4)	Protective Eyewear - Visibility of Emission Indicator	1040.10(f)(5)(iv)
June 22, 1976 (6)	Emission Indicators - Brightness	1040.10(f)(5)
June 23, 1976 (7)	Components and Repair	1040.10(a)
August 5, 1976 (8)	Viewing Optics - Sighting Telescope	1040.10(f)(8)
August 23, 1976 (9)	Certain Military Lasers Exempt From 21 CFR 1040.10 & .11	1002
August 31, 1976 (10)	Emission Indicator - Visibility	1040.10(f)(5)
September 7, 1976 (11)	Remote Interlock Connectors	1040.10(f)(3)
October 14, 1976 (13)	Laser Kits	1040.10, 1010.2
November 23, 1976 (14)	Lasers Manufactured and Used In-House	1010.2
December 8, 1976 (15)	Certain Military Lasers Exempt From 21 CFR 1040.10 & .11	1002
March 2, 1977 (16)	Warning Labels For Dye And Multiple Wavelength Lasers	1040.10(g)
March 2, 1977 (17)	Optional Interlocks - Labeling	1040.10(f)(2) & (g)
November 11, 1977 (21)	Emission Delay - Remote Interlock Connector	1040.10(f)(3) & (5)(ii)
November 23, 1977 (22)	Laser Light Shows Subject to Laser Performance Standard	1040.10(a) & 1040.11(c)

DATE & NO	SUBJECT	21 CFR CROSS REFERENCE
September 14, 1978 (25)	Exemption of Certain Lasers Used by DOE, NOAA and U.S. Dept. of Commerce	1010.5
August 25, 1980 (30)	Alternate Wording For Caution Statement	1040.10(h)(1)(iv)
October 16, 1980 (27)	Laser Diodes Used in Fiber Optics Communication Systems	1010.2, 1010.3, 1040.10, 1040.11
May 18, 1981 (31)	Investigational Medical Laser Significant Risk Device	812.2(b)
January 30, 1985 (34)	Medical Laser Delivery System Interlocks	1040.10(f)(1), &(2)
February 5, 1985 (35)	User Instruction Hazard Warnings	1040.10(h)(1)(iii)
August 23, 1985 (36)	Low Power Laser Exemption	1002.10, 1002.12
October 21, 1985 (37)	Walk-In Workstations	1040.10(f)(1) & (2)
May 22, 1987 (38)	Importation for Investigation And Evaluation	1005
June 24, 1987 (39)	User Instructions - Multi Axis Workstations	1040.10(h)
October 29, 1987 (40)	Class II and IIIa Laser Light Show Projectors and Shows	1040.10 & .11
August 9, 1988 (41)	Low Power Laser Reporting Exemption	1002.10, .12, .30(b), .40, .41, .50
December 18, 1989	Clarification of Compliance Requirements for Certain Manufacturers Who Incorporate certicied Class I Laser Products into Their Products	1040.10(i)
June 7, 1993 (43)	Beam Attenuators and Emission Indicators for Class II and IIIa Laser Systems	1040.10(f)(6)(ii) 1040.10(f)(5)

DATE & NO	SUBJECT	21 CFR CROSS REFERENCE
August 11, 1995 (44)	User Instructions for Medical Products	1040.10(h)(1)(i)
August 15, 1995 (45)	Labeling of Laser Products	1040.10(g)
Dec. 11, 1995 (46)	All Holders of Approved Variances for Laser Light Shows and Displays	
June 6, 1996 (47)	Effective Visual Control of Laser Projections	
Sept. 5, 1996 (48)	Identification Labels for Certain Class I Laser Products	1010.3(a)(1)
Sept. 5, 1996 (49)	Emitted Laser Beam as Emission Indicator for Class II and Class IIIa Laser Products	1040.10(f)(5)(i) 1040.10(f)(5)(iv)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

ADVISORY OPINION

SUBJECT: LASER ENERGY SOURCE: 21 CFR 1040.10(b)(17)

QUESTION: A company manufactures a multiple purpose electron beam accelerator. The beam is capable of providing the excitation energy for selected laser media as evidenced by several research reports of this application in the company's advertising literature for the accelerator. The company asks if this laser energy source meets the criteria for being a laser product within the meaning of 21 CFR 1040.10(b)(17) and as such, is subject to 21 CFR 1040.10 and 1040.11 for laser products and specific purpose laser products.

ADVISORY OPINION: This electron beam accelerator, as a laser energy source, does not meet the criteria for a laser product as defined in paragraph 1040.10(b)(17). Therefore, it would not be subject separately to 21 CFR 1040.10 and 1040.11.

The electron beam accelerator generates an electron beam which provides for energy transfer for many applications. One application is the coupling of this beam into an appropriate medium to provide the excitation energy for the production of laser radiation. Advertising the accelerator for use as a possible energy source for customer built laser systems does not make the accelerator a laser product.

DATED: NOV 21 1975

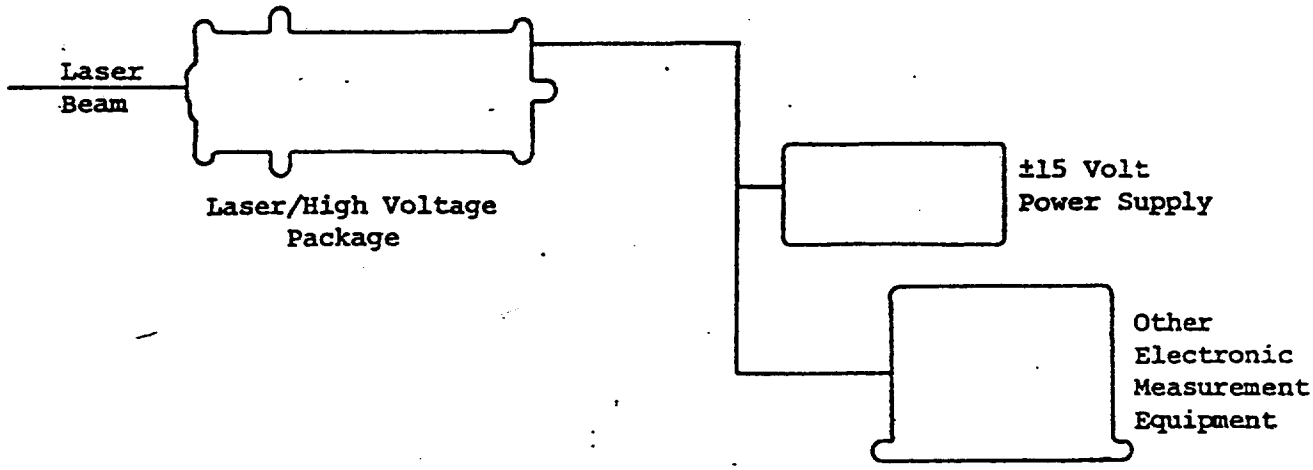
John C. Villforth
Director
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

ADVISORY OPINION

SUBJECT: REQUIREMENTS FOR LASER RADIATION EMISSION INDICATORS WHEN THE LASER AND LASER ENERGY SOURCE ARE HOUSED SEPARATELY: 21 CFR 1040.10(f)(5)(iii)

QUESTION: A company manufactures a laser product consisting of a Class II Helium Neon laser packaged with its high voltage supply, a ±15 volt power supply and other electronic measurement equipment including a computer and/or calculator with optional display units (See Diagram). Power is supplied to the laser/high voltage package by the ±15 volt power supply which derives its power from the electrical mains. The laser/high voltage package is housed in a single separate component located 6 ft to 100 ft from the ±15 volt power supply.



The laser is turned on with the other electronic measurement equipment when power is turned on to the ±15 volt power supply. It would be possible to operate the laser from a separate ±15 volt power supply but the laser, power supply and other electronic measurement equipment are sold as a complete system. An emission indicator is required on the laser/high voltage package. The question is whether the ±15 volt power supply is considered a laser energy source and as such is required to have an emission indicator, or is it considered a general energy source and therefore, is not required to have an emission indicator.

The Standard is a performance standard rather than a design standard. Thus, indicator lights of a specific color are not required, nor does the Standard prohibit an indicator consisting of a combination of two or more lights as long as there is one indicator and its meaning and significance are clear. An emission indicator fails to comply with the Standard if it is not visible through protective eyewear recommended by the manufacturer of the laser product or through other available protective eyewear generally considered as suitable for laser radiation emitted by the product. Laser product manufacturers should make every reasonable effort to assure visibility of emission indicators when used with all the protective eyewear which can be expected to be used with the laser product.

DATED: NOV 21 1975

John C. Villforth
Director
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

ADVISORY OPINION

SUBJECT: VISIBILITY OF LASER RADIATION EMISSION INDICATORS THROUGH PROTECTIVE EYEWEAR: 21 CFR 1040.10(f)(5)(iv)

QUESTION: What kind of visual laser radiation emission indicator would be acceptable to use in conjunction with protective eyewear? For a HeNe laser emitting a 632.8 nm wavelength there are several types of laser safety glasses which would safely attenuate the emitted laser beam. However, if a yellow light-emitting diode is used as the visible emission indicator it would not necessarily be visible through blue laser safety eye glasses, and similarly, a green light-emitting diode is not necessarily visible through other laser safety eye glasses with limited transmission in selected regions of the visible light spectrum. Is either a yellow or green light-emitting diode acceptable as an emission indicator for a Class II HeNe laser? If either one individually is not acceptable, then can both be used, or is it a requirement that an incandescent light bulb lamp be used as the laser radiation emission indicator?

ADVISORY OPINION: Section 1040.10(f)(5)(iv) of the Federal performance standard for laser products states that, "Any visible signal required by paragraphs (f)(5)(i) or (ii) of this section shall be clearly visible through protective eyewear designed specifically for the wavelength(s) of the emitted laser radiation." The phrase "protective eyewear designed specifically for the wavelength(s) of the emitted laser radiation" means protective eyewear which:

1. Attenuates laser radiation predominately at the wavelength(s) or within the wavelength range(s) of the emitted laser radiation.

2. Transmits sufficient luminous flux at visible light wavelengths to allow visibility of emission indicators.

The Standard is a performance standard rather than a design standard. Thus, indicator lights of a specific color are not required, nor does the Standard prohibit an indicator consisting of a combination of two or more lights as long as there is one indicator and its meaning and significance are clear. An emission indicator fails to comply with the Standard if it is not visible through protective eyewear recommended by the manufacturer of the laser product or through other available protective eyewear generally considered as suitable for laser radiation emitted by the product. Laser product manufacturers should make every reasonable effort to assure visibility of emission indicators when used with all the protective eyewear which can be expected to be used with the laser product.

DATED: NOV 21 1975

John C. Villforth
Director
Bureau of Radiological Health

ADVISORY OPINION

SUBJECT: RELATIONSHIP OF INTEGRATED RADIANCE TO SCANNED LASER RADIATION, RESPONSE TO 21 CFR 1040.10(d) and (e)

BACKGROUND: A manufacturer of a laser universal product code reader for supermarkets desires the accessible scanned laser radiation from the product to be within the limits of Class I. The manufacturer acknowledges that the product could exceed the Class I accessible emission limits for radiant energy given in Table I-A of Section 1040.10(d) of the standard. Therefore, pursuant to the dual Class I limits of Section 1040(d)(4), he has tried to design the product to be below the integrated radiance limits of Table I-A. In order to reduce the integrated radiance below the Class I limits, the manufacturer would like to incorporate an optical device which varies the apparent origin from which the scanned pattern is emitted. Thus, if the integrated radiance of the product is measured with an instrument in which the detector's *aperture and acceptance angle are fixed in position and orientation relative to the product* there would be an apparent reduction in the integrated radiance. The manufacturer asks whether this approach of reducing the integrated radiance is appropriate to use when designing a laser product to conform to the provisions of Class I and to the other provisions of the standard (21 CFR 1040.10 and 1040.11).

ADVISORY OPINION: Based upon the following rationale the above approach for reducing the integrated radiance, including the measurement protocol, would not be appropriate to use to ascertain compliance with the performance standard. The standard is specific in requiring that any device used for determination of integrated radiance must be positioned and oriented as to maximize the detectable radiation.

The intent of the integrated radiance alternative of the standard as stated in Comment 14 of the preamble to the standard, is to accommodate extended sources (real or virtual) such as holographic images, diffuse reflections, transmissions through diffusers, or diffuse collateral radiation (Federal Register 40, 32254 (July 31, 1975)). If the concept of integrated radiance is considered for the output from a stationary laser, either the source area or the intrinsic divergence (or both) is small, yielding a radiance level in excess of the radiance portion of the dual limits for Class I of Section 1040.10(d)(4). If sources of radiation are stationary, classification of both the extended source and the stationary laser source would be based upon measurements, pursuant to Section 1040.10(e)(2)(iv), in which the detector generally would remain fixed both in position and orientation so as to result in the maximum detection of radiation required by that section.

The performance standard for laser products provides that the measurement of accessible emission levels of scanned laser radiation shall be determined from the measurement of radiation detectable within a stationary circular aperture stop having a 7-millimeter diameter. The resulting temporal

variation of detected radiation shall be considered as a pulse or series of pulses (Section 1040.10(e)(4)). Thus, radiant energy, radiant exposure and integrated radiance may be used as measures of the level of scanned laser radiation for the purpose of classification. The measurement of integrated radiance would also involve, under Section 1040.10(e)(3)(iii), a solid angle of acceptance of 0.00001 steradian. However, pursuant to Section 1040.10(e)(2)(iv) the acceptance angle of the instrument for measuring integrated radiance would have to be instantaneously so positioned and so oriented with respect to the laser product as to result in the maximum detection of radiation by the instrument. Conceptually the orientation of the instrument would have to track the source, but its aperture stop would remain stationary. As noted in Section 1040.10(e)(3), techniques, including computations, that provide results equivalent to the above are permitted.

DATED: 1/26/76

John C. Villforth
Director
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

JUN 22 1976

REF:DOC
MA-3983

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Response to Question Concerning Brightness of Emission Indicators that Emit Visible Radiation, 21 CFR 1040.10(f)(5)

BACKGROUND AND QUESTION: A company manufactures leveling and alignment laser products that are typically used outdoors to project a beam several hundred feet under daylight illumination. The company desires to know over what distance a visual emission indicator is required to be visible and if an incandescent automotive type lamp would be adequate or if a xenon flash-lamp similar to an aircraft beacon must be used in order to be visible over the entire operational range.

RESPONSE: The emission indicator is to give indication concerning the emission of accessible laser radiation primarily to the operator of the laser product, and not necessarily to all persons within the distance the laser radiation could possibly project.

Although emission indicators are required by 21 CFR 1040.10(f)(5) for all laser systems of Class II or higher, the standard does not specify a minimum distance for visibility or audibility of the indicator; furthermore, the record of development of the standard indicates that the emission indicator should be suitable to the particular product (40 FR 32255). Active indicators such as xenon flashlamps may, in order to be visible at the working distances of the product, have to be of such intensity as to constitute at close range a more hazardous source of optical radiation than the laser itself. Furthermore, if a dangerously bright light would be needed to be visible even to the operator, the manufacturer should provide for a different visual signal or for an audible signal.

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

JUN 23 1976 REF:DOC:3984-MA

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Response to Question Concerning Component Lasers and Laser Systems for Repair of Laser Products, 21 CFR 1040.10(a)

BACKGROUND AND QUESTION: A manufacturer notes that there are many laser products in use that were manufactured before the effective date of the standard. These products will need to be repaired in order to be kept in operable condition. Occasionally the laser or laser system will need to be replaced. The manufacturer asks how the standard will affect the repair of these products.

RESPONSE:

The repair of certified or uncertified laser products to their original condition, whether performed in a factory or at the site of use, is not considered to be manufacturing or assembly under the Radiation Control for Health and Safety Act of 1968. Therefore, persons who engage in this activity will not be required to certify such products. However, certified laser products, when repaired according to the instructions provided by the manufacturer pursuant to 21 CFR 1040.10(h), must continue to meet the applicable provisions of 21 CFR 1040.10 and 1040.11 as when manufactured.

A laser or laser system for use as a replacement component in an (uncertified) electronic product manufactured before the effective date of the standard, would not be subject to the standard, if it were sold either to, for, or by the manufacturer of the electronic product. The replacement laser or laser system, in this case, would not be subject to the standard even if manufactured after the effective date of the standard. Also, removable laser systems replaced in laser products manufactured before the effective date would not be subject to the standard, if sold to, for, or by the manufacturer of the old product since 21 CFR 1040.10(c)(2) applies only to those removable laser systems used as components of products subject to the standard.

All lasers and laser systems manufactured after the effective date of the standard for use as components of an electronic product would be subject to the standard if <u>not</u> sold by, to, or for the manufacturer of such electronic product because they would be laser products under 21 CFR 1040.10(b)(17) which are not excluded by 21 CFR 1040.10(a) (Ref: 40 FR 32253).

Although the above is generally true, laser products manufactured before August 2, 1976, may become subject to the standard upon repair or refurbishment after the effective date of the standard, if the repaired product is incorporated as a removable laser system component into a laser product subject to the standard (21 CFR 1040.10(c)(2)).

The modification of a previously certifed laser product by any person engaged in the business of manufacturing, assembling or modifying laser products shall be construed as manufacturing under the Act if the modification affects any aspect of the product's performance or intended function(s) for which 21 CFR 1040.10 and 1040.11 have an applicable requirement. The manufacturer who performs such modification shall recertify and reindentify the product in accordance with the provisions of 21 CFR 1010.2 and 1010.3 (21 CFR 1040.10(i)).

Robert G. Britain

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

REF:DOC:4021:MA

AUG 5 1976

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Applicability of Viewing Optics Performance Requirements to a Sighting Telescope of a Surveying Laser Product, 21 CFR 1040.10(f)(8)

BACKGROUND AND QUESTION: A manufacturer of a surveying laser product incorporates into the product a sighting telescope that is intended to be used to aim the product and to view the laser light diffusely reflected from a target. When used as intended by the manufacturer the maximum level of laser radiation accessible through the telescope is well below the maximum accessible level for viewing optics despite emission from the laser product being well in excess of this level. The manufacturer is aware that users may employ retroreflective or specular mirror targets with the product, in which case the level of laser radiation accessible through the telescope may approach the level of the laser itself. The manufacturer is reluctant to utilize a lower power laser so that the product could be Class I since viewing of the reflected laser light from a diffuse target under normal daylight background conditions would be impossible. The manufacturer asks whether it is the intent to consider such sighting telescopes as viewing optics under 21 CFR 1040.10 and 1040.11.

RESPONSE: The telescope is intended for viewing the reflection of the laser light. Therefore the function of the telescope and the target is that of a viewing optic, and the performance of the unit must conform to 21 CFR 1040.10(f)(8).

