Guidance for Industry and FDA Staff

Applicability of the Performance Standard for High-Intensity Mercury Vapor Discharge Lamps (21 CFR 1040.30)

Document issued on November 6, 2005

For questions regarding this document contact Jerome E. Dennis, 301-827-2973, jerome.dennis@fda.hhs.gov.

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

Electronic Products Devices Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852.

When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/ocer/guidance/1565.pdf, or to receive this document by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (**1565)** followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Guidance for Industry and FDA Staff

Applicability of the Performance Standard for High-Intensity Mercury Vapor Discharge Lamps (21 CFR 1040.30)

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This document is intended to provide guidance to manufacturers and importers of high-intensity mercury vapor discharge lamps (HID) and to FDA import staff. The guidance clarifies that FDA's intent is to apply the performance standard at 21 CFR 1040.30 for HID lamps only to those lamps used for general purpose lighting. General purpose lighting includes lighting in gymnasia, auditoriums, and stores.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Background

What is a high-intensity mercury vapor discharge lamp?

A high-intensity mercury vapor discharge lamp consists of a quartz discharge tube enclosed within a hard glass outer envelope. The glass outer envelope blocks the transmission of short wavelength ultraviolet radiation from the discharge tube and also

protects the tube and interior structural and electrical elements. These lamps can continue operating when the outer envelope becomes partially or completely broken away, allowing ultraviolet radiation to escape.

How can exposure to this ultraviolet radiation affect health?

Exposure to ultraviolet radiation can cause painful injuries such as photokeratitis and erythema, also known as snow-blindness and sunburn. Because of numerous incidents involving scores of people requiring emergency room treatment, FDA issued a radiation safety performance standard that became effective in 1980. The overwhelming majority of these incidents occurred in school gymnasia after the outer envelope of a lamp in an open fixture was broken by a ball or other projectile. The injured people were usually spectators at a sporting event who sat beneath the broken lamp for many minutes to a few hours before they felt the symptoms of ultraviolet exposure.

Performance Standard

What does the performance standard say?

The entire performance standard can be found at 21 CFR 1040.30. The text we are addressing in this guidance document is 21 CFR 1040.30(a), which reads as follows:

Applicability. The provisions of this section apply to any high-intensity mercury vapor discharge lamp that is designed, intended, or promoted for illumination purposes and is manufactured or assembled after March 7, 1980, except as described in paragraph (d)(1)(ii) of this section.

FDA issued the performance standard to establish performance criteria for self-extinguishing (T Type) lamps. The standard also requires packaging for non-self extinguishing (R Type) lamps that warns they should not be used in locations where people congregate for more than a few minutes. The public health goal was to preclude the injuries that were occurring to people who gathered and remained in locations lighted by potentially broken HID lamps, such as gymnasia and auditoriums.

Issue

Why are some manufacturers and importers of high-intensity mercury vapor discharge lamps, which are not used for general purpose lighting, experiencing import delays?

As explained above, FDA intended the performance standard to apply only to HID lamps used for general purpose lighting, such as gymnasia (see the preambles to the proposed* and final** rules authorizing the standard), and FDA has been interpreting the regulation to apply only to those products since it was promulgated. However, the standard uses the term “illumination” rather than “general purpose lighting.” This has recently caused some

confusion because in its broadest sense, "illumination" can mean casting light on anything. Some FDA import officers have been applying this broad interpretation and detaining importations of lamps designed and intended for applications other than general purpose lighting. As the preambles to the proposed and final rule indicate, this is not the intent of the standard.

* The proposed rule can be found in the Federal Register of April 21, 1978 (43 FR 16997).

** The final rule can be found in the Federal Register of September 7, 1979 (44 FR 52195).

FDA interprets 21 CFR 1040.30 to be applicable only to the high-intensity mercury vapor discharge lamps that are intended for use in fixtures for general purpose lighting. This lighting is to aid vision within rooms such as gymnasia, auditoriums, or industrial locations where people are present for sports, entertainment, or work.

What is an example of a high-intensity mercury vapor discharge lamp that is outside the scope of the performance standard?

Large size projection televisions use high-intensity mercury vapor discharge lamp assemblies for illumination of the images that are projected on the screen. In this type of application, the lamps are installed inside the television so they are not subject to impact from external projectiles, unlike lamps in open fixtures in gymnasia. Additionally, the lamp assemblies for large size projection televisions are in precision mountings to ensure correct positioning when installed.

We do not consider HID lamps for specialized applications and for installation within products, such as large size projection televisions, to be within the scope of the standard.

What are the intended results of this guidance?

FDA import officers should refrain from asking for import papers, including FD Form 2877, for HID lamps other than those for general purpose lighting.

This restatement of the intent of the standard should result in expedited clearance of imports of HID lamps other than those for general purpose lighting. Importers may refer to this guidance in responding to questions from import officers.

Getting More Information

You can get more information about our requirements for high-intensity mercury vapor discharge lamps from our electronic products radiation control web page at http://www.fda.gov/cdrh/radhlth/mercury-vapor.html.

If you have questions about this guidance, contact Jerome Dennis, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.