HHS Publication FDA 86-8260

Compliance Guide for Laser Products

September 1985

(reprinted July 1989)

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

FOREWORD

In October 1982, the Food and Drug Administration established the Center for Devices and Radiological Health (CDRH) by merging the Bureau of Medical Devices and the Bureau of Radiological Health.

The Center develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness and proper labeling of medical devices, to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiation, and to ensure the safe, efficacious use of such radiation.

The Center publishes the results of its work in scientific journals and in its own technical reports. These reports provide a mechanism for disseminating results of CDRH and contractor projects. They are sold by the Government Printing Office and/or the National Technical Information Service.

Also, CDRH technical reports in radiological health are made available to the World Health Organization (WHO) under a memorandum of agreement between WHO and the Department of Health and Human Services. Three WHO Collaborating Centers, established under the Bureau of Radiological Health, continue to function under CDRH:

WHO Collaborating Center for Standardization of Protection Against Nonionizing Radiations;

WHO Collaborating Center for Training and General Tasks in Radiation Medicine; and

WHO Collaborating Center for Nuclear Medicine.

We welcome your comments and requests for further information.

John C. Villforth
Director
Center for Devices and
Radiological Health

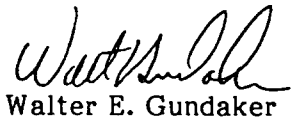
PREFACE

Manufacturers of products subject to performance standards under the Radiation Control for Health and Safety Act of 1968 are required to furnish various reports to the Center for Devices and Radiological Health. This guide is for use by manufacturers of lasers and products containing lasers in preparing Initial and Model Change Reports as required by paragraphs 1002.10 and 1002.12 of Title 21 CFR (Code of Federal Regulations).

This compliance guide contains much of the instructional material from, and is intended to be used in conjunction with, a companion publication, "Guide for Preparing Initial and Model Change Reports on Lasers and Products Containing Lasers." In addition, this publication incorporates changes from the 1985 amendments to the standard. You should read and understand this guide and determine how your product complies with the regulations before completing an initial, model change, or annual report. If you have specific questions, write to:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF COMPLIANCE
ELECTRONIC PRODUCTS BRANCH (HFZ-342)
2098 GAITHER ROAD
ROCKVILLE MD 20850

or call (301) 594-4654.



Walter E. Gundaker
Director
Office of Compliance

CONTENTS

COMPLIANCE GUIDE FOR LASER PRODUCTS

INTRODUCTION

This guide briefly summarizes the requirements of the regulations under the Radiation Control for Health and Safety Act of 1968 that apply to manufacturers of laser products. It explains the regulations in simple, direct language. It does not replace the regulations, however, and if there is any conflict between the guide and the regulations, the regulations must prevail. Throughout this guide, pertinent sections of Title 21, Code of Federal Regulations, Chapter I, Subchapter J, are cited in parentheses. *Please consult them before making design or procedural decisions.*

Specific questions may be directed to the Light Products Branch (HFZ-312), Office of Compliance and Surveillance, Center for Devices and Radiological Health, Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, (301) 427-1172.

The following definitions are basic to the regulations:

A *laser* is a device capable of producing or amplifying electromagnetic radiation in the wavelength range from 180 to 1 x 10^6* nanometers by the process of controlled stimulated emission (1040.10(b)(19)).

A *laser system* consists of a laser in conjunction with its power supply (1040.10(b)(23)).

A *laser product* is any device that constitutes, incorporates, or is intended to incorporate a laser or laser system (1040.10(b)(21)).

A *manufacturer* is any person or organization in the business of making, assembling, or importing laser products (1000.3(f)).

As explained in this guide, manufacturers of laser products must:

- design and manufacture their products to be in compliance with the standard;
- test their products to assure compliance;
- certify compliance of their products;
- maintain test and distribution records and a file of correspondence concerning radiation safety, safety complaints, and inquiries;
- use the published reporting guides to submit reports to CDRH, including Initial and Model Change Reports describing compliance of the product design and testing program and Annual Reports summarizing required records;

---

* This definition was effective August 20, 1986. The range was 250 to 13,000 nanometers before that date.

- report accidental radiation occurrences (i.e., possible, suspected, and known exposures);
- report any radiation defects or noncompliances; and
- recall (i.e., repair, replace, or refund the purchase price of) defective or noncompliant products.