If the manufacturer supplies or specifically recommends a diffusely reflecting target for use with the laser product, and provides instructions and warnings to use only that target, then if the viewing optic attenuates the beam reflected from the target to the level of Class I under all possible uses, the product would be compliant with the requirements of 21 CFR 1040.10(f)(8). The target in this case may be considered an integral part of the viewing optics system and of the laser product.

A specific warning not to use a target which would give a specular reflection or a retroreflection would be required in the instructions as being necessary for adequate safety information. A supplemental warning not to view the radiation in conjunction with mirror-like targets may be added to the warning logotype required to be on the exterior of the laser product pursuant to 21 CFR 1040.10(g)(2) and (3).

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

REF:DOC:4026-MA

AUG 23 1976

TO: ALL LASER PRODUCT MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Exemption of Certain Military Laser Products from the FDA Radiation Safety Performance Standard for Laser Products.

The purpose of this memorandum is to notify all laser product manufacturers of an exemption granted for all laser products which are manufactured after August 2, 1976, and used exclusively by DOD agencies, and which are designed for actual combat or combat training operations or are classified in the interest of national defense (Reference FDA Docket No. 76P-0335). The exemption does not apply to laser products intended primarily for use in indoor classroom training and demonstration, industrial operations, and scientific investigations; and medical laser products. The exemption is from the FDA performance standard for laser products in 21 CFR Part 1040.10 and 1040.11 and the associated reporting and record keeping requirements of 21 CFR Part 1002, except for paragraph 1002.20 relating to accidental radiation occurrences.

Mr. Sherwin Gardner, Acting Commissioner of Foods and Drugs, announced the exemption in a letter dated July 29, 1976, to Mr. George Marienthal, Deputy Assistant Secretary of Defense. The exemption was granted on the grounds that the special military requirements for such devices preclude full compliance with the FDA performance standard. However, DOD procurement specifications will prescribe compliance with the FDA standard to the extent practicable and will be supplemented with safety controls and procedures utilized by DOD. All exempted products are also to be clearly identified either by the label set forth below, or by other approved means:

"CAUTION

This electronic product has been exempted from FDA radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J, pursuant to Exemption No. 76EL-01DOD issued on July 26, 1976. This product should not be used without adequate protective devices or procedures."

In addition, DOD will restrict surplus disposal of these devices and report annually to FDA on the types of devices procured under the exemption, their manufacturers, and means of identification if different than the above label.

The exemption may be withdrawn or amended if any of the terms of the agreement between the Food and Drug Administration and Department of Defense are not adhered to, or if other information becomes available that indicates that the public health and safety are not adequately protected from electronic product radiation emitted by products exempted pursuant to this exemption.

Correspondence concerning the exemption should be directed to the Office of the Assistant Secretary of Defense (Installations and Logistics), Deputy Assistant Secretary of Defense for Environment and Safety, Pentagon Building, Washington, D.C. 20301; the office phone number is (703) 695-0221.

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

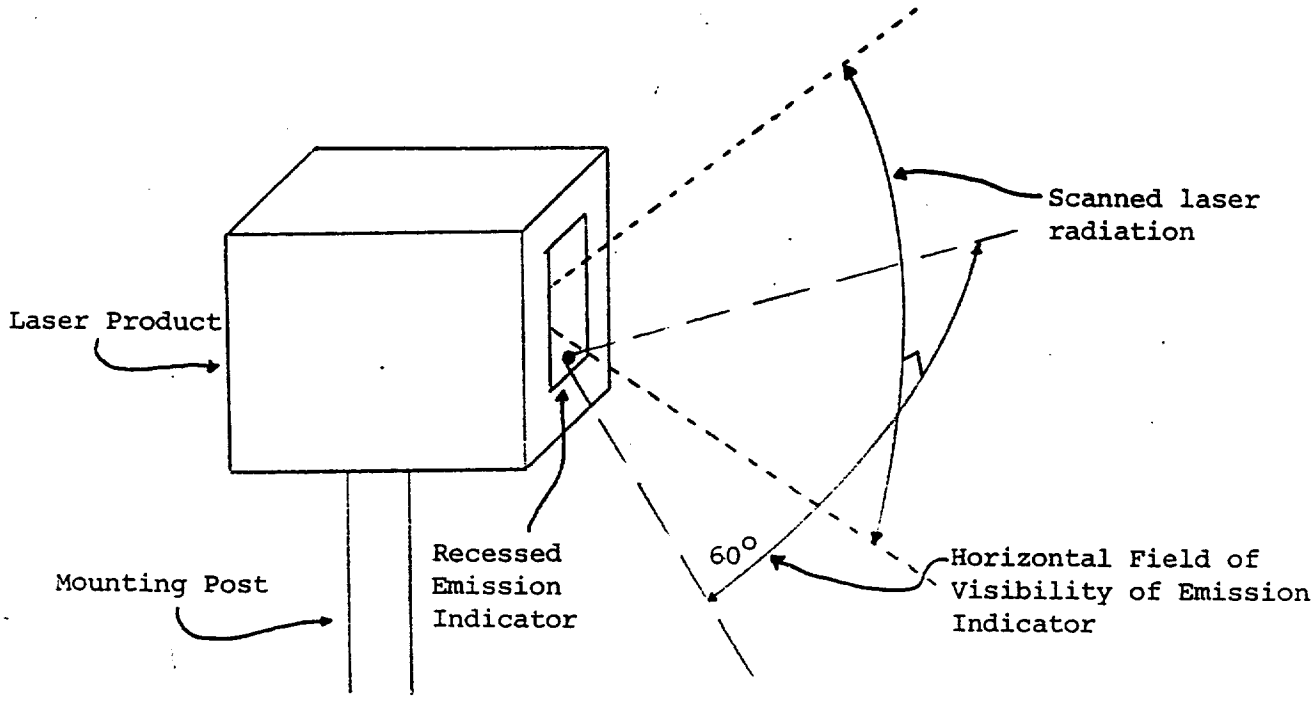
REF:DOC
MA-3991

AUG 31 1976

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Response to Question Concerning Visibility of Visual Emission Indicators, 21 CFR 1040.10(f)(5)

BACKGROUND AND QUESTION: A company manufactures a laser product that generates a vertical plane of accessible scanned laser radiation when the product is operated in an upright position, but is mounted on a post for operation in several optional positions (diagram below). To fulfill the requirement for an emission indicator, the manufacturer incorporates a lamp into the lower portion of the rectangular exit window. The company desires to know over what angle a visual emission indicator must be visible, and if an emission indicator incorporated into the exit window, that radiates over about 60° total in each orthogonal plane, is adequate.



RESPONSE: The purpose of an emission indicator is to give *indication of the emission of accessible laser radiation* primarily to the operator and others in the vicinity of the laser product.

Although each Class II, III and IV laser product will be required by 21 CFR 1040.10(f)(5) to incorporate an emission indicator, the standard does not specify the angle of visibility for a visual indicator. Furthermore, to specify visibility or audibility of emission indicators which would be appropriate under all conditions and for all products is not practical; the indicator, whether visual or aural, must fulfill its function and must be suitable to the particular product.

Visual emission indicators are to be located so that viewing does not require human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and Table III of Section 1040.10(d) (21 CFR 1040.10(f)(5)(v)), and to be readily visible to the operator in most operating configurations. Although a visible emission indicator that is recessed into the scanning window and is visible over 60° might not require exposure to laser radiation such a design may lead to the operator being exposed unwittingly while viewing the indicator, and therefore does not meet the intent of the standard, especially for Class III and Class IV products. Designs for emission indicators will be evaluated on an individual basis as to whether the feature performs its intended function and is suitable to the particular product.

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

REF:DOC:4001-MA

SEP 7 1978

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Response to Question Concerning Requirement for Remote Control Connectors, 21 CFR 1040.10(f)(3)

BACKGROUND AND QUESTION: A company manufactures a laser product which is operated from a battery or from an AC converter. The manufacturer desires to know if the connection to the battery or converter box meets the requirement for a remote control connector since both battery and converter box are portable and provide a means for quick disconnection.

RESPONSE: A primary electrical power cable connector for connection to the power line mains, battery, or converter box (if present) does not satisfy the requirement in the performance standard for a remote control connector (21 CFR 1040.10(b)(30) and (f)(3)). The requirement states that when the terminals of the connector are not electrically joined, human access to all laser and collateral radiation from the product ...shall be prevented. This language implies that human access would be possible when the terminals are electrically joined (simple connection between them). Connecting the terminals to the battery or supply mains cannot be considered as electrically joining in the sense used in the standard (21 CFR 1040.10(f)(3)). The connector is to be for the connection of an optional remote interlock switch or other appropriate control external to the product. *The remote control connector should be a separate, independent performance feature which is readily identifiable for that purpose.*

The connector may be supplied with a shorting plug to complete the circuit. The plug is left in place when the user does not wish to use the remote control feature; the connector, however, provides a convenient means of connection if the use of the remote control feature is desired. However, for a remote control connector to be considered satisfactory, the necessary mating plug for connecting the optional remote interlock switch or other appropriate control should be available commercially.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
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ROCKVILLE, MARYLAND 20852

SEP 9 1976

REF: DOC
MA - 4031

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Discussion of Safety Interlock Requirements and Concepts for Meeting These Requirements, 21 CFR 1040.10(f)(2)

BACKGROUND AND QUESTION: Several manufacturers have asked for elaboration on the safety interlock requirements of the Federal performance standard for laser products (21 CFR 1040.10(f)(2)), for an explanation of how the various interlock requirements relate to one another, and for a functional description of how interlocks may perform in order to satisfy these requirements. Manufacturers have also asked for confirmation whether interlock concepts which they propose to use in their products function as required.

RESPONSE: The Federal Performance Standard for Laser Products, 21 CFR 1040.10 and 1040.11, is applicable to all laser products manufactured on or after August 2, 1976, except as noted. The standard includes a requirement that safety interlocks be provided for each portion of protective housings designed to be removed or displaced during operation or maintenance, if removal or displacement could permit human access to laser or collateral radiation in excess of the limit of the lowest class necessary for the performance of the intended function of the product.

Safety interlocks must satisfy the following criteria in order to comply with the standard:

1. Prevent human access to the laser or collateral radiation upon removal or displacement of the interlocked portion of the protective housing.

2. Preclude removal or displacement of the interlocked portion of the protective housing upon failure of the interlock to prevent human access to the laser or collateral radiation in excess of the required limit.

3. If defeatable, provide an indication of defeat.

4. When defeated, preclude replacement of the removed or displaced portion of the protective housing.

In response to several requests for clarification, several conceptual techniques are discussed for satisfying those requirements. A few specific examples will be given; each will be traced through the requirements with an explanation of how the example complies or fails to comply. In addition, consideration will be given to possible modes of failure which fail to prevent human access to laser or collateral radiation.

1. Prevent human access to the laser or collateral radiation upon removal or displacement of the interlocked portion of the protective housing. For a given product, various schemes may be visualized which will satisfy this requirement. Electrical interlock switches are well known and widely used. For many products the ideal circuit location may be in the primary power lines, however, for others this may be very inappropriate. A non-electrical interlock may be better suited to other products; such may be the case for laser pumped dye lasers. Note, too, that this does not dictate that the interlock must interrupt operation of the laser, but merely prevent access; prevention of access may be more suitably accomplished by introduction of a baffle (or shutter) as the protective housing is removed or displaced.

a. Electrical interlock switches may be conveniently located in proximity to access doors and panels. Such switches may be actuated by the door, panel, or a latch which actuates a leaf spring, push-button or plunger. The switch may be located in a power or control circuit, or may operate a solenoid shutter or baffle in order to prevent human access to radiation upon movement of the protected portion of the housing or latch.

Failure modes that must be considered include:

Failure of the switch contacts to "break or make" upon actuation (switches are more commonly used in a "normally open" mode and are closed by the closure of the housing or operation of the latch. In this case failure to make contact would not be considered a failure in the sense of preventing access to radiation. This is not to imply that there may not be situations in which "normally closed" operation is more suitable); and

Failure of another component although the switch performed as intended (the switch may control the input to a control component - transistor, thyristor or vacuum tube. Such components and their failure modes must be considered part of the interlock).

b. Plug type interlocks such as those used on television sets are very familiar. In the case of television sets the primary electrical power is delivered to the product by a plug which is integrally mounted to the portion of the housing that is to be removed for access to the interior of the set. Removal of the back cover of the set removes all electrical power. The tele-

vision interlock is but one example of this type of interlock. Other types may mount only a portion of a circuit on the removable portion of the housing, while other types may employ a single prong plug to complete a circuit. As with switches, plug interlocks should be placed in the most suitable location and in the most suitable portion of the circuit of the specific product.

Failure modes to be considered include short circuits and other interlock circuit component failures as above.

Since plug type interlocks are likely to require more individual design than switch types, the laser product manufacturer is cautioned to consider the durability of his design and its ability to perform its required function over the useful life of the product.

Latching switches which employ contacts integrally mounted on a latch, so that the latch not only secures the access but also completes the circuit, should be considered an extension of the plug type. Component switches that are actuated by a latch are considered as merely electrical interlock switches (1.a.); only the actuating mechanism is different in this case.

c. Mechanical interlocks use baffles or shutters which may operate in various ways to prevent access to radiation. They can block the radiation from entering the area made accessible by removal of the housing, frustrate a laser cavity, remove an integrally mounted optical component, insert an attenuator, and so forth. Sturdiness of design and component failure modes must be considered.

2. Preclude removal or displacement of the interlocked portion of the protective housing upon failure of the interlock to prevent access. In the determination of the adequacy of an interlock, consideration must be given to all modes of failure which might fail to prevent access. Sticking of a push button or leaf actuator, shorting or welding of switch contacts, failure of another component in an interlock circuit, or a mechanical jamming of a shutter may result in failure to preclude human access to radiation when the housing is removed or displaced. All these modes of failure must be considered when designing an interlock system which will preclude removal or displacement of the interlocked portion of the protective housing upon interlock failure.

a. Electrical interlock switches are subject to all of the failures noted, and therefore, by themselves are inadequate to satisfy the requirement. In order to furnish this level of safety, such switches must be used in conjunction with other devices. For example, the circuit may include an electrically operated latch which keeps the housing secured until the electrical circuit is interrupted by opening of the contacts of the interlock switch or the cessation of laser radiation.

b. Plug type interlocks are not subject to as many types of unsafe failure as switches. Compliance with the prevent access or preclude removal criteria (21 CFR 1040.10(f)(2)(i)(b)) is in general more readily achieved with a plug than a switch interlock. Provided the plug is securely and permanently attached to the housing, sticking or shorting of the contacts will hold the housing in place, and preclude removal. Proper design can preclude socket short circuits or mechanical failure.

c. Mechanical interlocks typically employ a permanent mechanical linkage between the means to prevent access and the protected portion of the housing. As such, sturdiness of design may be sufficient to prevent displacement or removal of the housing in the event of jamming of the shutters or beam blocks.

3. If defeatable, provide an indication of defeat. Before explaining how this criterion may be met, it is necessary to define what is meant by defeatable. Any interlock system, regardless of its complexity, can be defeated by a person with sufficient motivation and cleverness. Therefore, an interlock system will not be considered defeatable merely because such persons may be able to defeat it. For the purpose of determination of compliance, an interlock may be considered to be designed to allow defeat: if its method of defeat is self evident, e.g., pushing a button or leaf spring, installing a clip lead across obvious switch terminals, pulling out a "pull to defeat" plunger, etc., or if instructions for procedures to defeat are contained in the user or service information.

An adequate indication of defeat may be audible or visible, or active or passive, as appropriate to the product.

a. Electrical interlock switches, when defeated, may contain an inherent indication of the condition of defeat. The indication must be clear in its meaning and appropriate for the product and its operating environment. In many cases, the presence of a particular sound level associated with operation may be an obvious indication. However, the visibility of a piece of tape holding a leaf spring depressed, or a clip lead, may not be a clear indication.

b. Plug type interlocks generally require the use of an auxiliary plug or cable for defeat. A familiar example is the television service power cable which permits the set to be operated for testing with the cover removed. The external cable is a visible indication in this case. If the plug merely completes a circuit, a shorting plug may be used for defeat. Any such plug must be readily seen and be clear in meaning when installed.

c. Mechanical interlocks may incorporate integral "flags" which indicate defeat. Alternatively, defeat may be accomplished by means of the installation of a tool which must give suitable indication of defeat.

4. When defeated, preclude replacement of the removed or displaced portion of the protective housing. This criterion requires either that the attempted replacement of the housing automatically resets the defeated interlock so that it will prevent human access to radiation the next time the housing is displaced, or that the defeated interlock interferes with the replacement of the housing.

a. Electrical interlock switches may or may not satisfy this criterion. "Pull to defeat" plunger switches generally provide this function and are reset by the replacement of the housing. A tape or clip lead defeated switch would probably fail to comply. If, however, a monitor was used to electrically operate a latch, the latch may impede the replacement of the housing and satisfy this criterion.

b. Plug type interlocks can generally be designed so that they satisfy this criterion. For example, the back of the television set cannot be replaced when the service cable is in place. If a shorting plug is used, it should be of sufficient size to interfere with the replacement of the housing, and in any case would probably do so by preventing seating of the housing mounted portion of the interlock.

c. Mechanical interlocks can be designed to satisfy this criterion. Mechanical shutters which can be reset by replacement of the housing should be used. If a defeating tool is used, it should be of sufficient size to interfere with replacement of the housing.

Please note in conclusion that mention has been omitted of portions of a protective housing which are intended to be removed or displaced for service only. The performance standard requires safety interlocks for access during operation or maintenance. Access, for service only, may be protected by means of either a safety interlock (one meeting the requirements of 21 CFR 1040.10(f)(2)) or a warning label. Attention is directed to 21 CFR 1040.10(g)(6),(7),(8),(9) and (10) for the contents of labels required for portions of a protective housing which may be removed or displaced for operation, maintenance or service.

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OCT 14 [illegible]

REF:DOC:MA-4048

To: All Manufacturers and Potential Manufacturers of Laser Products

SUBJECT: Manufacture and Certification of Laser Kits, 21 CFR 1040.10 and 1010.2

BACKGROUND AND QUESTION: A laser product is sold in kit form, complete with labels and instructions, such that the product will comply with the standard when properly assembled. How must such a product be identified and certified as complying with the standard?

RESPONSE: All laser products sold in kit form must meet all of the applicable requirements of the performance standard for laser products when properly assembled according to manufacturers' instructions.

For purposes of identification and certification the date of manufacture of a kit is considered to be that date on which the manufacturer assembles the components as a complete package for shipment. Because portions of the performance standard may be added to or changed and become effective at a later date, this particular date establishes the last date on which the manufacturer has control of a specific product and therefore determines the applicable requirements.

