



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

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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 manufacturer (A) who has a variance covering his projector and his light shows incorporating that projector and certain auxiliary 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

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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.

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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 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 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 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 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 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.