DESIGN AND MANUFACTURE OF THE LASER PRODUCT TO COMPLY WITH THE STANDARD

The laser standard applies to all laser products manufactured on or after August 2, 1976 (1040.10(a)), unless the products are either: sold to a manufacturer for use as components (or replacements) in products that will be certified (1040.10(a)(1)); sold by or for a manufacturer as repair or replacement components if they are properly labeled as such and have installation instructions (1040.10)(a)(2)); or intended for export only, are labeled as such, and comply with the requirements of the importing country (1010.20). Manufacturers of laser products that are sold to other manufacturers for use as components in their products are required to register and list such products.*

In designing laser products, manufacturers must first determine the level of laser radiation to which human access is necessary during operation (1040.10(b)(27)) in order for the product to perform its intended function. This level should be determined in terms of the nature of the product, as well as significant economic and design factors. A laser radiation field is within human access (1040.10(b)(15)) if it can be intercepted by any part of the body, or if the levels are in Class IIIb or IV and can be reflected by a single flat surface through any opening or hole in the product. Laser radiation to which human access is not necessary must be eliminated or contained within a protective housing (1040.10(f)(1)).

Manufacturers must then determine the Class of their products (1040.10(c)) according to the highest level of laser radiation accessible during operation. The Class of the product determines the requirements for controls, indicators, and warnings on the product and warnings in its literature. The wording of any required warning is based on the injury-causing potential of accessible laser radiation. The standard also contains additional requirements for specific-purpose laser products. Appendix A is a table summarizing the requirements of the standard.

CLASSIFICATION OF LASER PRODUCTS

Laser products are classified on the basis of the highest level of laser radiation to which human access (1040.10(b)15)) is possible *during operation only*. Other laser radiation fields to which human access is necessary *only during maintenance or service* do not affect the classification but may affect the labeling and safety interlock requirements. Use-factor data, if available and adequately convincing, may be used in determining the level of laser emissions from a product.

---

*Effective August 20, 1986

The standard establishes the following limits for the Classes:

Class I limits (1040.10(b)(5) and 1040.10(d)(Table I)) apply to devices that have emissions in the ultraviolet, visible, and infrared spectra, and are limits below which biological hazards have not been established. In the visible and near infra-red spectra there are separate Class I limits for radiant energy (power) and integrated radiance (radiance); both limits must be exceeded for the device to moved from Class I.

Class IIa limits (1040.10(b)(6) and 1040.10(d)(Table II-A)) apply to products whose visible emission does not exceed Class I limits for emission durations of 1000 seconds or less and are not intended for viewing. Class IIa limits therefore may not exceed the Class II limits. An example of a Class IIa laser product might be a supermarket scanner.

Class II limits (1040.10(b)(7) and 1040.10(d)(Table II)) apply to products that have emissions in the visible spectrum (400 to 710 nm) for emission durations in excess of 0.25 second, providing that emissions for other durations and/or wavelengths do not exceed the Class I limits. Class II products are considered a hazard for direct long-term ocular exposure.

Class IIIa limits (1040.10(b)(8) and 1040.10(d)(Table III-A)) apply to products that have emissions in the visible spectrum and that have beams where the total collectable radiant power does not exceed 5 milliwatts. Class IIIa products include most helium-neon lasers.

Class IIIb limits (1040.10(b)(9) and 1040.10(d)(Table III-B)) apply to devices that emit in the ultraviolet, visible, and infrared spectra. Class IIIb products include laser systems ranging from 5 to 500 milliwatts in the visible spectrum. Class IIIb emission levels are ocular hazards for direct exposure throughout the range of the Class, and skin hazards at the higher levels of the Class.

Class IV levels (1040.10(b)(11)) exceed the limits of Class IIIb and are a hazard for scattered (diffuse) reflection as well as for direct exposure.

The Class limit expressions are given in Tables I, II-A, II, III-A, and III-B and are functions of wavelength and emission duration. Included in the expressions of the limits are two factors, k_1 and k_2, dependent on wavelength and emission duration. The values of k_1 and k_2 are in Tables IV and V. The expressions also indicate the units of the limit:

J, the unit for radiant energy (joules);
J cm^{-2} sr^{-1}, the unit for integrated radiance; and
J cm^{-2}, the unit for radiant exposure.

Specific conditions are given for the determination or measurement of these parameters (1040.10(e)):

Radiant energy (J) or radiant power (W) is the energy or power detected through a 7 mm diameter circular aperture with a solid angle of acceptance* of 10^{-3} steradian with collimating optics of 5 diopters or less (1040.10(e)(3)(i)) for laser products intended to be used where viewing with optical instruments is unlikely. Otherwise a 50 mm aperture stop must be used.

---

* Solid angle of acceptance refers to that solid angle subtended by the source at the point of measurement. The solid angle of acceptance is therefore independent of detector aperture. A 7 mm diameter source subtends 10^{-3} sr at 20 cm, and a 0.7 mm source subtends 10^{-5}, sr at 20 cm.