As with all laser products manufactured on or after the effective date of the standard, these products, when assembled properly, must have affixed an identification label as specified in 21 CFR 1010.3 and a certification label as specified in 21 CFR 1010.2. The certification label may indicate that the product complies with all applicable HEW standards under the Radiation Control for Health and Safety Act of 1968 (or HEW radiation performance standards, 21 CFR Subchapter J) in effect on the date of manufacture shown when assembled in accordance with the manufacturer's instructions.

The manufacturer has the responsibility to assure compliance throughout the useful life of the product under reasonably foreseeable conditions of assembly and use. Therefore, the following criteria are offered for evaluating a product of kit design:

1. The design should be such that it would be unlikely that an untrained assembler could make mistakes or omissions in assembly that would lead to noncompliance with the standard. In addition, the manufacturer should pretest the product design with maximized laser radiation levels and supply the purchaser with the appropriate labels.

2. The instructions for assembly should be such that an untrained assembler could follow them and produce a finished laser product which would be and remain in compliance with the standard. All assembly operations that are of importance to radiation safety should be clearly identified. Where careful adherence to directions is necessary to assure compliance, clear instructions to take the necessary care in assembly should be provided. Where alterations or omissions could lead to noncompliance, the instructions should provide clear warning against such alterations or omissions.

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NOV 23 1976

REF:DOC:9066-MA

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Applicability of the Performance Standard to Products Manufactured by a Company For Use in its Manufacturing Process

BACKGROUND AND QUESTION: A company manufactures a variety of products that are not necessarily laser products but which require that rigid product specifications be met. The company has developed a laser product for exclusive use in their own plants to monitor product quality during manufacturing, inspection or service. The company desires to know if their laser product is subject to the Federal Performance Standard for Laser Products and other regulations.

RESPONSE: The central question revolves around whether the company is "engaged in the business" of manufacturing or assembling these laser products within the meaning of Section 355(3) of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (the Act), and is therefore a "manufacturer" required by Sections 358(h) and 360B(a)(5) of the Act to certify compliance of these laser products with the standard.

The Bureau of Radiological Health has been advised previously by General Counsel that an electronic product, including laser products, constructed on a one-time basis by a particular company for use by that company in its manufacturing process at the place where constructed is not considered "manufacturing". If, however, the products are made on a continuing basis in the course of a commercial enterprise and used by employees other than those directly involved in the manufacture of the electronic product, the company is considered to be "engaged in the business" of manufacturing products subject to the Act.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
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DEC 8 1976

REF:DOC:9090-MA

TO: All Manufacturers and Potential Manufacturers of Laser Products.

SUBJECT: Exemption of Certain Military Laser Products From the FDA Radiation Safety Performance Standard for Laser Products.

A number of manufacturers of laser products for the Department of Defense have informed representatives of the Food and Drug Administration that certain of their products are exempted from the Federal performance standard for laser products, 21 CFR 1040.10 and 1040.11. The basis for the exemption is stated to be the agreement of July 1976, between Mr. Sherwin Gardner, Acting Commissioner of the Food and Drug Administration and Mr. George Marienthal, Deputy Assistant Secretary of Defense, whereby an exemption from the performance standard for certain military laser products was granted to the DOD. However the Food and Drug Administration has contacted the Office of the Assistant Secretary of Defense (Installation and Logistics) and found that procedures for processing exemptions have not been implemented by the Department of Defense as of December 7, 1976, nor has DOD authorized an exemption for any laser product.

The exemption to the Department of Defense was granted on the grounds that the special military requirements for such products preclude full compliance with the FDA standard. In granting this exemption the Department of Defense agreed to establish procedures to assure that (1) only laser products designed expressly for actual combat operations or combat training operation and laser products classified in the interest of national defense will be procured or manufactured by the Department of Defense pursuant to the requested exemption, and (2) a permanent record of the status of all exempted laser products, including their ultimate disposition will be maintained. Furthermore, it was agreed that Department of Defense procurement specification for such exempted products are to include, to the extent practicable, the radiation safety provisions of the Federal standard (21 CFR 1040.10; 1040.11) unless adequate alternative controls are provided by the Department of Defense.

Manufacturers of military laser products who have not secured in writing a confirmation of their exemption from the Department of Defense along with the terms of the exemption for their specific laser product will not be considered exempt by the Food and Drug Administration and therefore are required by the Radiation Control for Health and Safety Act of 1968, to furnish reports, maintain records on such products and to comply with performance standards as applicable. All laser products manufactured on or after August 2, 1976 and which have not been specifically exempted, must be certified by their manufacturers as in compliance with 21 CFR

1040.10 and 1040.11. Manufacturers who have violated these requirements may be subject to the penalties prescribed by Section 360C of the Act. Introduction of military laser products into commerce which are not certified as being in compliance with the Federal standard must be terminated immediately until an exemption authorization is secured from the Department of Defense.

Manufacturers of a laser product for the Department of Defense who believe their product is eligible for an exemption should contact their contracting officer, as soon as possible, or they may contact the Office of the Assistant Secretary of Defense (Installations and Logistics), Deputy Assistant Secretary of Defense for Environment and Safety, Pentagon Building, Washington, D.C. 20301; the office phone number is (202) 695-0221. The Department of Defense will then determine whether the product can be exempted and will inform the manufacturer in writing as to whether the exemption is authorized.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
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REF:DOC:432-MA

MAR 9 1977

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Wording of Required Warning Labels For Dye Laser and Other Multiple Wavelength Lasers, 21 CFR 1040.10(g)

BACKGROUND: A laser is capable of emitting, at the discretion of the user, laser radiation in a number of ranges in the visible and invisible portions of the electromagnetic spectrum. The laser manufacturer asks what wording should be provided on the required warning logotype which would fulfill the requirements of 21 CFR 1040.10(g)(5) and (8) and be appropriate to the product. The manufacturer comments that the following problems exist: (1) A listing of all possible wavelengths would not accurately indicate the particular hazard that might be present at any given time, and (2) in the case of dye lasers, the maximum output of the pumped laser is also dependent on the laser used for pumping which cannot be controlled by the dye laser manufacturer.

POLICY: If a laser could be made to produce either visible or invisible laser radiation and perhaps both visible and invisible laser radiation simultaneously, it would be acceptable for a manufacturer to appropriately precede the word "radiation" on the required warning labels with the words "visible and/or invisible". The Bureau would not object to the addition of a note on warning labels refering the user to the operation or instruction manual for further information.

Since no specific wording is required for the radiation output information on the warning logotype (21 CFR 1040.10(g)(5)), the following statements of laser medium or wavelength of emitted laser radiation might be used at position 2 of the required warning logotype of a dye laser:

"DYE LASER - VARIOUS ULTRAVIOLET, VISIBLE OR INFRARED WAVELENGTHS MAY BE EMITTED. CONSULT INSTRUCTION MANUAL."; or

"DYE LASER - WAVELENGTHS EMITTED MAY RANGE FROM _____nm to _____nm. CONSULT INSTRUCTION MANUAL."

A similar statement would be used for other types of multiple wavelength lasers as appropriate.

Since the maximum output level of a dye laser is dependant upon and limited to that of the input radiation, a statement to this effect would be adequate, for example:

"MAXIMUM OUTPUT DEPENDS ON DYE, MIRRORS AND PUMPING LASER - CONSULT INSTRUCTION MANUAL AND LABEL ON PUMPING LASER FOR MAXIMUM POWER."

This statement would serve to direct the attention of the reader of this information to the warning logotype of the pumping laser.

INVITATION TO COMMENT: The Bureau is considering an amendment to the performance standard for laser products which may provide an opportunity in the future for manufacturers to seek greater flexibility in the wording of warning logotypes and other required labels. In the interim, the above policy shall apply to the circumstances as described. Comments on this policy are invited.

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MAR 2 1977

REF:DOC:9026-MA

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Optional Interlocks and Related Labeling, 21 CFR 1040.10(f)(2) and (g).

BACKGROUND: A laser product has a cover that is intended to be opened or removed for service only. The standard does not require the service cover to be provided with a safety interlock even though laser radiation in excess of Class I levels would be accessible when the cover is removed. However, the manufacturer has provided a defeatable interlock on the cover for protection from internal high voltage. As a result of removal of the high voltage, generation of laser radiation is terminated. However, the interlock does not comply with the requirements of 21 CFR 1040.10(f)(2) for safety interlocks in that removal of the cover is not prevented in the event of interlock failure, there is no indication of interlock defeat, and the cover could be replaced when the interlock is defeated. The manufacturer asks whether the product must be labeled in accordance with the requirements of either subparagraph (g)(6) or (g)(7) of 21 CFR 1040.10 and, if so, which subparagraph would apply.

POLICY: A portion of the protective housing can be intended by design or instruction to be displaced or removed only during service. The manufacturer has, within the requirements of the standard, the option of using:

1. A safety interlock that is not designed to be defeated, or
2. A safety interlock designed to be defeated, or
3. No safety interlock at all,

on that portion of the protective housing.

If a safety interlock is not used, then the product must be labeled in accordance with the requirements of Section 1040.10(g)(6) - Labels for noninterlocked protective housings. If a defeatable safety interlock is used, the product must be labeled in accordance with the requirements of Section 1040.10(g)(7) - Labels for defeatably interlocked protective housings. A label is not required when a safety interlock that is not designed to be defeated is used. An interlock, to be considered a *safety interlock* within the meaning of the definition of this term in the standard, must conform to all of the performance criteria set forth in 21 CFR 1040.10(b)(31) and (f)(2). Unless the interlock used conforms to all of the performance criteria for a *safety interlock* the protective housing must be considered to be without a safety interlock, and a label meeting the requirement of Section 1040.10(g)(6) must be used.

However, since the cover is interlocked (although not with a safety interlock), a modification in the wording specified by Section 1040.10(g)(6) would be appropriate. Therefore, the Bureau will not object if the wording "and interlock failed or defeated" is added to the required label statement as in the following example for Class II levels of laser radiation accessible under conditions of service (21 CFR 1040.10(g)(6)(i)):

> "CAUTION - Laser radiation when open and interlock failed or defeated. DO NOT STARE INTO BEAM."

INVITATION TO COMMENT: The Bureau is considering an ammendment to the performance standard for laser products which may provide an opportunity in the future for manufacturers to seek greater flexibility in the wording of warning logotype and other required labels. In the interim, the above policy shall apply to the circumstances as described. Comments on this policy are invited.

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MAY 5 1977 REF:DOC:4036:MA

To: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Response To Question Concerning An Aiming Beam For The Therapeutic Beam Of A Medical Laser Product, 21 CFR 1040.11(a)(1)

BACKGROUND AND QUESTION: A company manufactures a medical laser product that uses pulses of laser energy at Class IV levels for treatment. The product also uses a low level (Class II) laser beam for aiming the treatment beam. A meter on the product indicates what the level of laser radiation in the treatment mode is or will be within ±20 percent. Does the manufacturer also have to provide a means of measuring the level of laser radiation in the aiming beam within ±20 percent.

RESPONSE: The intent of the measurement requirement of 21 CFR 1040.11(a)(1) is to ensure accurate knowledge of the Class III or Class IV levels of laser radiation intended for in vivo diagnostic, surgical or therapeutic laser irradiation of patients. Without such knowledge, day-to-day reproducibility in patient irradiations would not be possible. However, if the laser radiation is at Class I or Class II levels, the means for this type measurement is not required by the standard. The product must, of course, comply with the applicable requirements of Section 1040.10.

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Policy Statement #18

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

JUL 1 1977

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Safety Interlocks to Prevent Access to Class II Levels of Laser Radiation

BACKGROUND: The Federal performance standard for laser products requires that safety interlocks, unless defeated, prevent human access to laser and collateral radiation upon removal or displacement of the interlocked portion of the protective housing and preclude removal or displacement of the housing upon interlock failure (21 CFR 1040.10(f)(2)(i)). Laser products which incorporate safety interlocks which are designed to allow interlock defeat must also have a visual or audible indication of defeat when the interlocked portion of the protective housing is removed or displaced (21 CFR 1040.10(f)(2)(ii)). Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated (21 CFR 1040.10(f)(2)(iii)).

The Bureau of Radiological Health has reassessed the need for certain of the safety interlock requirements of 21 CFR 1040.10(f)(2) as they pertain to operation and/or maintenance ports in the protective housing of laser products through which access to levels of visible laser radiation not exceeding Class II limits is possible. This reassessment has led to the regulatory policy stated below. This policy is considered warranted because eye damage, while possible from chronic exposure to Class II levels of laser radiation, is not likely to occur from acute exposure. Also, since the Class II limits can only be applied to visible radiation (400-700 nm) and any invisible radiation must be below the Class I limits, the user would have a visual indication of laser radiation in the event of interlock failure or defeat when the protective housing is removed or displaced. Therefore, in this case, the requirements of 21 CFR 1040.10(f)(2) are considered to be overly restrictive and properly designed standard electrical or mechanical interlocks with appropriate labels on the protective housing should be sufficient to meet the intent of the standard and protect the user from the hazards of Class II laser radiation.

POLICY: Under the following conditions the Food and Drug Administration will not object to certified laser products which deviate from the requirements of 21 CFR 1040.10(f)(2):

1. Interlocks Not Designed to Allow Defeat

   a. The requirements of 21 CFR 1040.10(f)(2)(i)(a) are satisfied,

   b. The interlock is operated according to its design specifications,

c. Failure of the interlock will not provide access to laser radiation levels in excess of the Class II limits in the wavelength range of 400 to 700 nm or in excess of Class I limits in all other wavelength ranges, and

d. The protective housing is labeled in accordance with 21 CFR 1040.10(g)(6)(i) with the following wording change - "CAUTION - Laser radiation when open and interlock failed. DO NOT STARE INTO BEAM."

2. Defeatable Interlocks

a. The requirements of 21 CFR 1040.10(f)(2)(i)(a) are satisfied,

b. The interlock is operated according to its design specifications,

c. Failure or defeat of the interlock will not provide access to laser radiation levels in excess of the Class II limits in the wavelength range of 400 to 700 nm or in excess of Class I limits in all other wavelength ranges,

d. The laser radiation is not emitted directly through the opening created by displacement or removal of the interlocked portion of the protective housing upon interlock defeat, and

e. The protective housing is labeled in accordance with 21 CFR 1040.10(g)(7)(i) with the following wording change - "CAUTION -Laser radiation when open and interlock failed or defeated. DO NOT STARE INTO BEAM."

INVITATION TO COMMENT: The Bureau of Radiological Health intends to propose an amendment to the Federal performance standard for laser products which will clearly permit performance under the conditions specified above. In the meantime, the Food and Drug Administration will not take action under Sections 359, 360B or 360C of the Radiation Control for Health and Safety Act of 1968 if certified laser products deviate from the requirements of 21 CFR 1040.10(f)(2) provided the above conditions are met since such deviation, while technically noncompliant with the present performance standard, does not create a significant risk of injury to any person. Comments on this policy are invited.

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NOV 11 1977

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: EMISSION DELAY FOLLOWING USE OF REMOTE CONTROL UTILIZING REMOTE CONTROL CONNECTOR, 21 CFR 1040.10(f)(3) and (5)(ii)

BACKGROUND: The Federal performance standard for laser products requires that each Class III and IV laser system have a remote control connector (21 CFR 1040.10(f)(3)) and an emission indicator (21 CFR 1040.10(f)(5)(ii)). The indicator must provide a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I and sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to laser radiation. The standard does not explicitly state that the emission indicator must deactivate when emission is terminated by a remote control operated through the remote control connector and that there must be a delay before emission of accessible laser radiation is resumed. Therefore, a question has arisen as to the intent of the standard as it applies to the functioning of the emission indicator and delay element upon termination of emission through use of the remote control connector.

POLICY: The remote control connector is intended to allow use of external protective barrier interlocks such as a door interlock or other remote control safety switch (38 FR 34085). Such switches are used to interrupt and prevent emission of laser radiation upon entry to a hazardous or controlled area and not as an operator control for the laser product. Laser emission in excess of the accessible emission limits should not resume immediately after closure of the contacts of an interlock or remote control safety switch functioning through the remote control connector since resumption of emission without adequate forewarning would defeat the purpose of the switch. Therefore, it is the intent of 21 CFR 1040.10(f)(5)(ii) to require that following termination of laser radiation emission by operation of a remote control through utilization of the remote control connector, a visible or audible signal precede resumption of such emission for a period of time sufficient to allow appropriate action to avoid exposure to laser radiation. This requirement is necessary to assure that remote control operation through utilization of the remote control connector can be accomplished with the same degree of safety as nonremote control operation.

This policy will not apply to laser products manufactured before March 1, 1978 in order to allow time for design modifications where necessary to bring laser products into conformance with this policy.

INVITATION TO COMMENT: The Food and Drug Administration may propose an amendment to Federal performance standard for laser products (21 CFR 1040.10 and 1010.11) which will explicitly incorporate the above policy into the standard. Therefore, comments on this policy are invited.

Consideration is also being given to the alternate possibility of an amendment requiring manual restart of laser products following termination of laser radiation emission by operation of a remote control through utilization of the remote control connector or by loss of supply voltage. Comments on the need for such amendment are also invited.

John C. Villforth
Director
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

NOV 23 1977

FDA COMPLIANCE POLICY GUIDE

SUBJECT: Applicability of Laser Product Performance Standard to Laser Light Shows (21 CFR §§ 1040.10(a) and 1040.11(c))

BACKGROUND:

The Bureau of Radiological Health has observed that there is a growing use of lasers in the music, entertainment, and advertising industries. In particular, musical groups and discotheque operators have been using lasers to create visual effects to complement the music being played. Lasers are also being used for visual effects in theaters and planetariums, and in the advertising industry. A system for creating the desired visual effects is frequently assembled using a general purpose laser (usually Class III or IV) with the addition of beam scanners, laser housing, fiber optic tubes, display screens, and/or other devices necessary for the creation of a laser light show.

In view of these applications of lasers, the FDA was asked if musical groups and other persons responsible for laser light shows are regarded as "manufacturers" of laser products subject to the laser product performance standard (21 CFR 1040.10 and 1040.11). The applicability of the FDA performance standard to the assembly of such products depends on whether (1) the assembly process described above constitutes "manufacturing" within the meaning of the Radiation Control for Health and Safety Act and, (2) the date of completion of the assembly process occurs before or after the effective date of the standard (August 2, 1976).

POLICY:

Laser products manufactured for use in light shows are considered to be demonstration laser products. A demonstration laser product is defined as a laser product designed, intended, or promoted for purposes of demonstration, entertainment, advertising display or artistic composition (21 CFR 1040.10(b)(10)). Demonstration laser products must comply with all of the applicable requirements for Class I or Class II laser products and not exceed the accessible emission limits of those classes (21 CFR 1040.11(c)).

Although a general purpose laser was "manufactured" when it was first assembled for commercial purposes by a person engaged in the business of such assembly, the act of assembly of a laser light show using a previously manufactured general purpose laser or laser product results in the creation or manufacture of a "new" product. The creation of this new product may involve addition of such components as scanners, display screens and optics but may also result from merely changing the intent and use of the original laser. Hence, the person who produces the "new" product is considered a "manufacturer" if such person is engaged in the business of manufacturing laser light shows.

