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Latest FDA Variances Ease Laser Illuminated Projector Restrictions

Disclaimer: This document is for guidance purposes only. It does not contain legal advice and it is the responsibility of the Variance applicant to research and review the applicable national, state and local laws and regulations and adhere to them when installing and operating the covered equipment.

Recent updates from the FDA regarding Risk Group 3 (RG3) laser-illuminated projectors (LIPs) have relaxed some important variance requirements for non-cinema installations in the US. The revised rules greatly increase the flexibility for installations and reduce possible loss of space within venues by reducing the size of the Hazard zone. We'll explain how.

What is a Variance?

Since the first laser-illuminated projectors were introduced to the US market nearly a decade ago, they have been regulated under "Laser Light Show Variances" issued by the US Food and Drug Administration (specifically, the Center for Devices and Radiological Heath (CDRH)). Laser regulations, when originally drafted in the 1970's, were intended to restrict human access to any potentially harmful levels of radiation contained in laser beams. At that time, it was not anticipated that laser light would be beneficially used in applications like video projectors, where the laser light is optically processed to no longer be contained in a collimated beam, and therefore not nearly as hazardous. To accommodate these new LIPS that deviated from the applicable FDA performance standards, the FDA started to issue "variances" to manufacturers. Variances grant permission to provide alternate means of radiation safety.

The first variance specifically targeted for a laser-illuminated projector was issued by the FDA at the request of the Eastman Kodak company in December of 2010. This variance applied to the Kodak Laser Digital Cinema Projector, a novel prototype projector developed by the Kodak R&D team in Rochester, New York. This was new ground for the FDA, in that the variance spelled out the conditions under which this specifically defined laser product ought to be operated. The FDA conditions included secure mounting of the projector to prevent movement or misalignment, restricted access to the projection room, detailed installation and operating guidelines and safety signage. But most notably, the Kodak variance specified that the projector must be mounted in a

manner that restricts any human access to laser light exceeding a certain energy level, termed the Maximum Permissible Exposure (MPE). Specifically, the Kodak variance specified a certain distance (Hazard distance) in front of the projection lens where a possible exposure to a human eye is still equal or higher than the MPE, and prohibited people to stand below the light beam in this zone if the beam was lower than 2.5 meters (8.2 feet) above the ground.

This 2010 document served as a template for dozens of other variances subsequently issued to many manufacturers for a wide range of projector models. These came to be known as “Kodak style variances”, and the future variance documents carried most of the same conditions for operation, including the 2.5 meter separation height – but only for projectors permanently mounted in a movie theater, or similar application. Laser projectors and LIPs used in enterprise or non-cinema applications, were subject to far more onerous compliance conditions.

Restrictions in the Hazard Zone (HZ)

In order to define the installation conditions in the variance documents, the FDA specified a minimum separation height (SH). The separation height is simply the distance from the floor to the bottom edge of the projected light beam of the projector, within the Hazard Zone (HZ). And as the name implies, the hazard zone is the area in which the projected light output contains enough energy to impact your vision, even temporarily. Fig.1 illustrates these concepts.

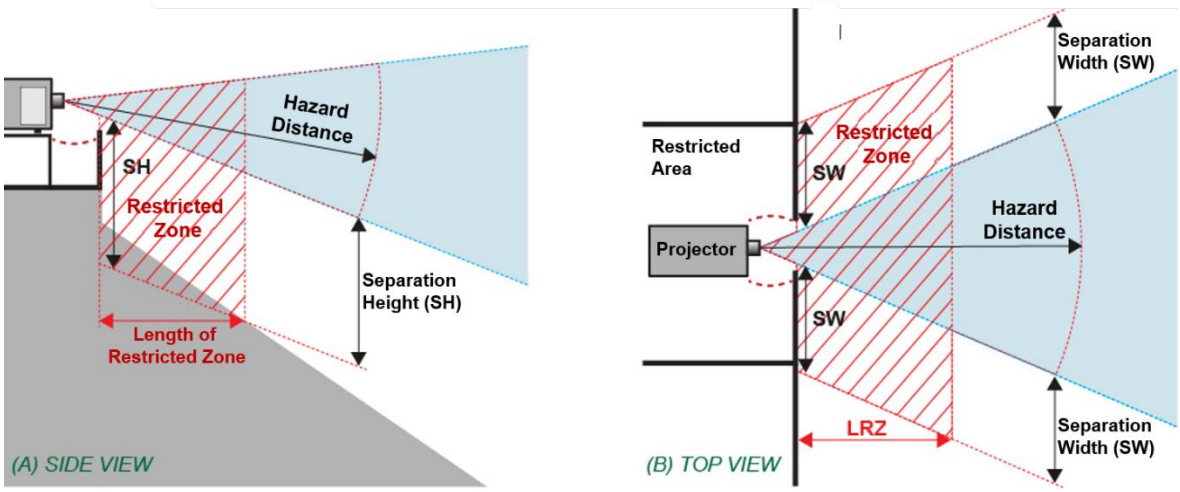

Fig. 1 An illustration of the concept of Hazard Distance (HD), Separation Height (SH) and Restricted Zone (RZ) for RG3 LIPs