Integrated radiance ($J\ cm^{-2}\ sr^{-1}$) *or radiance* ($W\ cm^{-2}\ sr^{-1}$) is the energy or power detected through a 7 mm diameter circular aperture with a solid angle of acceptance* of 10^{-5} steradian with collimating optics of 5 diopters or less, divided by that solid angle and by 0.385 cm^2, the area of the aperture (1040.10(e)(3)(iii)).

Radiant exposure ($J\ cm^{-2}$) is the energy detected through a 7 mm diameter circular aperture, divided by 0.385 cm^2, the area of the aperture (1040.10(e)(3)(ii)).

Irradiance ($W\ cm^{-2}$) is the power detected through a 7 mm diameter circular aperture with a solid angle of acceptance* of 10^{-3} steradian with collimating optics of 5 diopters or less, divided by 0.385 cm^2 (1040.10(e)(3)(ii)).

If the limit of a Class is exceeded at any emission duration, the product cannot be in that Class; all possible emission durations must be considered, ranging from single nanosecond pulses (1×10^{-9} sec) to the very long term average (greater than 10^4 seconds).

Measurements to determine classification must be made with the measuring instrument positioned for maximum detection and with all controls on the laser product adjusted to achieve maximum emission (1040.10(e)(2)). If calculations are used instead of measurements, all values must be justified and must represent a worst-case analysis.

The measurement parameters for radiant energy, power, and irradiance also state that collimating optics must be used, if appropriate, in order to account for diverging laser sources. The collimating optics must have an optical power of 5 diopters or less (20-cm or longer focal length), as necessary to maximize detection. Naturally collimated or expanded laser beams that have low divergence and maximum detectability without collimating optics must be measured so that all the energy collectable within the specified aperture stop is considered. Multiple beams or diffuse sources that lie within a solid angle of acceptance of 10^{-3} sr must be included in the measurement.

If the laser radiation is scanned, measurements of radiant energy and power are made with a 7 mm diameter** circular aperture having a solid angle of acceptance of 10^{-3} steradian with collimating optics of 5 diopters or less (1040.10(e)(3)). If the angular rate of scanning is less than 5 radians/sec, the direction of the solid angle of acceptance must also track the scan.

Note that products are classified according to the maximum level of laser radiation within human access *during operation only*. Levels accessible *only during maintenance or service* do not affect the classification. Hence, it is possible for Class I products to contain Class IV lasers.

---

* Solid angle of acceptance refers to that solid angle subtended by the source at the point of measurement. The solid angle of acceptance is therefore independent of detector aperture. A 7 mm diameter source subtends 10^{-3} sr at 20 cm, and a 0.7 mm source subtends 10^{-5} sr at 20 cm.

** After August 20, 1986 a 50 mm diameter circular aperture must be substituted for the 7 mm aperture in situations such as a laser light show where viewing with optical instruments is likely.

It is the responsibility of the manufacturer to determine whether specific functions are operation, maintenance, or service. In general, the following definitions apply.

Operation (1040.10(b)(27)) consists of functions by which the product accomplishes its intended purpose; these may include loading work-pieces or documents and setting and manipulating external controls.

Maintenance (1040.10(b)(24)) consists of functions performed by the user to assure performance; these may include cleaning and replenishment of expendables.

Service (1040.10(b)(38)) usually means repair. It may be performed by specially trained service personnel or by sophisticated users following instructions specifically indicated as service instructions. Certain maintenance procedures will be considered service if they are infrequent, complex, or highly specialized.

Collateral radiation (1040.10(b)(12)) is generally any optical, electromagnetic, or x radiation that is either necessary for, or occurs as a result of, the operation of a laser. Collateral radiation includes x radiation produced by a high voltage power supply, plasma glow in a discharge tube, excitation lamp light or reradiation from a workpiece. Limits for collateral optical radiation are the same as the Class I limits for laser radiation for 1000 seconds or less; limits for collateral x radiation are 0.5 milliroentgen in an hour averaged over an area of 10 cm^2 parallel to the product surface with no dimension greater than 5 cm (1040.10(d)(Table VI)).

If a laser product produces emissions of *multiple wavelengths* (1040.10(d)(1),(2),(3)), the levels of the emissions must be added if their wavelengths are within any individual wavelength range indicated in Table I, II-A, II, III-A, or III-B; the emission levels may be considered separately if they lie in different wavelength ranges.

REQUIREMENTS FOR LASER PRODUCTS

PERFORMANCE

The standard specifies performance requirements according to the Class of the laser product and the accessible laser radiation. Note that, where the standard requires a particular performance feature, the feature must be readily identifiable as such on the product. Failure to properly identify required features may lead to difficulties in determining product compliance. The applicability of many requirements depends on whether the product is a laser or a laser system (1040.10(b)(19),(23)).