A person is considered to be "engaged in the business" of manufacturing a laser product if he commercially sells his services as a manufacturer or assembler of light shows. Therefore, an individual, for example, under contract with a musical group, who is responsible for assembling a light show for the group would be a "manufacturer" within the meaning of the Act. Similarly one who creates his own laser light show and uses it in conjunction with the performance of services which he offers to the public for compensation would also be considered a "manufacturer". Consequently, a musical group that purchases a general purpose laser and creates its own light show could not evade the requirements of the Act if the light show was used as a part of the group's performances.

The second factor in determining the applicability of the laser performance standard is the date of manufacture of the product. There are three possibilities to consider:

(1) laser products originally manufactured after August 2, 1976;

(2) laser products originally manufactured prior to August 2, 1976 but "remanufactured" as a laser light show after August 2, 1976;

(3) laser products manufactured and converted to light show use prior to August 2, 1976.

Laser products in the first category are obviously covered by the performance standard and are therefore subject to certification when originally manufactured and to recertification if "remanufactured". Products in the second category would not be subject to the standard when first manufactured. "Remanufacture" after the effective date of the standard would, however, subject the laser to the performance standard. As for those laser products manufactured and "remanufactured" before August 2, 1976, they are not subject to the performance standard.

If a manufacturer desires to introduce into commerce a demonstration laser product that cannot comply with the requirements of 21 CER 1040.10 or 1040.11, he must apply for a variance from the standard as specified in 21 CFR 1010.4. The Bureau will review these requests as rapidly as possible and grant a variance only if there are adequate controls over both stationary (discotheque) and mobile light shows (musical groups). If the manufacturer's variance request does not assure suitable means for providing radiation safety or protection or if the manufacturer fails to conform to the conditions required by the variance, then the variance will be denied or canceled, as appropriate.

INVITATION TO COMMENT:

Once the Agency collects additional data on the variety of alternative means for providing radiation safety and protection in the operation of demonstration laser products of this type, consideration will be given to amending 21 CFR 1040.11(c) to establish new and specific requirements for demonstration laser products, thus avoiding the need for a variance. Until such a change in the standard becomes effective, the FDA will vigorously enforce the present regulations. Comments on this policy are invited.

John C. Villforth
Director
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

FDA COMPLIANCE POLICY GUIDE

FEB 21 1978

SUBJECT: Interim Enforcement Policy for Certain Laser Light Shows and Displays (21 CFR 1040.10 and 1040.11)

BACKGROUND:

On November 23, 1977, the Bureau of Radiological Health issued an FDA compliance policy guide on the applicability of the Federal laser product performance standard to laser light shows and displays (policy statement number 22). That document established the policy that a person who is engaged in the business of assembling laser light shows or displays is a manufacturer of a demonstration laser product and is thus subject to the requirements of the Radiation Control for Health and Safety Act of 1968 including the Federal performance standard for laser products (21 CFR 1040.10 and 1040.11). The policy also stated that laser light shows and displays which cannot comply with the requirements of the standard for demonstration laser products (i.e., they are classified as Class III or IV laser products) cannot be introduced into commerce unless a variance (specific authorization to vary from the standard) has been obtained. The intent of the agency to consider an amendment to the standard to negate the need for a variance was also expressed.

Either processing a variance application or promulgating a significant amendment to the performance standard involves a lengthy process. In the meanwhile the Bureau of Radiological Health is concerned with the fact that laser light shows which fail to comply with the performance standard have already been assembled since August 1, 1976, and are currently in operation. Also, if the lead time to produce a laser light show were too short to permit processing a variance, the show might be unnecessarily prevented from introduction into commerce.

While a laser light show or display might not fully comply with the performance standard requirements for a demonstration laser product in that it is classified as a Class III or even a Class IV laser product and a variance has not been granted, such light show may not create a significant risk of injury if properly designed, assembled and operated (i.e., it meets the safety criteria presented below). There should be no reason to institute enforcement action against a person who has assembled a laser light show if the person has applied for a variance and the agency has inspected the product in its operational configuration(s) and has concluded that it meets the safety criteria presented below.

POLICY:

The Bureau of Radiological Health will not object to the assembly and continued operation of a laser light show or display, regardless of its class, if the following conditions are satisfied:

(1) the laser light show or display meets the Federal performance standard for its class;

(2) the manufacturer has submitted a report as required by 21 CFR 1002.10 or 1002.12;

and in addition for Class III or IV laser products:

(3) the manufacturer has applied for a variance from the requirements of 21 CFR 1040.11(c);

(4) the laser light show or display is designed, and operated, in accordance with the safety criteria presented below; and

(5) the manufacturer allows representatives of the Food and Drug Administration to examine the product and the control procedures to assure conformance to the above conditions.

The Food and Drug Administration will take appropriate enforcement action to prevent the assembly, introduction into commerce and continued operation of laser light shows or displays which fail to meet the above conditions.

LASER SAFETY CRITERIA FOR CLASS III AND CLASS IV LASER LIGHT SHOWS AND DISPLAYS

1. Laser radiation emission at wavelengths outside the range from 400 to 710 nanometers must not exceed the emission limits of Class I under any possible conditions of operation.

2. Laser and collateral radiation, measured where the audience is normally located, must not exceed the limits of Class I during operation. Radiation to be measured includes reflections from targets and scattering materials.

3. Operators, performers and employees must be able to perform their functions without the need for exposure to laser and collateral radiation in excess of the limits of Class I if such radiation is intended to be viewed by them in order to perform their functions, or in excess of the limits of Class II if such radiation is not intended to be viewed.

4. Scanning devices, including mirror balls, must incorporate a scanning safeguard to prevent laser emission if scan failure or other failure causing a change in either scan velocity or amplitude would result in violation of criteria 2 or 3 above.

5. If the laser light show does not operate at all times under the direct supervision or control of an operator, laser radiation levels to which "human access" (21 CFR 1040.10(b)(12)) can be gained must not exceed the limits of Class II at any point less than 6 meters above any surface upon which a person in the audience is permitted to stand or at any point less than 2.5 meters in lateral separation from any position where a person in the audience is permitted during the performance or display.

6. Laser light shows or displays which do not meet criteria (5) shall be operated at all times under the direct supervision or control of a trained operator who shall maintain constant surveillance of the laser display and terminate emission of laser radiation in the event of equipment malfunction, audience unruliness or other unsafe conditions. Laser radiation levels to which "human access" can be gained must not exceed the limits of Class II at any point less than (1) 3.0 meters above any surface upon which the audience is permitted to stand, or (2) 2.5 meters in lateral separation from any position where a person in the audience is permitted to be unless physical barriers obstruct access by the audience to such levels.

7. All laser light shows or displays must be provided with one or more readily accessible controls to effect immediate termination of laser radiation. If the light show or display is not required to be under the continuous supervision or control of an operator during its operation, there must be a person at all times at the show or display who is designated to be responsible for the immediate termination of the laser radiation in the event of equipment malfunction, audience unruliness or other unsafe conditions.

8. The maximum output power above Class II shall be limited to that required to perform the intended function of the product.

9. The laser light show or display must meet any other radiation safety criteria which the Bureau of Radiological Health believes is necessary to adequately protect public health and safety.

10. All tests and measurements for the determination of compliance shall be performed in accordance with the conditions of 21 CFR 1040.10(e) with the understanding that all measurements of radiant power, radiant energy, irradiance, or radiant exposure shall be made with a detector having a solid angle of acceptance of 2π steradians, or its equivalent.

In addition, the laser operator and/or the laser safety officer responsible for producing a laser light show should contact the local or state radiation control officials or health department prior to a show to determine that any applicable local or state requirements are satisfied and clearances obtained before the show or display goes on.

John C. Villforth
Director
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

JUN 12 1978

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Modified Aperture Label For Laser Product Used For Patient Positioning and Alignment, 21 CFR 1040.10(g)(4)

BACKGROUND AND QUESTION: The Bureau of Radiological Health has observed that laser radiation at levels less than the limits of Class II is being used for the positioning or alignment of patients relative to certain medical devices. A manufacturer of a laser product for this function has requested relief from the requirement in 21 CFR 1040.10(g)(4) that the laser aperture label include the words "avoid exposure" and permission to use a label bearing the wording "Laser Aperture" as allowed by 21 CFR 1040.11(a)(3) for medical laser products. The manufacturer claims that although the laser products are not medical laser products since they are not "manufactured, designed, intended or promoted for purposes of in vivo diagnostic, surgical, or therapeutic laser irradiation of any part of the human body", the required warning is inconsistent with the purpose of the laser radiation, namely, exposure of the patient.

POLICY: Laser products that are medical devices utilizing visible lasers for patient illumination in aiming or patient positioning may in lieu of the aperture label specified by 21 CFR 1040.10(g)(4) utilize an aperture label with the following statement: "Laser Aperture - Do not stare into beam", providing that the level of laser radiation emitted through the aperture exceeds the limits of Class I but does not exceed the limits of Class II. The Bureau of Radiological Health concurs that, under these circumstances, the wording required by 21 CFR 1040.10(g)(4) is inconsistent with the function of the radiation and could cause unnecessary anxiety to the patient. The Bureau believes if the patient is exposed to levels for which a specific warning is appropriate, that the warning should be visible to the patient on the product. Since this caution should have already been communicated to the patient by the staff, the label should only be a reinforcement and not cause any undue anxiety to the patient. Users of such products should be cautioned to avoid ocular exposure in the user instructions furnished.

John C. Villforth
Director
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

SEP 14 1979

TO: ALL LASER PRODUCT MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Exemption of Certain Laser Products Used Exclusively by the Department of Energy or Its Contractors, and by the National Oceanic and Atmospheric Administration, U.S. Department of Commerce

The purpose of this memorandum is to notify all laser product manufacturers of exemptions granted for laser products intended for U.S. Government use (21 CFR 1010.5). These laser products may not be the same as models that are certified and sold or leased commercially. They are to be used exclusively by (1) the National Oceanic and Atmospheric Administration, U.S. Department of Commerce or by (2) the Department of Energy or by its contractors at DOE designated, government-owned contractor-operated (GOCO) facilities in unique research applications or as components in larger research and development systems. The exemption is from the FDA performance standard for laser products, 21 CFR 1040.10 and 1040.11, and the associated reporting and recordkeeping requirements, 21 CFR Part 1002, except for paragraph 1002.20 relating to accidental radiation occurrences.

The exemptions were approved by the Director, Bureau of Radiological Health, by letters dated May 26, 1978, to Mr. James Liverman, Acting Assistant Secretary for Environment, Department of Energy and June 4, 1979 to Mr. Ferris Webster, Assistant Administrator for Research and Development, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

The exemptions apply to all Department of Energy and to all National Oceanic and Atmospheric Administration, U.S. Department of Commerce, contracts and sub-contracts. However, DOE and NOAA procurement specifications will prescribe compliance with the FDA standard to the extent practicable and will be supplemented with safety controls and procedures utilized by DOE and NOAA.

All exempted products are to be clearly identified by labels permanently affixed to or inscribed on each such product so as to be legible and readily accessible to view when each product is fully assembled for

operation. The labels shall contain the wordings set forth below for DOE and for NOAA respectively:

Department of Energy

CAUTION

This electronic product has been exempted from FDA laser radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter 1, Subchaper J, pursuant to Exemption No. 78EL-01DOE issued on May 26, 1978. This product should not be used without adequate protective devices or procedures nor disposed of through excess or regular surplus property channels.

National Oceanic & Atmospheric Administration:

CAUTION

This electronic product has been exempted from FDA laser radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J, under Exemption No. 79EL-01 NOAA issued on June 4, 1979. This product should not be used without adequate protective devices or procedures nor disposed of through excess or regular surplus property channels.

In addition DOE and NOAA will report annually to FDA on the type of devices procured under the exemption, and their manufacturers.

The exemption may be withdrawn or amended if any of the terms of the agreement between the Food and Drug Administration and these agencies are not adhered to, or if other information becomes available indicating that the public health and safety are not adequately protected from electronic product radiation emitted by products exempted pursuant to these exemptions.

Correspondence concerning the DOE exemption should be directed to Mr. Kenneth R. Baker, United States Department of Energy, MS E301 Washington, D.C. 20545; the office phone number is (202) 353-5615. Correspondence concerning the NOAA exemption should be directed to Dr. Freeman Hall, Chief of Coherent Lidar and Wave Propagation Laboratory, Environmental Research Laboratories, Boulder, Colorado 80303; the office phone number is (303) 499-1000 X6359.

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

DEC 11 1979

TO: MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Enforcement Policy for Certain Laser Light Shows, Displays, and/or Devices. (21 CFR 1040.10 and 1040.11)

BACKGROUND:

On February 21, 1978, the Bureau of Radiological Health issued an interim enforcement policy for certain laser light shows and displays. That document established the policy that the Bureau would not object to the assembly and continued operation of any laser light show, display, and/or device in the absence of a variance, if a specified set of conditions including operational safety criteria were satisfied.

At that time, processing an application for a variance from one or more requirements of a performance standard involved a lengthy process. On August 17, 1979, an amendment to the administrative procedures for ruling on variance applications was published in the Federal Register and became effective on September 17, 1979. This amendment permits the Director of the Bureau of Radiological Health to approve or deny in whole or in part a requested variance, or amendment or extension of a variance. BRH must inform the applicant in a written notice that specifies, among other things, the conditions of the variance, as well as its effective date. The amended procedures no longer include formal publication of variance approvals in the Federal Register, with a 30-day objection period, thus expediting the process considerably. However, a notice of availability of an approved variance will be published in the Federal Register.

In addition the Bureau has developed a variance application form to assist laser light show manufacturers in providing all of the information needed by the Bureau to rule on their variance request. The use of this form will also speed up the variance evaluation process within the Bureau, and is available upon request.

Since these actions will result in reducing the time required to obtain a variance, there is no longer any reason to permit laser light shows, displays, or devices that do not comply with the requirements of the standard for demonstration laser products (i.e., they are Class III or IV laser products) to be introduced into commerce unless a variance (specific authorization to vary from the standard) has been obtained.

POLICY:

Effective May 1, 1980, all manufacturers or assemblers of Class III or IV laser light shows, displays, and devices manufactured or assembled after August 1, 1976, must have an approved variance before introducing them into commerce or continuing their operation. The Food and Drug Administration will take appropriate enforcement action to prevent the manufacture, assembly, introduction into commerce, and continued operation of Class III or IV laser light shows, displays, and devices which fail to comply with the laser product performance standard and with the conditions of the applicable variance. This effective date has been chosen to provide adequate time for all known manufacturers to apply for and obtain a variance and for the laser light show industry to implement policies and procedures necessary to assure compliance.

Please note that Part 1010.4(c)(3) of the Regulations requires the Director, Bureau of Radiological Health, to amend or withdraw a variance whenever the Director determines that such action is necessary to protect the public health or is otherwise justified by 21 CFR, Chapter I, Subchapter J. Therefore, introduction into commerce of any laser light show, display, or device which fails to comply with the applicable requirements of the performance standard or the conditions of its approved variance may be considered grounds for withdrawal of the variance. Also, if the Bureau subsequently determines that the conditions of an approved variance are insufficient to protect the public health, the Director must amend or withdraw the variance.

Although the variance approval process is substantially shortened, it will still require some time to rule on the application. It is recognized by the Bureau that quite often a very short lead time may be given to the manufacturer to produce a show. Even in such a situation, it will be necessary for the manufacturer to obtain an approved variance before producing the show. Therefore, we urge manufacturers to apply for a variance(s) for all of the types of laser light shows, displays, and devices that they would consider producing so that an approved variance can be obtained thus enabling the manufacturer to accept such projects on short notice. Manufacturers may apply for a single general variance or for several different variances to cover distinct types of projects such as indoor shows versus outdoor shows or permanent installations versus touring shows.

Manufacturers are reminded that each laser light show, display or device, regardless of its class, must be reported (by model family) as required by 21 CFR Part 1002; the purpose of the report is to demonstrate compliance with the performance standard and must follow the reporting guide issued by the Bureau. For those laser light shows, displays, and/or devices produced under a variance, the report must also provide the details showing how they comply with the conditions of the variance. A new reporting guide is being prepared specifically for laser light

shows, displays and devices. Copies of this new guide will be available upon request in the near future.

In addition to the reports, we request that the Director, Division of Compliance, BRH be notified in writing of any planned installations or tours (and any changes to such) at least 30 days in advance so that inspections can be arranged and local authorities can be notified. If the Bureau cannot be notified in this manner, we request that you telephone the Light Products Section with the information at the earliest possible date.

If there are any questions regarding this policy, please contact the Light Products Section, Division of Compliance, Bureau of Radiological Health, HFX-430, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443-4874.

John C. Villforth
Director
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

OCT 16 1980

TO: All Manufacturers of Laser Diodes and Fiber Optic Communications Equipment

SUBJECT: Application Of the Federal Performance Standard for Laser Products to Laser Diodes in Fiber Optics Communications

BACKGROUND: Laser diodes/fiber optics are already well established in telephony, instrumentation, video and many military applications. This rapidly expanding field needs direction on the criteria employed by the BRH in classifying and applying the Federal performance standard for laser products (21 CFR 1040.10 and 1040.11) to these varied products.

GUIDANCE:

1. The standard defines a laser product as "any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system which is intended for use as a component of an electronic product shall itself be considered a laser product." A laser is "any device which can be made to produce or amplify electromagnetic radiation in the wavelength range of greater than 250 nm but less than or equal to 13,000 nm primarily by the process of controlled stimulated emssion." A laser system is defined as "a laser in combination with an appropriate laser energy source with or without additional incorporated components." Laser energy sources are devices "intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries shall not be considered to constitute laser energy sources."

2. Converters or pulse generators sold individually but without a laser diode are not considered laser products and do not require certification.

3. Laser diodes and diode arrays are laser products but are only lasers, not laser systems. They must be certified unless sold only to original equipment manufacturers (OEM's). The manufacturer of the uncertified product must know it will be incorporated into an electronic product which will be certified. (Note: A fiber optic network may be the final certified product.) In the absence of this verification the manufacturer must certify the product prior to sale. Certified lasers do not have to meet those requirements of the standard applicable to laser systems only, i.e., remote control connector, emission delay and key control for

Classes III and IV, or emission indicator and beam attenuator for Classes II, III and IV but must have the protective housing and labeling required by the standard. The labeling required consists of product certification (Section 1010.2), identification of manufacturer (Section 1010.3), and warning logotype and aperture label (Section 1040.10(g)). Many manufacturers have requested alternate labeling as provided in 21 CFR 1040.10(g)(10) due to the small size of laser diodes.

4. A pulse generator with a compatible laser diode is also a laser but not a laser system and is, therefore, not subject to the performance features required of a laser system. However, it must be certified to meet all requirements for a laser or be sold OEM.