To understand what this means, consider a stream of water from a hose: a narrow, concentrated jet of water could contain significant energy when aimed at one flower in your garden. But if you adjust your nozzle for a wide spray of water, the energy is broadly distributed, producing a gentle

drizzle onto the same flower. Light energy behaves in a similar manner – when spread out to a large wide beam, the farther the light travels from the projector (the hose nozzle), the less energy arrives at any given spot (your flower). In a typical Risk Group 3 laser illuminated projector, the Hazard Zone extends from at least 1 meter to possibly a few meters from the lens – depending on the projector specifications and lens type -- after which there is no longer any worrisome hazard, and therefore no installation constraint.

Updating the Separation Height (SH)

Until recently, FDA variances issued to virtually all manufactures of laser-illuminated projectors called for a 3 meter – or nearly 10-foot – separation distance for non-cinema applications. This meant that a hotel, auditorium, conference hall or boardroom using such a projector needed a significant ceiling height (as indicated in Fig.2), and a complex (and expensive) mounting system to keep the beam of projected light so far from the floor. Wherever the hazard zone beam might be lower than 3 m, physical barriers were required to restrict public access. This often resulted in blocked areas or limited the application of LIPs in such cases.

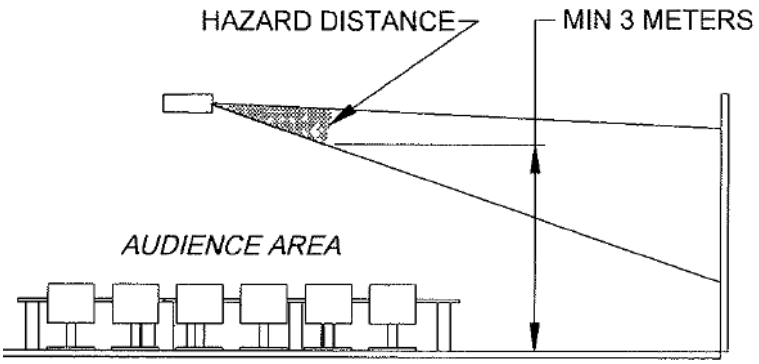

Fig.2 An illustration of a board room with a RG3 projector where a 3 meter separation height s required.

Such a situation was prohibitive for LIPs in the market, and LIPA engaged with the CDRH to discuss this issue. As a result of this discussion, in December 2019, the FDA issued their first variance containing revised – and more reasonable – set of conditions. This variance, issued at the request of Barco nv (a LIPA founding member company), included a provision allowing the separation height to conform to international standard ISO 13857:2008 (Table 1 – Section 4.1.1.), rather than just a blanket 3 m constraint. This broadly adopted international standard recognizes that a separation height of 2.5 m (8-ft, 2 in) is sufficient for safety. Since the International Organization of Standardization (ISO) is a network standards bodies from 164 countries, this regulation is very well-vetted and accepted worldwide. This FDA Variance is documented under FDA Docket Number: 2016-V-0144. Since then, FDA applies the same provision in all new variance approvals for RG3 LIPs.

What this means

The benefits of using laser-illuminated, rather than lamp projectors, are already well known: elimination of lamp replacement, lower power consumption, easier maintenance, simpler thermal management and more flexible installation options. But until recently, the 10-foot rule for separation height meant that these projectors needed to be mounted in inconvenient (or impossible) locations -- or seats and floor-space needed to be blocked off. With the new FDA variance terms, the installation options become much more flexible. You will need to consult with your projector manufacturer regarding the specific variance terms that apply to the projector model you intend to use. But it is good news for the industry that the FDA is now comfortable in harmonizing to established international standards for this more reasonable solution for laser-illuminated projectors.

LIPA – the Laser Illuminated Projector Association (www.LIPAinfo.org) – is very interested in your questions and requirements. Please contact us if you need more information or have other issues regarding deployment of laser light for the future of projection technology.

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