A *protective housing* (1040.10(f)(1)) is required for all laser products. The protective housing must prevent human access to laser radiation in excess of the limits of Class I (and collateral radiation in excess of the collateral radiation limits) at all places and times where and when such human access is not necessary in order for the product to accomplish its intended function. In essence, this requirement means that the product must be of the lowest possible Class. The manufacturer must be prepared to justify the necessity of human access to laser radiation greater than Class I limits. If the purpose of the laser system is to generate a laser beam, the justification is self-evident. In other cases, a detailed analysis may be required. Generally, a protective housing must be contiguous. The most common difficulties with protective housings have been human access to laser radiation through cooling vents or through a poor fit between sections of

a protective housing. A protective housing must be sturdy enough to prevent access caused by bending or warping as the product ages.

Safety interlocks (1040.10(f)(2)) may be required on any laser product. They must prevent human access to laser or collateral radiation that exceeds the limits of Class I and Table VI when a protective housing is opened during operation or maintenance, and human access to the interior radiation is not always necessary during such operation or maintenance. (Note that if the housing must be opened during *operation* and it is necessary to have access to the interior radiation, the level of the interior radiation must be considered when classifying the product, i.e., the classification is determined by the interior level, if it is higher than the exterior level. If the intermittent access to laser radiation occurs only during a *maintenance* procedure, it does not affect the Class of the product.) If access to the interior radiation is sometimes needed, the interlock may be defeatable and the housing must be so labeled. Safety interlocks need not prevent access to interior radiation otherwise accessible only during service.

Safety interlocks to protect from Class IIIb or IV levels must also be redundant or fail-safe; if fail-safe, they must either prevent opening the housing in case they fail or they must be incapable of failing in a mode that would permit access. Defeatable safety interlocks must provide a visible or audible indication of defeat; further, it must not be possible to close the housing with the interlock remaining defeated. A redundant or fail-safe safety interlock is also required if failure of a single interlock would allow access to laser radiation in excess of the accessible emission limits of Class II to be emitted directly through the opening created by removal or displacement of the interlocked portion of the protective housing.

Snap-action spring switches are subject to short-circuit failure; they cannot serve as fail-safe safety interlocks. However, such a switch could be used in series with a second such switch or with a solenoid-operated door latch if the access door would remain latched in the event of switch failure. CDRH has not objected to the use of switching elements consisting of shorting bars or plugs and sockets that operate by physical removal of a part of the electrical circuit when the housing is opened. CDRH has also not objected to the use of cam- or wedge-driven switches in conjunction with a mechanical latch or key.

A *remote interlock connector* (1040.10(f)(3)) is required on all Class IIIb and IV laser systems. The purpose of the remote interlock connector is to permit the user to connect a remote barrier interlock, emergency stop switch, or similar device. The circuit must be such that, when the terminals of the connector are open, human access to laser radiation is prevented. The electrical potential across the connector terminals must not be greater than 130 volts rms. A shorted mating connector may be provided by the manufacturer to allow the product to be operated when the remote interlock connector is not being used.

A *key control* (1040.10(f)(4)) is required for Class IIIb and IV laser systems in order for the user to prevent unauthorized operation. The key must not be removable in the "on" position.

An *emission indicator* (1040.10(f)(5)) is required on Class II, IIIa, IIIb, and IV laser systems. The indicator can be visible or audible. On Class IIIb and IV laser systems the indication must precede emission by a length of time sufficient to allow users and others in the area to recognize that the product has been energized so they can avoid exposure. Depending on the action required and the level of laser radiation involved, the time needed can vary considerably; typical values are in the range of 2 to 20 seconds.

Emission indicators must be duplicated on lasers (heads) and operation controls if they are capable of being separated by greater than 2 meters.

A *beam attenuator* (1040.10(f)(6)) is required on Class II, IIIa, IIIb, and IV laser systems. The beam attenuator is a mechanical or electrical device such as a shutter or attenuator that blocks emission. The beam attenuator blocks bodily access to laser radiation above Class I limits without the need to turn off the laser. The beam attenuator must be available for use at all times during operation. Power switches and key controls do not satisfy the beam attenuator requirement. Manufacturers may apply for approval of alternate means of providing this protection if a beam attenuator is inappropriate to the product.

Operating controls (1040.10(f)(7)) on a Class II, IIIa, IIIb or IV laser product must be located such that it is not necessary for the user to be exposed while manipulating them.

Viewing optics, viewports, or display screens (1040.10(f)(8)) may not provide human access to laser or collateral radiation in excess of the limits of Class I and Table VI during operation or maintenance. If the viewing optics employ a shutter or variable attenuator, the shutter or attenuator must be fail-safe; that is, it must be designed such that, upon failure, it is impossible to open the shutter or vary the attenuation. Viewing optics include such devices as viewports, windows, microscopes on welding and drilling devices, and operating microscopes on surgical lasers. Attenuation may be total, or it may be partial as with a filter. Acceptable designs may prevent laser operation until the attenuator has moved into position. Service instructions must include instructions on procedures to avoid hazardous exposure through viewing optics.