5. The combination of an AC or DC to DC converter with a pulse generator and a compatible laser diode is a laser system and must meet all the certification requirements of such systems or be sold OEM.

6. A converter and pulse generator sold together for a specified laser product application are considered a laser product and require certification or OEM sale (this combination is equivalent to a power supply and product intended to incorporate a laser).

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 31 1980

TO: ALL LASER PRODUCT MANUFACTURERS

SUBJECT: Approval of Alternative Wording for Labels Involving Visible Laser Radiation Only.

BACKGROUND: In response to requests from some manufacturers, the Bureau of Radiological Health has approved the substitution of the words "Laser Light" for "Laser Radiation" in the label required by 21 CFR 1040.10(g)(1)(i) for certain Class IIa laser products. The bases of these approvals are that the accessible laser radiation is visible light only, that the word light more understandably describes the nature of the radiation, and that there is less likelihood of confusion with ionizing, particulate or other electromagnetic radiation.

Upon further consideration, the Bureau believes that this same reasoning can be applied without compromise of safety to all labels and warnings required by the laser product performance standard where the warnings are related to laser radiation in the visible wavelength range from 400 to 710 nanometers only.

GUIDANCE: In accordance with 21 CFR 1040.10(g)(10) approval is hereby given for the substitution of the words "Laser Light" for "Laser Radiation" in all labels and warnings required by 21 CFR 1040.10 and 1040.11 providing that all laser radiation exceeding the limits of Class I requiring such labels is within the visible wavelength range from 400 to 710 nanometers.

John C. Villforth
Director
Bureau of Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Laser Notice No. 29

CLARIFICATION OF CERTAIN LASER LIGHT SHOW REQUIREMENTS

The Bureau is concerned that there are a number of areas of confusion in the understanding of the requirements for Class III and IV laser light shows and devices. In addition, several of the conditions used in most variances are not understood and are being ignored. This notice provides guidance to help manufacturers understand (1) what a variance is, (2) who is or is not covered by a specific variance, (3) when a variance must be amended, (4) what the various reporting and notification conditions mean, (5) the role of the laser product reporting guide, the laser light show reporting guide, and the notification letter, and (6) what certain misunderstood variance conditions actually mean.

VARIANCE (21 CFR 1010.4)

A variance is formal permission to deviate from a requirement of the regulations. For laser light shows and devices a variance permits use of laser radiation levels that exceed the limits (Class II) for demonstration laser products as specified in 21 CFR 1040.11(c). A variance for laser light shows and devices is generally granted based on a determination that the product is required to perform a function which cannot be performed with equipment in compliance with the standard and that suitable means of radiation safety and protection will be provided. These suitable means are specified in the conditions of the variance and constitute, together with the balance of the laser product performance standard, an individual performance standard for a specific manufacturer of those specific laser products that may be certified by the manufacturer under the variance. Several points require additional comment.

1. The approval of a laser light show variance is limited to approval of the conditions of the variance that specify the required means of radiation safety and protection that apply to the laser products covered by the variance. This approval in no way constitutes FDA approval, certification, or endorsement of those laser products produced under the variance. Further, the variance is not a license for the manufacturer, since the approval of a variance does not depend on a determination of the competence of the manufacturer to meet the specified conditions. The manufacturer is responsible for ensuring by suitable quality control/assurance procedures that

each product complies with all requirements of the variance and the laser product performance standard and to so certify in a label on the laser product. In order to meet this responsibility, it may indeed be necessary for a manufacturer to expand his technical capabilities. Manufacturers who fail to demonstrate basic technical capabilities essential to ensure safety may have their variances revoked.

2. Some manufacturers do not understand clearly that there are two laser light show products involved in any laser light show. One is the basic projection and central control system which constitute the source of the laser light. The second product is the laser light show itself which includes the basic projector and all the auxiliary components (such as projection surfaces or screens, remote scanning components, mirror balls, fixed mirrors, termination targets, etc.) in their final assembled configuration at a given performance site. Both of these laser light show products are subject to the laser standard, must be reported, and must be covered by an approved variance(s) if the level of laser radiation emitted by the projector exceeds the limits of Class II. Thus, a laser light show projector manufacturer must have an approved variance under which a Class III or IV projector may be certified. Likewise, a laser light show/display manufacturer must have an approved variance under which the Class III or IV laser light show/display may be certified. If the laser light show manufacturer also manufactures the projector, then that manufacturer must have an approved variance under which both the projector and the laser light show may be certified.

3. A variance is a special performance standard not a general standard. As such, it is limited to cover certain specific products and is only applicable to such products produced by the variance holder. Thus, a variance is not transferrable from one manufacturer to another. Also the holder of the variance may not introduce equipment that was not specifically covered by the variance. For example, a laser projector manufactuer (A) who has a variance covering his projector and his light shows incorporating that projector and certain auxillary equipment, can not transfer the coverage of his variance to light show manufacturer (B) who purchases the projector and incorporates it with equipment he (B) already has to make a light show. In such a case manufacturer (B) would be required to obtain his own variance for laser light shows. Also, manufacturer (A) could not incorporate other equipment unless this equipment is included in his variance.

VARIANCE AMENDMENTS (21 CFR 1010.4(b)(2))

A variance may need to be amended and reports submitted if the product is changed. The necessity of amending the variance is determined by whether or not the change(s) to the projector or light show would be a

substantial change that required changing the conditions of the variance to achieve the required radiation safety and protection. Thus, when effects that were not previously included in the variance application are added, or when the variance was granted for a Class IIIb light show and a Class IV light show is being planned, or when types of lasers and/or projectors other than those originally listed in the variance application are incorporated, an application for an amendment to the variance should be submitted to the FDA Dockets Management Branch (formerly the Hearing Clerk) using Form FDA-3147. The Bureau recognizes that it may be difficult for the manufacturer to make the needed determination in every case. In such a situation, the manufacturer is urged to contact the Light Products Section at (301) 443-4874 for assistance in determining whether an amendment is required.

As a matter of policy, the Bureau encourages manufacturers to minimize the need for amendments by making the initial variance application as broad as possible.

REPORTING (21 CFR 1002.10 and 1002.12)

In addition to the variance or variance amendment required for Class III and IV laser light show or display products, such products of all classes must be reported to the Bureau. To satisfy this reporting requirement you must submit:

(1) a report on the laser projection system equipment, including any auxiliary components, in accordance with the general reporting guide, "Guide for the Submission of Information on Lasers and Products Containing Lasers Pursuant to 21 CFR 1002.10 and 1002.12" dated July 1976;

(2) a detailed report on the laser light show or display, including quality control or testing procedures, set-up procedures, installation diagrams, and the types of effects incorporated into the laser light show, in accordance with the "Reporting Guide for Laser Light Shows and Displays (21 CFR 1002)" dated March 1980; and

(3) a notification to the Bureau, as soon as possible, containing the specific date(s) and location(s) with complete addresses for each assembly and presentation of the laser light show and the specific laser effects to be produced in each laser light show.

The combination of all the information in the above submissions must be adequate for the Bureau to determine what effects are being used in any given show, what relationships exist between the locations of Class III and IV laser radiation levels and the locations of people present at the laser light show, and that the projector and the show comply with the conditions of the applicable variance(s) and the laser standard. If the information submitted is inadequate to permit the Bureau to make such determinations, then the reporting and notification requirements have not been satisfied.

In satisfying the reporting requirements indicated above, it is permissable to:

(1) Use the general reporting guide to provide the report required for all projectors, projection systems, and auxiliary components. In your report you must describe those aspects of the design of your product that satisfy specific requirements of the standard and of your variance.

(a) If you are the manufacturer of the projector and the light show, then the general reporting guide must be used to provide a complete report on the whole projection system. This report must identify the auxiliary components in the projection system and describe any aspects of the design of those components that satisfy a requirement of the variance or the standard.

(b) If the projector or projection system was purchased and is certified by its manufacturer, you may provide the information concerning the projector by reference to the manufacturer's report on the projector or projector system specifying the model number, and model name, and the BRH Accession Number of that report.

(c) If you have modified the projector or added auxillary equipment such as mirrors, mirror balls, remote scanners, screens etc., the modified projection system must be reported using the general reporting guide. As above, the projector manufacturer's report may be referenced for any items of information that were not affected by the modification(s).

(2) Use the Laser Light Show Report Guide (March 1980) to provide the following information:

(a) Fixed effects repertoire, such as for a touring show:
- Set-up procedures.
- Quality control and testing procedures including check lists or test record forms used on-site to assure compliance.
- General description of all planned effects and the means employed to assure their compliance.
- General diagrams of an installation including plan and elevation drawings showing laser beam paths or scanned fields, audience and performer/operator/worker locations, clearance dimensions, etc. in sufficient detail to show the spatial relationship of the audience and of the performers/operator/workers to regions where Class III or IV levels of laser radiation may be present. Sufficient information must be provided to show how your laser light show complies with your variance conditions.

(b) Permanent and semi-permanent shows:
- The written quality control or testing procedures including any check lists and test record forms used for set-up and subsequent performances to assure initial and continued compliance.
- Specific description of the effects in the show and the means employed to assure their compliance.
  Specific diagrams of the installation providing the same type of information listed above for touring shows.

(c) Special Project Shows (such as a one-time engagement):
- Description of all proposed effects and the means for assuring compliance.
- Quality Control and testing procedures to cover all types of installation, e.g., outdoor, indoor, etc., and all proposed effects.
- Although specific, installation diagrams for such individualized shows may not be possible at the time of reporting, provide as much detail as possible to show that you understand how to comply with the conditions of your variance in the location in which you plan to perform the show.

(3) Use the notification letter to provide the following information on a laser light show:

(a) Show schedule including the date(s), time(s), and location(s) (giving the full address) for each show or for a complete tour. Each outdoor show must be clearly identified as such.

(b) By reference to the appropriate laser light show report, indicate the effects planned for the show(s).

(c) Diagrams of the installation providing the information requested above, if such applicable diagrams have not been previously provided in a report. If diagrams have been previously submitted, please specifically reference them.

The Bureau is willing to be flexible regarding which submission, the notification letter or the laser light show report, contains specific information. However, the failure of the total information provided in these submissions to describe the manner of compliance with the conditions of your variance is a violation of P.L. 90-602 and 21 CFR 1002.10 and 1002.12. Repeated failures to report or inadequate reporting will be grounds for revocation of a variance. Also, failure to provide timely notifications of show schedules and effects is a violation of a condition of your variance and may result in an amendment requiring 30 days advance notice for all of your shows or, in the worst cases, revocation of the variance.

CLARIFICATION OF CERTAIN VARIANCE CONDITIONS

1. Audience Scanning & Scanning Safeguards

Any scanning effect which may expose members of the audience to the scanned laser radiation either directly from the projector or indirectly by nearly specular reflection from some auxiliary component of the projection system is considered to be audience scanning. When the scanned laser radiation has peak power levels above 1 mW, there is an acute risk for injury to someone's eyes if the scanning were to stop or slow down to a rate that would produce Class III or IV levels of laser radiation. Thus a requirement for a scanning safeguard is included in every variance that covers any type of scanning effect.

The scanning safeguard condition in the laser light show product variances is very similar to the scanning safeguard requirement specified in the laser product performance standard. However, the variance condition is more explicit in several respects. First, the "accessible emission limit(s) which are applicable to the scanned laser radiation" are specifically indicated, i.e., Class I limits apply to laser radiation in audience areas and Class I or II limits apply for show personnel depending on whether or not the laser light must be viewed by these personnel during the performance of their duties. Second, the requirement that an adequate scanning safeguard must have a short enough reaction time to prevent human exposure to laser radiation in excess of the applicable accessible emission limit(s) is explicitly stated. Because of the high risk of injury to someone's eyes, this latter item is considered to be a critical performance feature for any Class III or IV laser light show which would employ scanning effects directed into the audience. Satisfying this condition has also proven to be a very difficult technical problem.

To understand why this is so, consider an audience scanning situation in which a 1 W beam is scanning at rates sufficient to achieve laser radiation levels below the Class I limits both for single pulses and for average power. If this beam were to stop, the time required for the laser radiation to exceed the Class I limit would be 200 nanoseconds. The reaction time of the entire scanning safeguard system from the detection of scan failure to attenuation of laser radiation below the Class I limits would have to be less than 200 nanoseconds if it were triggered when the scanning stopped. We recognize that this hypothetical situation is an extreme limit and that the effects of inertia and other factors have not been considered. These factors may be taken into account if sufficient information is provided by the manufacturer to show that the total reaction time of the scanning safeguard system is shorter than the minimum time needed for the level of the scanned laser radiation to exceed the applicable emission limits. As of this time, the Bureau has not received data to show that any scanning safeguard system is

adequate for audience scanning, although several manufacturers have discussed various types of high-inertia scanning systems which seem promising.

In light shows that employ the reflection of a scanned laser beam off of a rotating mirror ball, careful analysis of the configuration is needed to determine whether or not a scanning safeguard is required on both the projector and the mirror ball. If either one of the scanning systems could be stopped without exceeding the applicable accessible emission limits, then that scanning system would not be required to have a scanning safeguard. The Bureau's experience with laser light shows indicates that the projectors scanning small diameter beams onto mirror balls generally need a scanning safeguard, while the need for a scanning safeguard on the mirror ball depends on such factors as the beam peak power and the minimum size of the scan pattern at the mirror ball.

2. Beam Stops/Overfilling Mirrors

In laser light shows that contain aerial beam patterns formed by projection to termination points or reflection by one or more fixed mirrors to a termination point, adequate means to terminate or contain any laser radiation must be provided for each remote mirror and the final termination target. Of concern in this requirement is the assurance that laser radiation that misses a mirror due to overfilling the mirror or beam movement will be terminated by some suitable beam stop or beam containment and thus be prevented from projection directly or by reflection into areas that may be occupied. In assessing whether or not the mirror is overfilled it is necessary to consider the low-angle forward-scattered laser radiation which would project into areas that may be occupied and whether or not this radiation would exceed the applicable limits in the occupiable area. If the forward scattered laser radiation were to exceed the applicable limits it would have to be terminated if it misses the mirror.

However, under the following conditions in some laser light shows adequate protection may be provided without the use beam stops:

a. The areas of potential projection are occupied <u>only</u> by employees;

b. The employees are educated by the laser safety officer concerning the hazards; and

c. Control measures (posting warning signs and marking hazard areas) are implemented as discussed in the next section.

The condition specifying the beam stop requirement suggests that the beam stop should subtend an angle of 50 milliradians (3 degrees) from the projector. This is a suggestion. If the beam and any forward scatter can be adequately terminated by a smaller beam stop, that would be acceptable.

In outdoor shows, the size of the beam stop can present considerable wind resistance and may make the mirror unstable if attached to the same mount. Under such conditions, independent mountings for the mirror and the beam stop may be needed.

The other requirement specified in the condition concerning remote mirrors is that the mounting must be secure. This covers two concerns. First, the mounting must be a sturdy design that provides for a very positive locking of the mirror's orientation. Second, there must be adequate protection in the context of the specific show or display to prevent accidental misalignment of the mirrors by someone bumping into them or dropping something on them. In some situations, there may have to be beam containment enclosures or baffles to prevent a beam from a misaligned mirror from entering audience areas. The Bureau's concern for adequate protection from accidental mirror misalignment increases when the beams have a long projection range and the allowable angular deviation is quite small.

3. Set-up Safety Control Measures

The condition requiring the use of minimum possible beam power and the use of control measures in accordance with a recognized safety standard during set-up, alignment, and testing procedures appears to be commonly misunderstood. The use of low beam power for these initial procedures is generally used, but use of the control measures is overlooked in too many cases. The manufacturer is responsible for becoming familiar with the control measures of recognized laser safety standards (such as ANSI Z136.1) and applying them during his set-up, alignment, and testing procedures and during the show also for any areas that may be occupied by anyone other than members of the audience. Such control measures are not difficult but do require some planning to implement. In general all personnel not needed for the alignment should be cleared from the projection area until the initial alignment is done. With planning, a time slot can be agreed to in the contract and a minimal interruption of the other aspects of the production set-up will be achieved. It is considered important that the laser light show manufacturer implement such control measures because failure to do so makes accidental radiation exposures much more likely to occur.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

AUG 25 1980

TO: MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Alternate Wording of Caution Statement in User Information (21 CFR 1040.10(h)(1)(iv))

The warning statement, "Caution - use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure" required by 21 CFR 1040.10(h)(1)(iv) to be provided in the user information with laser products has been found to be inappropriate or misleading for certain products. Such instances occur when there are no controls available to the user or there are no adjustments or procedures which the user could reasonably perform during conditions of operation or maintenance which could result in hazardous radiation exposure. Some Class I laser products that have evidenced this condition are business machines, and sealed consumer products.

The Bureau of Radiological Health will not object to the use of alternative warnings to the statement required by 21 CFR 1040.10(h)(1)(iv) under the following conditions:

1. The required warning statement must be inappropriate in the context of the design or use the product.

2. The alternative warning statement(s) must be more appropriate than the required statement.

3. The alternative warning statement(s) must be related to the laser hazard possible as a result of procedures other than those given in the user instructions, e.g. removal of protective housing, attempting to defeat nondefeatable interlocks, etc.

Under 21 CFR 1040.10(g)(10) as amended the Director, Bureau of Radiological Health may approve on the Director's own initiative or upon written application by the manufacturer alternate means or wording. Manufacturers are requested to apply for approval of alternate labeling in advance of use of alternate labeling. In cases where a manufacturer substitutes approved alternative warnings, it is also requested that the alternative warnings be specifically identified in the initial or model change report on the product.

Sincerely yours,

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

#30

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 13 1991

TO: ALL LASER PRODUCT MANUFACTURERS

SUBJECT: Criteria for Considering an Investigational Medical Laser Device as a Significant Risk Device

Background:

The sponsor of an investigation of any new medical device that exposes human subjects to the risk of serious injury must submit an application to the Food and Drug Administration (FDA) for an investigational device exemption (IDE). If, however, an investigation is considered by the sponsor and by an appropriate institutional review board (IRB) to involve no significant risk, then the sponsor may be considered to have an IDE under the abbreviated requirements of Section 812.2(b). A manufacturer may not deliver a new medical device to an investigator for use on human subjects without an IDE, either formally approved by FDA or deemed granted under the abbreviated requirements. FDA believes that some guidance is appropriate for manufacturers of laser products to enable manufacturers to ascertain the degree of risk and hence the extent of regulatory requirements.

Definitions:

Medical devices are products used in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health. A product becomes a medical device when it is intended for that use. A medical device is considered a new device if substantially equivalent products were not in commercial distribution, prior to May 28, 1976, for the same intended use. New medical devices used in investigations that "present a potential for serious risk to the health, safety, or welfare of a subject" are called "significant risk." Investigations are any clinical trials exposing human subjects to determine the safety or effectiveness of a medical device.

Criteria:

FDA believes that devices used in investigations involving laser products that are Class IV according to the laser standard would present a potential for serious harm and in general must be considered significant risk devices. So also, higher power Class III laser products could be expected to satisfy this criterion, depending on emission level, wavelength, and medical application and may be considered significant risk devices. This does not imply that other laser products are never significant risk devices. After due consideration of the details of the investigation, (e.g., the controls, the patient characteristics, the qualifications of the operator, etc.), an IRB or the FDA may find any investigation to involve significant risk.

Requirement:

Sponsors of investigations using new medical devices that incorporate a Class IV laser product must comply with all of the requirements of 21 CFR 812 applicable to significant risk devices. If a sponsor or manufacturer believes that circumstances indicate that the investigation should not be considered significant risk, the sponsor is urged to write to the Director, Division of Compliance (HFX-400), Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20857, and provide a justification that includes supporting technical data. Sponsors of investigations of new medical devices that use Class III laser products should obtain a determination from the Director, Division of Compliance, whether the FDA considers the investigation to involve significant risk.

Manufacturers, importers and exporters of investigational devices are further advised to consult the regulations of 21 CFR 812, that contain requirements pertaining to the labeling, promotion, and commercialization of such devices.

Sponsors of investigations may contact the IDE Coordinator of the Bureau of Radiological Health (HFX-460), telephone (301) 443-3426, for assistance in developing their IDE submission or in interpreting the IDE regulation.

Sincerely yours,

Walter E. Gundaker
Acting Director
Division of Compliance
Bureau of Radiological Health

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland 20857

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Jerry
Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 19 1994

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF MEDICAL LASER PRODUCTS

SUBJECT: Performance Requirements for Medical Laser Products Incorporating Visible Laser Aiming Beams

BACKGROUND: Some medical laser products incorporate a separate lower power laser to provide a visible beam for aiming the higher power medical/surgical laser beam (usually an invisible laser beam). The aiming beam has no direct diagnostic, surgical or therapeutic purpose. The National Center for Devices and Radiological Health has been asked for relief from the measurement requirement (21 CFR 1040.11(a)(1)) for the aiming beam in cases where the aiming beam may exceed the accessible emission limits of Class II. Since aiming beam lasers generally have low power (5mW or less) and fixed output, the incorporation of a means for measurement of the aiming beam level would serve little or no useful purpose.

DISCUSSION: NCDRH has evaluated this proposal and agrees that measurement of the level of a low-power, fixed output aiming beam would be of little benefit since 1) the output power of the aiming beam can not be varied; 2) if the output changes, it would be expected to decrease rather than increase; and 3) a significant decrease in output power of the aiming beam would be readily seen by the user since visibility would be adversely affected. Therefore, granting the requested relief will not compromise the public health and safety.

POLICY: When a medical laser product incorporates an aiming beam laser, the Food and Drug Administration will not object if the incorporated aiming beam laser does not meet the requirements of 21 CFR 1040.11(a)(1) for a means of measuring the level of the aiming beam, provided that the aiming beam laser:

1. Is Class III b with fixed output power not exceeding 5mW;

2. Emits only visible (400 to 710nm) laser radiation in excess of the limits of Class I;

3. Is used solely for aiming purposes; and

4. Is not employed in ocular procedures.

INVITATION TO COMMENT: The National Center for Devices and Radiological Health intends to propose an amendment to the Federal performance standard for laser products which will clearly permit performance under the conditions specified above. In the meantime, the Food and Drug Administration will not take action under Section 359, 360B, or 360C of the Radiation Control for Health and Safety Act of 1968 if certified laser products deviate from the requirements of 21 CFR 1040.11(a)(1) for aiming beams provided the above conditions are met, since such deviation, while technically noncompliant with the present performance standard, does not compromise the public health and safety. Comments on this policy are invited.

Sincerely yours,

John C. Villforth
Director
National Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 30 1985

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF MEDICAL LASER PRODUCTS

SUBJECT: Delivery System Interlocks for Medical Laser Products

BACKGROUND: Medical laser products deliver laser radiation to patients through a wide variety of means. These include various sizes and lengths of fiber optic cables, bare fibers, and multi-mirrored articulating arms. These may in turn be attached to accessories such as hand pieces, operating microscopes, slitlamps, etc. The bare fibers may also be used by insertion into endoscopes for treatment internal to the body. Many circumstances during a surgical procedure may require that the physician exchange or request exchange of accessories or of the delivery system as a whole. Clearly, any such exchange involves removal of a part of the protective housing, since any accessory is protective housing when in place. A question has been raised concerning the need for a safety interlock to prevent access to radiation when such protective housing (beam delivery accessory) is removed during operation or maintenance.

DISCUSSION: It has been the policy of CDRH to require safety interlocks at the laser console-delivery system connection point, if the delivery system as a whole may be removed during operation or maintenance. An example of such a situation is the fiber delivery system on a surgical Nd:YAG laser for which the fiber may often be exchanged during a procedure. In this case, safety is enhanced by the interlock since the point of laser radiation delivery and the point of disconnection may be physically separate, presenting the possibility of accidental exposure due to communication errors between the surgeon and attendants. However, the presence of safety interlocks for passive accessories attached to the distal end of the delivery system and immediate to the surgeon and the point of delivery would not significantly enhance safety, providing that the surgeon has control of emission by means of a foot switch or other control. There should then be little risk of accidental exposure. In addition, these accessories may be supplied by other than the laser manufacturers so that there is a question of the practicality of universal interlock devices.

POLICY: CDRH will not object to the absence of a safety interlock in a user removable beam delivery accessory attached to the distal end of its delivery system provided the laser product incorporates a means to allow the user to positively control and terminate laser radiation emission from a point in close proximity to such accessory.

INVITATION TO COMMENT: We encourage submission of comments on this policy from manufacturers and users of medical laser products. In the meantime, we also encourage the use of additional safety mechanisms for all laser accessories, including the use of "smart" accessories which can disable the laser if detached or if a new calibration of the delivered output is necessary in order to comply with the requirements of 21 CFR 1040.11(a)(1) and (2).

Sincerely yours,

James S. Benson
Deputy Director
Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 5 1985

TO: All Manufacturers and Potential Manufacturers of Laser Products

SUBJECT: Reproduction of Hazard Warnings in User Instructions

BACKGROUND: 21 CFR 1040.10(h)(1)(iii) requires that the user instructions or operation manual for laser products contain legible reproductions (color optional) and indicate locations of all labels and hazard warnings that are required by 21 CFR 1040.10(g) and 1040.11 to be affixed to the product. Some manufacturers have enclosed their laser product protective housings within additional external "cosmetic" enclosures. Such enclosures are intended to preserve the aesthetic integrity of the products and to discourage users from opening the products. Since protective housing warning labels are covered by the "cosmetic" enclosures and are not visible in operation and maintenance configurations, manufacturers have asked whether operation or maintenance manuals need to contain reproductions of these labels.

POLICY: CDRH will not object to the omission of reproductions of those labels and hazard warnings required by 21 CFR 1040.10(g)(6) or (g)(7) from operation and maintenance information provided such labels are not visible in any operation or maintenance configuration. However, such labels and warnings must be visible during service and must be reproduced in service literature in the manner specified in 21 CFR 1040.10(h)(2)(ii).

INVITATION TO COMMENT: The Center for Devices and Radiological Health intends to propose an amendment to the Federal performance standard for laser products which will clearly permit the conditions specified above. In the meantime, the Food and Drug Administration will not take action under Section 359, 360B, or 360C of the Radiation Control for Health and Safety Act of 1968 if certified laser products deviate from the requirements of 21 CFR 1040.10(h)(1)(iii) for the reproduction and locations of certain labels and hazard warnings required by 21 CFR 1040.10(g) in user instructions, since such deviation, while technically noncompliant with the present performance standard, does not compromise the public health and safety. Comments on this policy are invited.

James S. Benson

James S. Benson
Deputy Director
Center for Devices
and Radiological Health

Laser Notice #35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 23 1985

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Exemption From Reporting Under 21 CFR 1002.10 and 21 CFR 1002.12 For Certain Low Power Laser Products

The majority of laser systems produce collimated beams whose irradiance varies little with distance from the source, so that retinal and skin hazards may be present near to and at considerable distance from the lasers. Reports on such products allow Center staff to evaluate compliance at the time the product is first introduced into commerce, and thus to respond to potential problems in a timely fashion.

Large numbers of laser products employing low power lasers with sharply converging/diverging beams are also introduced into U.S. commerce. Certain products, such as compact disc players, non-impact printers, and fiber optic transmission equipment, generally employ laser diodes which may themselves be Class I laser products when measured according to 21 CFR 1040.10(e). These lasers emit beams which either rapidly diverge or are of such low power that the Class I limits cannot be exceeded, limiting the potential for injury. However, these products are subject to the Radiation Control for Health and Safety Act of 1968 and to the regulations promulgated under the authority of the Act (21 CFR 1002-1010, 1040.10 and 1040.11).

As a step toward the reduction of the regulatory burden on the manufacturers of such products and the reduction of unnecessary use of Center staff time, the Center, under the authority of 21 CFR 1002.50, hereby grants exemption from the reporting requirements of 21 CFR 1002.12 (Model Change Reports) and from supplemental reports pursuant to 21 CFR 1002.10 (Initial Reports) and 1002.12 for those products which meet the conditions described below.

Conditions for use of the Exemption: The Center will not require submission of reports for laser products under 21 CFR 1002.12 or supplements to reports pursuant to 21 CFR 1002.10 and 1002.12 when the following conditions are met:

1. The maximum accessible laser radiation under any condition of operation, maintenance, or service does not exceed the Class I accessible emission limits (21 CFR 1040.10(d)) when determined in accordance with 21 CFR 1040.10(e).

2. Such laser products are tested and certified by the manufacturer to comply with the Federal performance standard, 21 CFR 1040.10 and 1040.11.

3. All other applicable requirements are complied with including the annual reporting requirements (21 CFR 1002.11).

It should be noted that this exemption is not applicable to the requirements of 21 CFR 1002.10 (Initial Reports), 21 CFR 1002.11 (Annual Reports), 21 CFR 1002.20 (Reporting of Accidental Radiation Occurrences), 21 CFR 1002.30 and 1002.31 (Manufacturing Records), 21 CFR 1003 (Notification of Defects or Failure to Comply) and 21 CFR 1004 (Repurchase, Repair or Replacement of Electronics Products).

The Agency reserves the right to request information concerning these products or full reports if it determines this to be necessary in keeping with the intent of the Radiation Control for Health and Safety Act of 1968.

Comments on this notice are invited.

James S. Benson
Deputy Director
Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 21 1985

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Walk-In Workstations

BACKGROUND: The advent of very large materials processing machines that use lasers causes serious concern to manufacturers and the Agency with respect to product classification and protective housing requirements for these products. The protective housing is that portion of the product that prevents human access to laser or collateral radiation and is required wherever and whenever access is not necessary in order for the product to perform its intended function. Those levels of laser radiation to which access is necessary during operation in turn determine the class of the product.

The concept of a protective housing is relatively simple for small, table-top products where the protective housing is clearly recognized. However, the concept of protective housing becomes much more complex in cases where the product is very large. Many products incorporate work stations that enclose large multi-axis positioning tables and parts handling machinery. The enclosures may be large enough for persons to enter and in many instances may be considered as rooms. How can such an enclosure be an adequate protective housing when it is large enough for a person to be inside while the laser might be activated? There is considerable interest on the part of purchasers of such machines and from labor organizations for the products to be classified as Class I laser products. In addition, the standard requires that a laser product be in the lowest class in which the intended function can be accomplished. Although the product may have a safety interlock as required by the standard, the Agency is concerned about the possibility of an operator opening an access door, entering the work station enclosure, and closing the door, thereby gaining access to high laser radiation levels. The questions are: Under what circumstances will the Agency consider such a product to be Class I and the protective housing to be adequate?

POLICY: The Center for Devices and Radiological Health will not object to laser products that include work station enclosures large enough to permit entry to persons being classified as Class I laser products, and will accept the enclosure as meeting the requirement for a protective housing, providing the following conditions are met:

- The enclosure is adequate to satisfy the requirement for a protective housing during operation, i.e., when closed, human access is prevented,

- The enclosure is safety interlocked and labeled as required by the standard,

- A means is provided as part of the overall safety interlock scheme to detect the presence of persons within the enclosure, and/or to prevent operation of the laser when a person is inside the enclosure, and

- The user information clearly instructs operators to avoid procedures that could give access to hazardous levels of laser radiation.

The Center invites comments from the public on this interpretation of the requirements of the standard. Please address any comments to the Director, Office of Compliance, HFZ-300, Center for Devices and Radiological Health, 8757 Georgia Avenue, Silver Spring, Maryland 20910.

James S. Benson

James S. Benson
Deputy Director
Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 22 1987

Rockville MD 20857

To: All Manufacturers and Importers of Laser Products

Subject: Importation of Certain Laser Products for Investigations and Evaluations

Federal regulations require that all imported electronic products for which applicable FDA radiation performance standards exist shall comply with these standards and shall bear certification of such compliance. Before these products can be permitted to enter the U.S., manufacturers and importers are required to submit with each shipment certain required import entry papers through the District Director, U.S. Customs Service to the appropriate FDA district office. Currently, imported laser products manufactured after August 2, 1976, must meet the requirements of the performance standard (21 CFR 1040.10 and 1040.11) or be detained.

Section 360B(b) of the Radiation Control for Health and Safety Act of 1968, provides for possible exemption from certification of electronic products for the purpose of research, investigations, studies, demonstrations, or training. Current FDA policy is that exemptions for such electronic products may be granted for a period of 180 days. During this period of time, the products remain in import detention status and are allowed in the country by means of a written declaration (Form FD 2877 "Affirmation C") filed with the FDA and through a Temporary Import Bond (TIB) filed with Customs. Liquidation of the Customs bond for these products is attained only through their exportation or destruction.

From our review of this process, it is now the opinion of the Center for Devices and Radiological Health that these procedures are unnecessarily restrictive for certain Affirmation C type laser products such as audio or video disc players that do not exceed the limits of Class I during any conditions of operation, maintenance or service. These shipments are usually of small quantity and are tested and evaluated under controlled conditions by technically trained individuals. These products pose no public health hazard as long as they are limited in number and kept out of commercial distribution.

Therefore, under the authority of Section 360B(b) of the Radiation Control for Health and Safety Act of 1968, laser products that do not exceed the limits of Class I during any conditions of operation, maintenance or service, that are imported for the purpose of research, investigations, studies, demonstrations, or training, and that consist of 10 or fewer units per shipment are hereby exempt from the performance standard for laser products. This exemption is granted on the condition that the following requirements are strictly adhered to by the manufacturer/importer:

1. Each laser product and its shipping carton bear a label which states "TESTING/EVALUATION Laser audio/or video disc players - NOT TO BE SOLD IN THE UNITED STATES. THIS PRODUCT HAS NOT BEEN TESTED FOR COMPLIANCE WITH THE U.S. FEDERAL PERFORMANCE STANDARD FOR LASER PRODUCTS."

2. Form FD 701, Importer's Entry Notice is filed with the FDA which describes the laser products as testing/evaluation laser audio video disc players and attests that the products will not be commercially distributed at any time. This form should be submitted before the shipment arrives, if possible. Shipments in excess of 10 units shall be subject to the normal bonding procedures unless a written exemption is obtained from the Director, Center for Devices and Radiological Health.

Movement in commerce of uncertified products imported under this exemption is a violation of Section 360B(a)(1) of the Act and violators shall be subject to civil penalties of $1,000 per violation up to a maximum of $300,000.

Any questions regarding this exemption or any imports procedure should be directed to the imports officer at the FDA District Office nearest you.

Sincerely yours,

John C. Villforth, Director
Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

JUN 24 1987

To: All Manufacturers and Potential Manufacturers of Laser Products

Subject: User Instructions for Industrial Multi-axis Laser Workstations

BACKGROUND:

The multi-axis, robotic medium/high power laser workstations which are not Class I laser products are of concern to the manufacturer, users, laser safety officers, and the Agency with respect to installation of such products and the hazard to personnel during use of these machines.

The capability of such machines to project the working beam in almost any direction is often a design requirement to permit working on parts having complex shapes. This requirement is often accompanied by a requirement for workstations to accommodate all sizes of workpieces which make designing a Class I protective housing for all possible workpieces infeasible. In addition, the mobility of the focusing optic introduces the possibility of the beam being projected or reflected beyond what would be considered a normal working area.

The combination of extreme flexibility of working beam direction and the justifiable absence of a Class I protective housing for the workstation present a significant danger that personnel will be exposed to hazardous levels of direct, reflected, or scattered laser radiation or collateral radiation.

Manufacturers of laser products are required by 21 CFR 1040.10(h)(1) to provide user instructions that include instructions for assembly or installation of the equipment. These instructions must include adequate safety precautions and warnings to avoid exposure of the operator or other persons to levels of radiation greater than Class I. What information, in addition to that which the manufacturer would normally provide, must be included in user instructions for this type laser of product to comply with the laser performance standard?

POLICY:

For the type of laser products of concern here, user instructions [21 CFR 1040.10(h)(1)] must include an identification of the locations at which laser radiation levels that exceed Class I may be present. Specifically, user instructions must include a complete description of the space surrounding the equipment within which the level of direct, reflected, or scattered laser radiation can exceed the Class I limits or the Maximum Permissible Exposure (MPE) of the American National Standard for the Safe Use of Lasers, Z136.1-1986, while the machine is in its normal operational mode.

In situations where the configuration of the machine or the output pattern or level of the laser radiation may be varied, the instructions must include procedures for calculation or measurement of the radiation output. Boundaries must be designated in the user information (manual) or the user information must provide instructions on how to determine such boundaries to assure that the operator and other personnel are not exposed to hazardous levels of laser radiation.

Further, if operational or maintenance personnel are required to be within these boundaries to perform their duties, appropriate control measures must also be specified in the user instructions.

Please note that this guidance is not to be interpreted as a relaxation of the performance requirements of 21 CFR 1040.10(f)(7) Location of Controls. This section requires manufacturers to position their product's operations controls so that exposure in excess of Class I levels is not necessary during operation of these controls. User information or warnings are provided in addition to, not in place of, proper positioning or shielding of controls.

The Center invites comments from the public on this notice. Please address any comments to the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, 8757 Georgia Avenue, Silver Spring, Maryland 20190.

Sincerely yours,

Edwin A. Miller

Edwin A. Miller, Director
Division of Radiological Products
Office of Compliance
Center for Devices
and Radiological Health

American National Standard for the Safe Use of Lasers, Z136.1-1986
American National Standards Institute
1430 Broadway
New York, New York 10018

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 29 1987

TO: TO ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Class II and IIIa laser light show projectors and shows.