A *scanning safeguard* (1040.10(f)(9)) must prevent emission in excess of the limits of the class of the product. For Class IIIb or IV laser products that operate in both scanned and unscanned modes, the scanning safeguard also must prevent emission in excess of the limits of the class of the scanned laser radiation (and whose failure would result in emissions exceeding Class IIIa). Scanned laser radiation is laser radiation that is moved in translation or by changing direction. A scan failure safeguard must have a reaction time short enough to operate before levels of a higher Class are emitted; it is possible to achieve this performance by means of a high inertia scanner in conjunction with an electromechanical shutter.

A *manual reset* (1040.10(f)(10)) is required on Class IV laser systems manufactured after August 20, 1986. It must prevent automatic restart after an interruption due to remote interlock activation or from an interruption for more than 5 seconds due to unexpected loss of main electrical power.

LABELING

A *warning logotype* (1040.10(g)(1),(2),(3)) is required on Class II, IIIa, IIIb, and IV laser products. The regulations specify the warning statement and design, by product Class, for visible radiation. If there is emission in the ultraviolet or infrared spectrum there must be a warning for invisible radiation as well (1040.10(g)(8)). The CAUTION warning logotype is for Class II laser products and for IIIa laser products that have an irradiance not exceeding $2.5 \times 10^{-3} W\ cm^{-2}$. The DANGER warning is for Class IIIa laser products that have an irradiance exceeding $2.5 \times 10^{-3} W\ cm^{-2}$, and for Class IIIb and IV laser products.

A specific warning statement without logotype is required on Class IIa products (1040.10(g)(1)(i)).

The warning logotype must also contain (1040.10(g)(4)) a statement of the maximum output, pulse duration (if pulsed), and the laser medium or emitted wavelength(s).

Removable or displaceable protective housings (1040.10(g)(6),(7)) that are not safety-interlocked or that have defeatable safety interlocks also require warning labels. The severity of the warning depends on the type and level of the interior laser radiation. Wording is specified; invisible, electromagnetic, and x radiation must also be indicated if present. Labeling must also be visible on the product prior to and during removal or displacement of the housing and close to the opening involved.

An *aperture warning label* is required for each aperture through which laser radiation in excess of Class I or IIa or collateral radiation in excess of Table VI is emitted during operation (1040.10(g)(5)). Wording is specified; invisible, electromagnetic, and x radiation must also be indicated if present.

A *certification label* is required (1010.2) and must state that the manufacturer certifies that the product complies with the standard or with an approved variance. The certification statement must appear on a label on the product and make specific reference to the regulations with which the product complies. Minimum suitable statements would include:

"Complies with 21 CFR Chapter 1, Subchapter J." or
"Complies with 21 CFR 1040.10 and 1040.11."

An *identification label* must be provided and must contain the name and address of the manufacturer and the place, month, and year of manufacture; the month and year of manufacture *may not be abbreviated* (1010.3). Alternate brand names, other company names, or a coded place of manufacture may be used if an explanation is provided to CDRH.

All required labels must be permanently affixed, and must be readable without requiring exposure to levels exceeding Class I.

INFORMATION

Informational requirements apply to user information for operation and maintenance, to purchasing information such as brochures and specification sheets, and to servicing information.

User information must contain (1040.10(h)(1)):

- instructions for operation and maintenance, with appropriate warnings to avoid exposure;
- radiation specifications;
- reproductions and locations of labels that are required by the standard and that are accessible during operation and maintenance;

- a listing of all controls and adjustments; and
- a caution statement, as specified in the regulations, concerning possible hazardous exposure if instructions are not followed.

Brochures and specification sheets must include a reproduction (color optional) of a complete warning logotype or Class IIa warning statement as required on the product (1040.10(h)(2)(i)).

Servicing information must contain (1040.10(h)(2)(ii)):

- procedures for service with appropriate warnings to avoid exposure;
- a schedule of maintenance to maintain the product in compliance;
- a listing of controls that could increase the level of accessible radiation;
- identification of removable portions of protective housings;
- procedures to avoid exposure; and
- reproductions of required labels (color optional) and warnings.

At the discretion of the manufacturer, user and service information may or may not appear in the same manual. Service procedures, however, must be clearly identified as such. In many cases, the classification of a given procedure as maintenance or service determines whether a safety interlock is required.

SPECIFIC-PURPOSE PRODUCTS

Medical laser products are laser products that are medical devices manufactured, designed, intended, or promoted for in vivo irradiation of the human body for diagnosis, surgery, therapy, or determining relative position of the human body. Class IIIa, IIIb, and IV medical laser products must contain a means for measuring the delivered exposure or treatment level of radiation, accurate within ±20 percent. This requirement is not applicable to Class IIIa aiming devices except ophthalmic application. The instruction manual must include a procedure and schedule for recalibration of the measurement system. A modified aperture label is also specified (1040.11(a)).

Surveying, leveling, and alignment laser products are generally used in agriculture and in the construction industry. They are restricted to 5 mW visible radiant power and to Class I for other wavelengths and pulses less than 3.8×10^{-4} seconds (1040.11(b)).

Demonstration laser products (1040.10(b)(13)) include:

- laser products promoted for classroom demonstration of optical phenomena;
- artistic displays and their associated apparatus;
- laser light show projectors; and
- laser light shows and displays themselves.

A general-purpose, scientific, medical or industrial laser product is not considered to be a demonstration laser product when it is demonstrated to a prospective purchaser.

Demonstration laser products are restricted in their outputs to Class IIIa with its accompanying restrictions to Class I for short pulses and invisible wavelengths (1040.11(c)). Because these levels are too low for effective use in commercial theatrical lighting effects, CDRH may grant variances (1010.4) to manufacturers of laser light shows and display devices. As a condition of the variance, the manufacturer must agree to adhere to several safety conditions to provide a level of safety to the public equivalent to a fully compliant product. Consult Appendix B, Clarification of Certain Laser Light Show Requirements, for more information.

RECORDKEEPING, REPORTING, AND NOTIFICATION

RECORDKEEPING

The certification of compliance that the manufacturer places on the product must be based upon a testing program that is adequate to ensure the claimed compliance (1010.2(c)). An adequate testing program will consist of procedures for testing or inspecting the product to assure that all required performance features are present and functioning properly, that all required labels are present and in their proper locations, and that the user and service instructions and promotional brochures or catalogs contain the required safety information. The program will further specify the testing records that are to be maintained. Recognized sampling plans may be appropriate for laser products that are in high volume production; sampling, however, is not without some risk of noncompliance for which the manufacturer would be liable. If CDRH believes a manufacturer is not operating in a state of control so as to assure product compliance, the testing program may be disapproved, making further introduction of the product into commerce illegal until such time as the testing program is re-evaluated and approved.

Manufacturers are required to maintain records (1002.30) that include:

- a written description of the quality control procedures;
- results of tests or checks for compliance with the standard;
- results of life testing to substantiate that the product will not emit increased levels of radiation with age as a result of deterioration and that the product can be expected to remain in compliance when maintained in accordance with the procedures given in the user and servicing information;
- copies of written communications between the manufacturer and dealers, distributors, and purchasers concerning radiation safety, including complaints and instructions; and
- distribution of the products, to permit tracing in the event of recall.*

Manufacturers must preserve the required records for a period of 5 years; must, upon reasonable notice, permit FDA to inspect the records; and must submit copies of records to CDRH upon request (1002.31).

---

* Effective August 20, 1986, distribution records must be maintained for non-certified laser products sold as components to original equipment manufacturers (OEMs).

Dealers and distributors must also maintain distribution records to permit tracing in the event of recall (1002.40). Distributors may furnish the distribution records to the manufacturer or retain the records themselves. Distributors who elect to maintain the records must:

- notify the manufacturer, in writing, of their intention to maintain the records;
- maintain the records for a period of 5 years or, if they cease distribution, furnish the required information to the manufacturer; and
- provide the information to the manufacturer when advised by the manufacturer or by CDRH that the information is required for a product recall.

REPORTING AND NOTIFICATION

Manufacturers are required to furnish reports to CDRH to substantiate compliance with the standard, to describe the testing program, and to provide other information. Initial and Model Change Reports (1002.10 and 1002.12) are used to describe the:

- reported product and labeling;
- manner in which the product complies with the standard;
- testing program to assure compliance;
- life testing; and
- test equipment used.

The Initial Report is the first report submitted by a manufacturer. Subsequent reports on new or different models are called Model Change Reports. Changes in a reported model should generally be reported in a supplement to the Initial or Model Change Report on that model. Manufacturers are required to submit the Initial or Model Change Report prior to introduction of the reported product into commerce. CDRH considers delivery of a product to a prospective purchaser or for exhibition at a trade show to be introduction into commerce. CDRH has issued a "Guide for Preparing Initial and Model Change Reports on Lasers and Products Containing Lasers." The Guide must be used and the report format must follow that of the Guide (1002.7(b)).

An individual or firm that makes only one unit of a product on an occasional basis is considered to be a manufacturer and must certify and report such units. As a result, the report may in some cases be briefer, especially in the area of quality control procedures. Nevertheless, the report must clearly describe the product and how it complies. The manufacturer of such products is encouraged to point out that the report is for a product manufactured on a one-time, one-unit basis.