BACKGROUND: On August 20, 1985, the Food and Drug Administration (FDA) published amendments to the Federal performance standard for laser products. As a result, Class IIIa laser light show products no longer require a variance from the standard for introduction into commerce. There was no change in the requirements for the manufactufer to certify and report the projection system with its supporting literature and the general show configuration prior to its introduction into commerce.

This has resulted in the increased promotion of Class II and IIIa low/moderate power laser products for producing laser light show effects in establishments or at locations having severely restricted space limitations, which, in some cases, may constitute unsafe installation and use of these products.

The preamble to the final rule published in the Federal Register [50 FR 33687, Aug. 20, 1985, Comment 27] recognizes that this type of demonstration laser product, although of moderate power, still presents a hazard if not installed and used safely. The preamble also advised manufacturers: "... that instructions for assembly, operation, and maintenance need to include warnings to avoid possible exposure to laser and collateral radiation in excess of the limits of Class I. Such warnings should be based on the laser safety concepts contained in laser light show variances issued by FDA."

POLICY: In keeping with this recognition of a hazard and the advice given, the Center for Devices and Radiological Health (CDRH) will object to any intentional exposure of the public to hazardous levels (i.e., greater than Class I levels) of laser or collateral radiation (light) from this type of equipment. Further, the CDRH will object to any instructions or promotion of Class II or IIIa demonstration laser products (projectors, scanners, shows, etc.) that do not adequately warn the user to prevent such exposure.

MANUFACTURER GUIDANCE: The manufacturer, during production and marketing of Class II and IIIa demonstration laser products, must consider the following points. This is necessary to assure that the user is adequately informed of the hazards involved with the use of the product as well as the responsibility of the purchaser/operator to provide a safe environment for their patrons.

1. Class I audience exposure levels.

   Only Class I levels of laser radiation have no known hazard and these are the only exposure levels that are considered safe for direct exposure of people. Exposure of the audience to levels in excess of the Class I limits is not to be promoted or encouraged in any way.

2. Class II warning: CAUTION Laser Radiation (or Light)
Do Not Stare Into Beam

Class IIIa warning: DANGER Laser Radiation (or Light)
Avoid Direct Eye Exposure

These levels are hazardous to the eyes. No direct or reflected beams may be directed into audience areas or used to scan the audience in any way. A projector certified as Class II or IIIa cannot be used for audience scanning unless the projector is equipped with an adequate scanning safeguard which will prevent scanning above the Class I limits and adequate user instructions for achieving the Class I levels are provided (as discussed below.)

3. Installation restrictions/limitations.

Although the purchaser/operator is responsible for providing a safe environment for patrons and for configuring the laser light to avoid public exposure to unsafe levels of laser light, the projector manufacturer is required to provide the purchaser/operator with adequate directions for creating such an installation.

The CDRH is aware that the laser Class II and IIIa emissions are a lesser hazard than the higher levels emitted in shows that require a variance. Nevertheless, the CDRH recommends that the 3 meter (about 10 feet) vertical and 2.5 meter (about 8 feet) lateral clearance distances from audience area floors be used for Class II and IIIa laser light shows. This will provide the same degree of safety that is imposed by the variance requirements for higher power laser light shows. Smaller clearance distances should be used only if there is assurance that people in the audience and general public areas are not exposed to Class II and IIIa levels. It would be prudent to use a minimum beam height of 7 feet if it is not possible to achieve the standard laser light show clearance distances in a particular installation. This clearance gives some assurance that people in the audience will not receive direct eye exposures.

The American National Standard for the Safe Use of Lasers, ANSI Z136.1 - 1986, published by the American National Standards Institute, Inc. should be consulted before undertaking any laser light shows or effects. This is a voluntary safety standard established by representatives of the laser industry for users of all types of lasers. It should be noted that this standard also requires that Class IIIa and Class II projection devices be set up so as not to expose people to the direct beam (or its mirror reflection) unless the beam irradiance has been dropped to (or below) the applicable MPE (Maximum Permissible Exposure). The beam should NOT be directed at the eye, and, in an unsupervised location, steps must be taken to PREVENT access of the public to the direct beam (or its mirror reflections.)

4. Scanning safeguard.

   As noted above, projection systems designed for scanning beams or images into a public area with possible exposure of the audience must have a scanning safeguard. The scanning safeguard must be designed to meet the laser performance standard (21 CFR 1040.10 and 1040.11) and therefore must maintain all beams and effects scanning the audience within Class I at all times or terminate the effect before the Class I limits are exceeded.

5. Measurement parameters.

   When determining the levels of laser radiation to which the audience could be exposed, appropriate measurement parameters must be used. This must include the use of a 50 mm aperture since viewing optics such as cameras, binoculars, and similar devices may easily be used by the audience. Likewise, worst case considerations must be applied in this evaluation, including (but not limited to) such factors as: (1) the worst case scan pattern permitted by a scan safeguard system, (2) the closest point of approach to the projector within the audience area, etc.

6. User information, Owner's Manuals, or Instructions.

   a. The written information provided to the purchaser/owner must be clear enough so that someone not technically oriented and/or not familiar with lasers can learn of the hazards associated with lasers, can install and operate the product (projector and show) correctly, and can produce the intended effects without creating a hazardous environment for the viewer.

   b. The user manual must contain specific warnings that any levels exceeding the Class I limits are considered hazardous to the eye and exposure of the viewer by direct or reflected beams must not be permitted. If Class I levels can be achieved by following the manufacturer's instructions (discussed below) and the projector is equipped with a scanning safeguard that meets the Federal requirements, then, and only then, may intentional exposure of people be used as an effect.

   c. User instructions for projectors equipped with scanners and scanning safeguards must thoroughly explain in simple, nontechnical language the procedures for setting up, adjusting, and operating the equipment in a manner to achieve and maintain the Class I levels in audience areas.

   d. The user instructions must contain a description or graphic representation of typical show installations and effects. This provides the essential elements of the required show report for products intended for sale only. Thus, the laser light show reporting requirement may be considered satisfied in this case.

e. The manufacturer must submit a FINAL (not preliminary) user manual in the required product report. This will allow FDA to evaluate the user instructions to determine whether adequate warnings have been provided. Also, if audience exposure to Class I effects is intended, this manual will be reviewed to ensure that adequate, straightforward instructions have been provided to achieve and maintain the required Class I radiation levels.

7. Advertising and promotion.

A manufacturer is responsible for promotion of the product(s) in accordance with the safety instructions contained in the users' manual. Failure to do this would be considered inadequate user instruction and the manufacturer would be in noncompliance with the laser standard.

8. Misuse or disregarding user instructions.

a. The manufacturer is responsible for providing user information which will instruct the purchaser/operator how to use the product safely.

b. The purchaser/operator is responsible for learning and following the operational procedures for safe use provided in the instructions.

The CDRH invites comments from the public on this notice. Please address any comments to the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, Silver Spring, Maryland 20910.

James S. Benson
Deputy Director
Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

AUG - 9 1988

TO: ALL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Exemption from Certain Reporting and Recordkeeping Requirements for Certain Low Power Laser Products.

BACKGROUND

Every manufacturer of laser products to be introduced into commerce in the United States is required to submit initial and model change reports pursuant to 21 CFR 1002.10 and 1002.12. However, the Center for Devices and Radiological Health (Center) has exempted manufacturers of certain low power laser products from some reporting requirements provided the exempted models meet the criteria stated in its August 23, 1985, notice to laser product manufacturers. The Center has been requested to expand its approval to include exemption from certain recordkeeping requirements.

EXEMPTION

As a step toward further reduction of the regulatory burden on manufacturers of certain laser products meeting the criteria given below, and to reduce the cost associated with administering the regulation, the Center, under authority of 21 CFR 1002.50 hereby grants exemption from the recordkeeping requirements of 21 CFR 1002.30(b), 1002.40 and 1002.41 in addition to the exemption previously granted from the reporting requirements of 21 CFR 1002.12 and from supplemental reports pursuant to 21 CFR 1002.10 and 1002.12 for those products meeting the criteria described below.

CONDITIONS FOR USE OF THE EXEMPTION

The Center will not require the submission of reports for laser products under 21 CFR 1002.12 or supplements to reports pursuant to 21 CFR 1002.10 or 1002.12 or the keeping of record required by 21 CFR 1002.3(b), 1002.40 and 1002.41 when the following conditions are met:

1. The maximum accessible laser radiation emitted by the product under any condition of operation, maintenance, service or failure does not exceed the Class I accessible emission limits given in 21 CFR 1040.10(d) when determined in accordance with 21 CFR 1040.10(e).

2. Such laser products are tested and certified by the manufacturer to comply with the Federal performance standard, 21 CFR 1040.10 and 1040.11.

3. All other applicable requirements are met including the annual reporting requirements of 21 CFR 1002.11.

It should be noted that exemption is not granted from the requirements of 21 CFR 1002.10 (Initial Reports), 21 CFR 1002.11 (Annual Reports), 21 CFR 1002.30(a) and 1002.31 (Manufacturer's Records), 21 CFR 1003 (Notification of Defects or Failure to Comply) and 21 CFR 1004 (Repurchase, Repair or Replacement of Electronic Products).

The Center reserves the right to request information concerning these products or full reports and recordkeeping if it determines this to be necessary in keeping with the intent of the Radiation Control for Health and Safety Act of 1968.

Comments on this notice are invited.

Sincerely yours,

Kshitij Mohan

Kshitij Mohan, Ph.D.
Acting Deputy Director
Center for Devices and
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

DEC 18 1989

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Clarification of Compliance Requirements for Certain Manufacturers Who Incorporate Certified Class I Laser Products into Their Products

BACKGROUND:

Numerous questions have arisen regarding the applicability of 21 CFR 1040.10(i), Modification of a Certified Product, in those situations in which a firm purchases a certified Class I laser product and incorporates it into another product for sale. Examples of this practice include certified Class I optical disc drive units incorporated into computers, compact disc players installed in home entertainment centers, and compact disc players installed in automobiles.

POLICY:

The Center for Devices and Radiological Health (CDRH) will consider firms incorporating certified Class I laser products into another product to be distributors of laser products certified and reported by other manufacturers provided the following conditions are met:

1. No modification of performance or intended use of the certified product is made and incorporation of the certified laser product results only in concealment of the original manufacturer's certification and identification labels required by Part 1010; and

2. The labeling requirements of 21 CFR 1010 and 1040.10(g) for the Class I laser product would be met when the certified product is removed from the product into which it had been incorporated; and

3. The labeling requirements of 21 CFR 1040.10(g) for the Class I laser product would be met in any service configuration of the certified laser product, even when that product could be serviced without removal from the incorporating product; and

4. The laser safety information provided by the certifying manufacturer is distributed with the final product.

Distributors of laser products must only comply with the recordkeeping requirements of Part 1002. Distributors need not submit initial and annual reports described in Part 1002 nor apply new certification and identification labels to the outside of the final product.

Edwin A. Miller

Edwin A. Miller, Director
Division of Standards Enforcement
Office of Compliance and Surveillance
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

JUN - 7 1993

To: Manufacturers and Importers of Laser Products

Subject: Beam Attenuators and Emission Indicators for Class II and IIIa Laser Systems

BACKGROUND: The 1985 amendments to the Federal Performance Standard for Laser Products gave the Director, Office of Compliance and Surveillance, Center for Devices and Radiological Health (CDRH) authority to approve, upon written application by the manufacturer, alternate means to accomplish the radiation protection provided by the beam attenuator (21 CFR 1040.10(f)(6)(ii)). This amendment recognized that for many laser products, a beam attenuator, usually a shutter, provides little if any improved safety, especially for laser systems that have short beam recovery times and can readily be turned off by their operators. Many approvals have been granted since the amendment became effective. When, through its review of product reports or inspectional findings, the CDRH becomes aware of noncompliance with the requirement for a beam attenuator, notification to the manufacturer is required to be given in accordance with 21 CFR 1003.11. In many cases, the notification results in an application from the manufacturer for approval of an alternate means of safety, usually a power switch, and for exemption in accordance with 21 CFR 1003.30 from the notification to affected persons as required by 21 CFR 1003.21. These cases are most common for Class II and Class IIIa visible laser products.

Similarly, the performance standard requires Class II and Class IIIa visible laser systems to incorporate an indicator that provides a visible or audible indication of emission. The standard does not give the director the authority to approve alternate means of providing an indication except through the procedures for variances in 21 CFR 1010.4. Many variances have been requested and granted for battery operated products that emit low powers of visible laser radiation and that incorporate normally off, momentary on switches for emission control. It is understood that a normally off, momentary on switch is on only while physical pressure is applied. The CDRH in granting variances, has accepted the reasoning that an active light or sound indication would only provide indication to the immediate user who certainly should be aware of the tactile indication provided by the physical pressure necessary to activate a momentary power control switch.

In addition, the CDRH has made known that it intends to propose new amendments to the standard under which neither beam attenuators nor emission indicators would be required for visible laser systems that are now classified in Class II or Class IIIa. The administration of these applications has been of considerable burden to the industry and to the Center from which little or no significant protection of the public safety results.

POLICY; The CDRH will not object to:

1. The omission of a beam attenuator on a Class II or Class IIIa laser product that is a visible laser system and that incorporates a specific, suitable means of emission control such as a switch, or

2. The omission of a visible or audible indication of emission from a Class II or Class IIIa laser product that is a visible laser system and that incorporates, as the control for laser emission, a normally off, momentary on switch that provides a clear, tactile indication of emission.

The CDRH intends to incorporate this policy into amendments that it plans to propose. Comments are invited and should be addressed to the Non-Medical Radiological Devices Branch, HFZ-312, Division of Enforcement III, Center for Devices and Radiological Health, 1390 Piccard Drive, Rockville, Maryland 20850

Sincerely yours,

Ronald M. Johnson
Director
Office of Compliance
and Surveillance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 11 1995

To: All Manufacturers and Potential Manufacturers of Medical Laser Products

Subject: User Instructions for Medical Laser Products.

BACKGROUND:

Medical laser systems are very varied in their construction and configuration. Some emit radiation of wavelengths in the ultraviolet, visible and infrared spectral bands and may include delivery optics that may be fixed, articulated or flexible. Emissions may be collimated or have differing degrees of convergence or divergence. Some systems deliver their energy through unsheathed fiber optics that are subject to breakage during use which can result in emission at unintended locations and in unintended directions. Other concerns involve applications with endoscopes, side-firing fibers, and interactions of the laser with substances likely to be encountered in the use environment. These factors make it difficult to determine the precautions that are necessary to avoid possible exposure to hazardous levels of radiation.

The Federal Performance Standard for Laser Products, 21 CFR 1040.10 and 1040.11, requires that user instructions for laser products include "Adequate instructions for assembly, operation and maintenance, including clear warnings concerning precautions to avoid possible exposure to laser and collateral radiation..." [See 21 CFR 1040.10(h)(1)(i)]. The Center for Devices and Radiological Health (CDRH) has received numerous inquiries from manufacturers and users about the practical implementation of this requirement.

The CDRH recognizes that the American National Standards Institute (ANSI) Z136 series are the most widely accepted standards of safety in the use of lasers in the United States. These standards include Z136.1 (1993) - American National Standard for the Safe Use of Lasers, and Z136.3 (1988)[1] - American National Standard for the Safe Use of Lasers in Health Care Facilities. These standards define maximum permissible exposures, give procedures for establishment of hazard zones in the vicinity of laser equipment, provide guidance on protective equipment such as eyewear and establish the responsibilities of laser safety officers.

[1] A revision to this standard may be published in 1995.

INTERPRETATION:

The CDRH interprets the regulation in 21 CFR 1040.10(h)(1)(i) to require that the user information to be supplied with medical laser products is to be in sufficient detail to enable users to readily comply with accepted user safety standards such as the ANSI Z136.1 and Z136.3. This information would include:

- Definition of the emitted radiation propagation pattern(s) and the nominal hazard zone in which the radiation level exceeds the Maximum Permissible Exposure (MPE) level during operation, maintenance and reasonably expected conditions of failure;
- Protective equipment, such as eyewear, by make and model or performance specifications and the location and conditions of recommended use;
- Placement of the laser and delivery system relative to the location of doorways or other access to minimize the risk of accidental exposure; and
- Description of failures that may be reasonably expected to occur, such as optical fiber breakage, that would result in unintended emission and the safety measures to be taken to avoid exposure to hazardous emission in such occurrences.

The CDRH believes that the manufacturers of health care laser systems are the most knowledgeable in the operation and emission characteristics of their products and are best able to provide this information. The CDRH is also concerned that many health care facilities, especially individual practices or free-standing facilities, may lack the capability to establish a laser safety program as comprehensive as might be expected in major hospitals. For this reason, the CDRH is issuing this notice of interpretation to underscore the requirement already contained in the regulation for manufacturers of laser products to furnish adequate instructions for assembly, operation and maintenance including procedures to avoid unnecessary exposure to laser or collateral radiation.

The CDRH welcomes comments on this notice. Please address any comments to Director, Office of Compliance (HFZ-342), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, MD 20850.

Sincerely yours,

for Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 15 1995

To: Manufacturers and Importers of Laser Products

Subject: Labeling of Laser Products

BACKGROUND:
The Federal Performance Standard for Laser Products specifies in 21 CFR 1040.10(g) safety related labels for laser products. Logotype labels are specified for laser products in Classes II, III and IV. The logotypes are based on designs found in the American National Standards Institute (ANSI) Z535 series.

However, laser products intended for export are often required to be labeled in accordance with the standard, Document 825-1 of the International Electrotechnical Commission (IEC 825-1)[1]. This standard requires similar information to be provided but specifies a different configuration of the logotype labels. This requirement for dual labeling presents additional cost and confusion for manufacturers and has prompted several requests for permission to use labels as specified in IEC 825-1. It is further noted that the ANSI standard, Z136.1-1993[2] for the safe use of lasers permits labeling in accordance with IEC 825-1.

However, there are differences between the Federal standard and IEC 825-1 in how measurements of laser power and energy are made for the purposes of classification, in the accessible emission limits of the classes, and in the numerical designations of the classes.

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[1] Safety of Laser Products - Part 1: Equipment classification, requirements and user's guide, International Electrotechnical Commission, International Standard IEC 825-1, 1993. Available from American National Standards Institute (ANSI), 11 West 42nd Street, New York, NY 10036.

[2] American National Standard for the Safe Use of Lasers, ANSI Z136.1-1993. Available from Laser Institute of America, 13434 Research Parkway, Suite 130, Orlando, FL 32826.

POLICY:
The Center for Devices and Radiological Health (CDRH) believes that the different geometries of the ANSI and IEC warning logotype designs have little or no effect on the safety of the product. Therefore, the CDRH will not object to the use of the labeling specified in IEC 825-1 providing that the classification is determined and shown as specified in the CDRH standard, 21 CFR 1040.10(c), (d), (e) and (g). The CDRH will also not object to the classifications being show as determined according to both standards if the standards result in differing classifications. For example, a 4 milliwatt visible laser may be designated as:

Class IIIa laser product (CDRH)
Class 3B laser product (IEC).