Annual Reports (1002.11) summarize the records the manufacturer is required to maintain (1002.30). Annual Reports must be submitted by September 1 of each year for the year ending the preceding June 30. Each year, CDRH provides guidelines for submission of Annual Reports that must be followed (1002.7(b)).

Accidental radiation occurrences must be reported to CDRH by manufacturers (1002.20), regardless of whether injury occurred. The report must include identification of the product involved, the circumstances and details of the incident, and actions taken to prevent recurrence.

Radiation defects or failure to comply with the standard must be reported to CDRH (1003.10). Notification must also be provided to distributors and purchasers.

PRODUCT RECALLS

Manufacturers may be required to recall a laser product (1003), i.e., repair or replace it or refund its purchase price, if the product fails to comply with the standard or has a radiation defect (1003.2).

Notification to CDRH is required if the manufacturer becomes aware that a product is defective or fails to comply (1003.10). Notification must be sent immediately to CDRH and with reasonable promptness to distributors and purchasers.

Notification to the manufacturer will be made if CDRH becomes aware (through product inspection or report review) of a defect or failure to comply (1003.11). The manufacturer will be advised of these findings and will be given a reasonable time to refute the claimed defect or noncompliance.

Notification to distributors and purchasers is required (1003.21) if the manufacturer does not successfully refute the alleged defect or noncompliance or is not granted an exemption from the requirements for notification and repair. CDRH will review the draft of the notification to avoid the need for a second notification.

The manufacturer must also provide to CDRH a report (1003.20) stating:

- the total number of products so produced;
- the location of the violative products;
- an evaluation of the resultant hazards; and
- a corrective action plan (CAP) (1004).

Each corrective action plan is reviewed and may be approved with any necessary changes or conditions. The manufacturer must then implement the approved plan. FDA field offices monitor corrective actions for effectiveness.

An exemption from the requirements for notification and corrective action may be requested if the manufacturer can demonstrate that the defect or noncompliance does not create a significant risk of injury (1003.30 and 1003.31).

A manufacturer may not legally introduce products into commerce that have a radiation defect or that fail to comply with the standard. Shipments of violative products must cease when the manufacturer becomes aware of a defect or noncompliance. Shipments of corrected products may be made following changes to achieve compliance. Submission of a supplement to the Initial or Model Change Report on the product that details how the product now complies is required prior to resumed introduction.

VARIANCES AND EXEMPTIONS

The regulations allow for variances and exemptions from all or part of the standard and from the reporting and recordkeeping requirements.

A *variance* (1010.4) is permission to vary from one or more requirements of the standard. Upon application by a manufacturer, the Director of CDRH may grant a variance for a product if it is determined that the variance is so limited in applicability that an amendment to the standard is not justified, or is of such need that there is not sufficient time for amending the standard, and that granting the variance is in agreement with the Radiation Control Act. Specifically, a variance may be granted if:

- there are alternate but at least equal means of safety; or
- there are suitable means of safety and, further, either the product could not perform its function if it were in compliance, or one or more requirements of the standard are inappropriate for the product.

In requesting a variance, a manufacturer should carefully follow the format for submission set forth in the regulations (1010.4(b)). Failure to provide all the required information may result in delay in issuance of the variance; the variance is required *before* the product may be introduced into commerce.

Exemptions from the standard and from the recordkeeping and reporting requirements have been granted to several Federal agencies (1010.5), including the Departments of Defense and Energy, some NASA facilities, and NOAA, for certain unique or classified products. Vendors to these agencies should inquire through the contracting officers whether the products being purchased are covered by the exemptions.

Manufacturers of certain specialized products may also be exempted from annual reporting and recordkeeping (1002.50). Manufacturers who wish such an exemption should apply by submitting, with the Initial Report, justification and evidence showing that:

- the product cannot under any conditions emit levels of radiation that are hazardous; or
- the product is produced in such small numbers that the need for continuous reporting and recordkeeping is negated, and the product is to be used by individuals trained and knowledgeable in the hazards of such use.

The Director of CDRH may also exempt manufacturers from any part of the reporting and recordkeeping requirements if the exemption is judged to be in keeping with the purposes of the Act.

THIS PAGE IS BLANK
(PURPOSELY)

APPENDIX A. TABULATION OF FDA REQUIREMENTS FOR LASER PRODUCTS

Requirements	Class[1]					
	I	IIa	II	IIIa	IIIb	IV
Performance (all laser products)						
Protective housing (1040.10(f)(1))	R[2]	R[2]	R[2]	R[2]	R[2]	R[2]
Safety interlock (1040.10(f)(2))	R[3,4]	R[3,4]	R[3,4]	R[3,4]	R[3,4]	R[3,4]
Location of controls (1040.10(f)(7))	N/A	R	R	R	R	R
Viewing optics (1040.10(f)(8))	R	R	R	R	R	R
Scanning safeguard (1040.10(f)(9))	R	R	R	R	R	R
Performance (laser systems)						
Remote control connector (1040.10(f)(3))	N/A	N/A	N/A	N/A	R	R
Key control (1040.10(f)(4))	N/A	N/A	N/A	N/A	R	R
Emission indicator (1040.10(f)(5))	N/A	N/A	R	R	R[10]	R[10]
Beam attenuator (1040.10(f)(6))	N/A	N/A	R	R	R	R
Reset (1040.10(f)(10))	N/A	N/A	N/A	N/A	N/A	R[13]
Performance (specific-purpose products)						
Medical (1040.11(a))	S	S	S	S[8]	S[8]	S[8]
Surveying, leveling, alignment (1040.11(b))	S	S	S	S	NP	NP
Demonstration (1040.11(c))	S	S	S	S	S[11]	S[11]
Labeling (all laser products)						
Certification & identification (1010.2, .3)	R	R	R	R	R	R
Protective housing (1040.10(g)(6),(7))	D[5]	R[5]	R[5]	R[5]	R[5]	R[5]
Aperture (1040.10(g)(4))	N/A	N/A	R	R	R	R
Class warning (1040.10(g)(1),(2),(3))	N/A	R[6]	R[7]	R[9]	R[12]	R[12]
Information (all laser products)						
User information (1040.10(h)(1))	R	R	R	R	R	R
Product literature (1040.10(h)(2)(i))	N/A	R	R	R	R	R
Service information (1040.10(h)(2)(ii))	R	R	R	R	R	R

Legend

R - Required
N/A - Not applicable.
S - Requirements: Same as for other products of that Class. Also see footnotes.
NP - Not permitted.
D - Depends on level of interior radiation.

Footnotes

[1]Based on highest level accessible during operation.
[2]Required wherever & whenever human access to laser radiation above Class I limits is not needed for product to perform its function.
[3]Required for protective housings opened during operation or maintenance, if human access thus gained is not always necessary when housing is open.
[4]Interlock requirements vary according to Class of internal radiation.
[5]Wording depends on level & wavelength of laser radiation within protective housing.
[6]Warning statement label.
[7]CAUTION logotype./
[8]Requires means to measure level of laser radiation intended to irradiate the body.
[9]CAUTION if 2.5 mW cm^{-2} or less, DANGER if greater than 2.5mW cm^{-2}.
[10]Delay required between indication & emission.
[11]Variance required for Class IIIb or IV demonstration laser products and light shows.
[12]DANGER logotype.
[13]Required after August 20, 1986.

APPENDIX B. CLARIFICATION OF CERTAIN LASER LIGHT SHOW REQUIREMENTS

March 31, 1981
Revised: September 1985

The Center for Devices and Radiological Health (Center) is concerned that there are a number of areas of confusion in the understanding of the requirements for Class IIIb 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 a 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 IIIa) 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, because 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 IIIa. Thus, a laser light show projector manufacturer must have an approved variance under which a Class IIIb or IV projector may be certified. Likewise, a laser light show/display manufacturer must have an approved variance under which the Class IIIb 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 manufacturer (A), who has a variance covering his projector and his light shows incorporating that projector and certain auxiliary equipment, cannot 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 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 Center 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 Electronic Products Branch at (301) 594-4654 for assistance in determining whether an amendment is required.

As a matter of policy, the Center 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 IIIb and IV laser light show or display products, such products of all classes must be reported to the Center. 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 Preparing Initial and Model Change Reports on Lasers and Products Containing Lasers," dated September 1985;

(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 Center, *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 Center 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 Center to make such determinations, then the reporting and notification requirements have not been satisfied.

In satisfying the reporting requirements indicated above, it is permissible 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 system 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 Accession Number of that report.

(c) If you have modified the projector or added auxiliary 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 Reporting Guide for Laser Light Shows and Displays (May 1988) to provide the following information.

(a) Fixed effects repertoire, such as for a touring show:

- *Set-up* procedures.
- *Quality control and testing procedures* including checklists 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 IIIb 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 checklists 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 Center 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 and Scanning Safeguards

Any scanning effect that 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 5 mW, there is an acute risk of injury to someone's eyes if the scanning were to stop or slow down to a rate that would produce Class IIIb 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 IIIb or IV laser light show that 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 needed for the level of the scanned 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 Center 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 that 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 Center's experience with laser light shows indicates that the projectors scanning small diameter beams onto mirror balls generally need a scanning safeguard, although 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 that would project into areas that may be occupied and whether 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 *only* 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 is 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 covering 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 Center'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. 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 set-up, alignment, and testing procedures, and during the show, as well as to 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.