The CDRH has announced its intention to consider amendment of its standard to permit this concession in the interests of international harmonization. Comments are welcome and should be addressed to the Nonmedical Radiological Devices Branch (HFZ-342), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Rd., Rockville MD 20850.

Sincerely yours,

Paul L. Leggett, Jr.

for Lillian J. Gill, Director
Office of Compliance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

December 11, 1995

To: All holders of approved variances for laser light shows and displays

Effective immediately, all outdoor laser displays within a radius of 20 miles of any of the operating airports in Clark County, Nevada are required to cease operation until the manufacturers and or operators can demonstrate that they are in compliance with the Recommended Interim Guidelines (RIGS), issued by the Federal Aviation Administration (FAA) and have established a specific quality assurance program to assure such compliance.

This letter amends all FDA approved variances applicable to the production and operation of laser displays that include projection into airspace in Clark County, Nevada. Organizations involved in the assurance of air traffic safety are expressing increased concern about the numbers of instances in which the interiors of aircraft cockpits have been illuminated by laser displays. This concern is exacerbated by those displays that are in the Las Vegas area because of the number of displays operating in close proximity to the McCarran International Airport. However, the safety considerations have much larger implications than the situation that exists in Las Vegas. Impairment of a pilot's or copilot's vision by exposure to the light of a laser display is intolerable. It makes little difference if the impairment is of short duration; all avoidable impairment should and must be prevented. **Although this letter addresses displays in the Las Vegas area, we will not hesitate to extend its coverage to other locales or nationwide if we obtain information supporting the appropriateness of such action.**

The quality assurance programs for the displays must be well documented and at least address such parameters as radiant power and energy, beam divergence, pointing accuracy, and scanning specifications. We will advise the industry if we become aware of any additional elements that are needed. Accurate and timely measurements and recordkeeping are also essential parts of the quality assurance program. Skilled engineers or technicians may be necessary to perform these tasks. Only if and when these conditions are met may resumption of operations be considered. Resumption may not occur until a detailed description demonstrating compliance with the RIGS and the quality control program and its results has been submitted to the FAA regional office and to this office and has been evaluated.

(46)

This Agency has been engaged in meetings with several other Federal and local agencies, the military and industry. These meetings have resulted in the dissemination of interim guidance, Recommended Interim Guidelines (RIGS), issued by the Federal Aviation Administration (FAA) that are to be used in aeronautical studies of laser displays projecting into the airspace. These guidelines are intended to prevent ocular injury and also to prevent temporary visual impairment due to flashblinding or dazzle.

The conditions imposed by this notice are in addition to those already contained in approved variances.

I am sure that you share our concern for the flight safety of the public. We must all do our parts to prevent the occurrence of a tragedy that could cost hundreds of lives. Be advised that the primary responsibility for the safety of a laser display belongs to the manufacturer/operator of the display. It is that party's responsibility to be in control of the quality of the projections and to be sure that the equipment is operated in accordance with its specifications and in compliance with the guidelines for safety.

Please recognize that the interim guidelines of the FAA <u>are interim</u> and are subject to change as their science bases develop or if events occur that indicate that the guidelines are not effective in preventing future incidents involving visual impairment of aviators. We are confident that you will receive this notification in a spirit of cooperation and commitment to the public safety. There have already been too many instances of hazardous illuminations of aircraft by laser displays. Steps must be taken now to assure that they are stopped.

Sincerely yours.

Lillian J. Gill

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 6 1996

TO: All Holders of Approved Variances for Laser Light Shows and Displays.

SUBJECT: Effective Visual Control of Laser Projections.

BACKGROUND:

All variances issued by the Food and Drug Administration (FDA) for laser light shows contain the following condition in Attachment A of the variance:

> "All laser light shows shall be under the direct and personal control of a trained, competent operator(s). The operator(s) shall:
>
> (a) be an employee of the variance holder who shall be responsible for the training and conduct of the operator;
>
> (b) be located where all beam paths can be directly observed at all times; and
>
> (c) immediately terminate the emission of light show radiation in the event of any unsafe condition and, for open air shows, at the request of any air traffic control officials."

The requirements of clauses (b) and (c), that the operator shall be located where all beam paths can be directly observed at all times and that laser emissions can be terminated in the event of any unsafe condition, are basic principles for effective visual control. These general principles have usually been sufficient when applied to laser light shows or displays with limited projection ranges such as indoor displays where the projection paths do not extend beyond the range of effective visual control.

However, in the case of outdoor laser light shows and displays, unterminated projections into airspace may be used. While one may be able to look along the direction of a beam path, the operator can only see objects effectively for a limited distance.

POLICY:

Effective immediately, the requirements in clauses (b) and (c) of the above condition are interpreted more specifically to require that the operator have effective visual control of all the beam paths at all ranges for which the laser emission levels are a hazard for injury to the eye or for major temporary visual impairment such as flashblindness.

The FDA, in consultation with the Federal Aviation Administration (FAA), the industry, and other interested parties has determined that the reasonable range of effectiveness for visual aircraft observers to spot small, minimally lit planes or helicopters in clear air and the conditions typically encountered in outdoor laser light show operations is three miles horizontal range from the laser projector. This is the range of effective visual control for aircraft observers. FDA has further determined that projection of laser emission levels which are capable of producing flash-blindness beyond the range of effective visual control for the means used to detect approaching aircraft is inconsistent with the variance requirements cited above.

The FAA accepts, as a requirement for the Sensitive Flight Zone, a Sensitive Zone Exposure Limit (SZEL) of 100 $\mu W/cm^2$ maximum irradiance (equivalent to 25 $\mu J/cm^2$ maximum radiant exposure in one quarter second or less). This is published in the FAA Order (FAAO) "Procedures for Handling Airspace Matters," 7400.2D Change 1, used in aeronautical studies of proposed entertainment and advertisement outdoor laser operations submitted to the FAA. This limit is intended to protect against flashblindness.

Therefore, laser beams projected into navigable airspace shall not have an irradiance or radiant exposure in excess of the SZEL (100 $\mu W/cm^2$ or 25 $\mu J/cm^2$) at horizontal ranges in excess of the reasonable range of effectiveness for the means used to detect possible aircraft intrusions into the projection space.

We understand that this may limit the beam power and/or require a MINIMUM beam divergence to be implemented.

It should be understood that assuring compliance with the SZEL makes the determination of minimum beam divergence and maximum beam power critical determinations in the assurance that the laser show or display is in compliance with the conditions of the variance. Other parameters such as pointing accuracy, minimum required scanning specifications, and adequate scanning safeguards (when applicable) are also significant for assuring compliance. We will advise the industry if we become aware of any additional elements that are needed. These determinations shall be made using well documented and defensible test procedures. Accurate and timely measurements and recordkeeping are also essential parts of the manufacturer's testing program which is in accordance with good manufacturing practices. Skilled engineers and/or technicians may be necessary to perform these tasks.

Measurements of beam characteristics must clearly identify whether beam diameter and divergence are determined using 1/e- or $1/e^2$-values. Whichever value may be reported, the 1/e-divergence value shall be used to determine that the irradiance limit is not exceeded.

The FDA has been engaged in meetings with other Federal and local agencies, the military, and concerned industries. These meetings have resulted in the dissemination of interim guidance, the Recommended Interim Guidelines (RIGS), which were adopted by the FAA and issued in their Order 7400.2D; Change 1, effective March 11, 1996. These guidelines are intended to prevent ocular injury and also to prevent temporary visual impairment due to flashblinding, dazzle, or glare.

The conditions given by this notice more specifically define requirements that are already implicit in all currently approved variances.

I am sure that you share our concern for the flight safety of the public. We must all do our parts to prevent the occurrence of a tragedy that could cost hundreds of lives. Be advised that the primary responsibility for the safety of a laser display belongs to the manufacturer/operator of the display. It is that party's responsibility to be in control of the quality and safety of the projections and to be sure that the equipment is operated in accordance with the conditions of their variance and in compliance with all applicable guidelines for safety.

Please recognize that the policy guidance in FAAO 7400.2D is subject to change as the science develops or as events require the disemination of new information for the prevention of future incidents involving visual impairment of aviators. We are confident that you will receive this notification in a spirit of cooperation and commitment to public safety.

Lillian J. Gill

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Laser Notice No. 47

DALE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 5 1996

To: All Manufacturers of Laser Products

Subject: Identification Labels for Certain Class I Laser Products

BACKGROUND AND QUESTION

The regulations for electronic products require each electronic product for which a standard has been promulgated to be identified with the name and address of the manufacturer (21 CFR 1010.3). This identification is to be on a tag or label permanently affixed to the product. Identification of the product is required so the product may be traced for recall in the event there is a defect in the product or the product is found to be noncompliant. This requirement is applicable to all laser products certified as complying with the Federal performance standard for laser products, 21 CFR 1040.10 and 1040.11.

A manufacturer of certain types of laser products that are Class I under all circumstances of operation, maintenance, service or failure has requested that its company name not appear on the identification label. The products are certified and may be, for example, compact disc players or CD ROM units that will be integrated into other products such as music systems, automobiles, or computers. The manufacturer (the integrator) of the music system, automobile or computer is intended to be the primary contact for service rather than the manufacturer of the laser product. The laser product manufacturer wishes to hold large quantities of products as ready-to-ship inventory that can be sold to any integrator without having to be relabeled. The regulations already permit, under 21 CFR 1010.3(a)(1), labeling a certified product with a brand name other than that of the manufacturer as long as the Center for Devices and Radiological Health (CDRH) is advised of the true identity of the affected product.

POLICY

The CDRH will not object to the name of the original laser product manufacturer not appearing as part of the identification label when the following criteria are met:

1. The certified product is not modified in any aspect of performance or intended use,

2. The level of laser radiation accessible during any conditions of operation, maintenance, service or single failure does not exceed the accessible emission limits of Class I.

3. The identification label required by 21 CFR 1010.3 contains a code in lieu of the name and address of the manufacturer, such as: FDA/CDRH ID: XXXX. This code will be assigned by the CDRH to the manufacturer of the certified product upon application, as permitted under 21 CFR 1010.3(b).

Comments are invited and should be addressed to the Electronic Products Branch, HFZ 342, Office of Compliance, Division of Enforcement III, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, MD 20850.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 5 1996

TO: All Manufacturers and Importers of Laser Products

SUBJECT: Emitted Laser Beam as Emission Indicator for Class II and Class IIIa Laser Products.

BACKGROUND:

The Federal Performance Standard for Laser Products requires, (21 CFR 1040.10(f)(5)(i)), that Class II and Class IIIa laser systems incorporate an emission indicator that provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I. Paragraph 1040.10(f)(5)(iv) requires that any visible signal used as an emission indicator be clearly visible through protective eyewear designated specifically for the wavelength(s).

It is often necessary for the operator to observe the emitted beams of certain types of visible laser products in order for the products to perform their intended functions, i.e. to observe the path of the beam when the product is used for leveling, pointing or aiming. It is also believed to be very unlikely that laser safety eyewear would be used in conjunction with Class II or Class IIIa laser products.

The Center for Devices and Radiological Health (CDRH) has made known that it intends to propose amendments to the standard under which neither beam attenuators nor emission indicators would be required for laser systems that are now classified in Class II or Class IIIa. This proposal would bring the CDRH standard into agreement with the standards of the International Electrotechnical Commission, IEC 825-1:1994, and the American National Standards Institute, ANSI Z136.1:1993, on this requirement. The administration of these requirements has been a burden to the industry and to the CDRH from which little or no significant protection of the public safety results.

POLICY:

The CDRH will not object to the use of the emitted laser beam as the indication of emission of visible laser radiation from Class II and Class IIIa laser products.

Comments are invited and should be addressed to: Electronic Products Devices Branch, HFZ-342, Division of Enforcement III, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

Sincerely yours,

Lillian Gill

Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

LASER NOTICE NO. 49

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 1997

TO: Manufacturers and Importers of Consumer Electronic Products

SUBJECT: Date of Manufacture Label for Electronic Products Subject to Radiation Standards

ISSUE

The Consumer Electronics Manufacturers Association has requested that the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), exempt manufacturers of electronic products from the required label providing the date of manufacture or to permit date coding.

BACKGROUND

Manufacturers of electronic products are required to comply with radiation performance standards promulgated under Section 534(a)(1) of the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (the Radiation Control for Health and Safety Act of 1968). The regulations, 21 CFR 1010.3, specify that an identification label or tag must be affixed to each product with the date of manufacture.

On March 7, 1996, the Consumer Electronics Manufacturers Association (CEMA), a sector of the Electronic Industries Association, requested a change in the date format specified in the regulations and then subsequently questioned the need for providing a date on the label at all. The original intent of the label was to identify which products are subject to a standard (as opposed to ones manufactured prior to the effective date) and to identify products subject to differing requirements when the performance standards are amended. Since the television and microwave oven standards have not been amended since 1983 and the laser standard is seldom amended in any manner that affects the consumer product industries, CEMA asks that the requirement for the label be exempted until any future amendments to these standards are promulgated. The change is expected to reduce the tracking resources and paperwork burden on industry, with negligible impact on FDA or public health.

GUIDANCE

The CDRH concurs that there is little need for the date of manufacture on the identification label at this time and failing to provide the information does not impact public health. As permitted by Section 539(d) of the Act, the CDRH

will not object to manufacturers omitting the date of manufacture from the identification label required by 21 CFR 1010.3 from consumer (non-medical) electronic products under the following conditions:

1. Each product is marked with a serial number or other identification by which the manufacturer may identify the date of manufacture in case of any regulatory action or investigation.

2. The date of manufacture is included on the label within 30 days after a final rule to amend an applicable standard is published in the Federal Register, if the amendment adds or amends (not reduces or eliminates) any aspect of performance to which that electronic product must comply.

Failure to comply with an applicable standard is a violation of Section 538(a)(1) of the Act. Violations will result in disallowing this guidance by the responsible parties and are subject to civil penalties not to exceed $1000 per violation and $300,000 maximum. Providing false information to the U.S. government is a violation of the U.S. Code, Title 18, and subject to criminal prosecution.

In accordance with FDA's Good Guidance Practices, comments are invited. This guidance document represents the agency's current thinking on date of manufacture labeling on consumer electronic products. It does not create or confer any right for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and/or regulations.

Any comments or questions should be directed to the Electronic Products Branch at the address above, by telephone at 301-594-4654 or by facsimile at 301-594-4672.

Sincerely yours,

Lillian J. Gill

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 1997

TO: Manufacturers and Importers of Consumer Electronic Products

SUBJECT: Importation of Radiation-Emitting Electronic Products for Investigation and Evaluation During Design Development

ISSUE

The Consumer Electronics Manufacturers Association has requested that the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), expand the exemption for consumer products imported for the purpose of test and evaluation during design and production development.

BACKGROUND

Section 536(a) of the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (the Radiation Control for Health and Safety Act of 1968) requires that all imported electronic products, for which applicable radiation performance standards exist, shall comply with the standards and shall bear certification of such compliance. Before the products can be permitted to enter the U.S., importers are required to submit with each shipment certain import entry papers through the District Director, U.S. Customs Service, to the appropriate FDA district office.

Exemption from certification of electronic products for the purpose of research, investigations, studies, demonstrations, or training is permitted by Section 538(b) of the Act. Current policy permits FDA district offices to grant such exemptions for individual entries, usually for 180 days, while the products remain in import detention status. Importers must make a written declaration to FDA (Form FDA 2877, "Affirmation C") and execute a bond with the U.S. Customs Service. Liquidation of the Customs bond is attained only through exportation or destruction of the products.

By letters dated May 17, 1982; August 25, 1983; and May 22, 1987, CDRH exempted up to 10 units of the following products from the applicable performance standard when they are intended for investigations: television products, microwave ovens, and laser products that do not exceed the limits of Class I during any conditions of operation, maintenance, or service (hereafter referred to as inherent Class I laser products). The products are not subject to certification requirements or the Customs bonding process under certain conditions. These products are generally used for acceptance testing (FCC, UL, etc.), establishment of production line procedures, and applications evaluation. While they may be fully operational, they may not be the final design and have not received final acceptance testing.

On March 7, 1996, the Consumer Electronics Manufacturers Association (CEMA), a sector of the Electronic Industries Association, requested a change to the industry-wide investigations and evaluation exemption. CEMA asks that the number of units to which the exemption applies be increased to 50 units for TV products and Class I laser products and to 200 units for CD-ROM and new DVD (digital versatile disc) laser products, to reduce unnecessary costs to manufacturers in both time and money. Increase to 50 units will accommodate the industry need for establishing production processes. Increase to 200 units for CD-ROMs and DVDs will accommodate the need for software evaluation and development. Because there will be no commercial distribution of the products, the change is expected to reduce the tracking and paperwork burden on industry, FDA, and U.S. Customs, without impact on public health.

EXEMPTION

Under the authority of Section 538(b) of the Act, exemption from certification to the applicable radiation performance standards and the execution of a Customs bond is granted for consumer electronic products imported into the U.S. for investigations and evaluation during the design and production development phase with the following conditions:

1. The quantity of products in any single import entry of television products, microwave ovens, and inherent Class I laser products can not exceed 50 units; except other laser products requiring software to operate, such as CD-ROMs and DVDs, are limited to 200 units.

2. Each product and its shipping carton must bear a label stating: "TESTING/EVALUATION ELECTRONIC PRODUCT - NOT TO BE SOLD IN THE UNITED STATES. THIS PRODUCT HAS NOT BEEN TESTED FOR COMPLIANCE WITH THE APPLICABLE U.S. RADIATION PERFORMANCE STANDARD."

3. The importer or consignee must establish written procedures for maintaining control and final disposition of the products.

4. Form FDA 2877 (Declaration For Electronic Products Subject to Radiation Performance Standards), or the equivalent electronic filing, must be submitted to the FDA district office before the shipment arrives. Until the Form 2877 is revised to provide an affirmation for this exemption, mark Affirmation A and write: "These products meet the CDRH Exemption For Product Development and will not be commercially distributed at any time."

5. Shipments in excess of the quantities specified in item 1, or otherwise not meeting the conditions above, shall be placed in import detention status.

Movement of uncertified products in U.S. commerce is a violation of Section 538(a)(1) of the Act. Violations will result in voiding this exemption for the responsible parties and are subject to civil penalties not to exceed $1000 per violation and $300,000 maximum. Providing false information to the U.S. government is a violation of the U.S. Code, Title 18, and subject to criminal prosecution.

This exemption supersedes the previous exemptions dated May 17, 1982; August 25, 1983; and May 22, 1987.

Any questions regarding this exemption or any imports procedure should be directed to the imports officer at the FDA district office nearest the port of entry.

Sincerely yours,

Lillian J. Gill

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health