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FORM FDA 3646 (06/24)

Abbreviated Reports on Radiation Safety for High-intensity Mercury Vapor Discharge Lamps

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This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

More industry guidance and assistance can be found at the FDA homepage, see: http://www.fda.gov/Radiation-EmittingProducts/.

Send your completed report to RadHealthCustomerService@FDA.HHS.GOV or by mail to:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

Questions about reporting and suggestions for changes to this guide may be sent to the above address or may be discussed by calling 1-800-638-2041.

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REPORTING GUIDE FOR ABBREVIATED REPORTS ON HIGH-INTENSITY MERCURY VAPOR DISCHARGE LAMPS

(21 CFR 1002)

Compiled by:
Center for Devices and Radiological Health

September 1995

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Devices and Radiological Health

Silver Spring, MD 20993

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Foreword

The Center for Devices and Radiological Health (CDRH) developed this guide. This guide will assist manufacturers[1] of electronic products which emit radiation in providing adequate reporting of radiation safety testing and compliance with federal performance standards. Title 21 of the Code of Federal Regulations (CFR), Parts 1002 and 1003 specify Reporting and Notification requirements[2,3].

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7). If the report does not follow an applicable guide it must contain a sufficient justification for any deviations. The submitter of the report will receive an acknowledgment letter with the accession number we assign to the report. Please reference this accession number in the future when contacting CDRH about this model family. If a report is incomplete or inadequate CDRH may reject it and return it for completion. CDRH will not enter a rejected report into our database. Also, a rejected report will not receive an accession number.

WE DO NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with all applicable standards (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. Prior to the shipment of products in interstate commerce 21 CFR 1002 requires the manufacturer to submit the report and to comply with all applicable importation requirements (21 CFR 1005). If there are deficiencies, we may disapprove the firm's quality control and testing program, determine that the product contains a radiation defect, or determine that the product fails to comply with a standard. We will notify the manufacturer if we make such a determination. CDRH may require the manufacturer to cease introduction into U.S. commerce until deficiencies are corrected, and to initiate a corrective action program (21 CFR 1003 - 1004) for products already introduced into commerce.

Please email or mail your reports to the address below. Provide the original report with appropriate signature(s) (no facsimiles, please). Submit the report written in the English language. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy of the completed reports in your records.

We are making our reporting guides and other regulatory information available on the Internet under http://www.fda.gov/Radiation-EmittingProducts/. No copyright exists for these guides. Reproduce these guides as needed. If you would like to comment on the reporting guides, web site, or future electronic submissions, you may direct the comments to the address below.

All reports may now be submitted to CDRH by email to: RadHealthCustomerService@fda.hhs.gov mailbox.

MAILING ADDRESS for reports and correspondence (see 21 CFR 1002.7 for further information):

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

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[1] **Manufacturer** (see 21) CFR § 1000.3(n)) means any person engaged in the business of manufacturing, assembling, or importing electronic products.

[2] **Accidental Radiation Occurrences:** 21 CFR 1002.20 requires manufacturers to immediately report accidental radiation occurrences (see 21 CFR 1000.3(a) for the definition).

[3] **Notification:** Title 21 CFR Part 1003 requires manufacturers to provide Notification of Defects or Failure to Comply. Send these notifications to the above address.

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INTRODUCTION

Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C-Electronic Product Radiation Control are required to furnish various reports to the Center for Devices and Radiological Health (CDRH). This reporting guide has been prepared for use by manufacturers in the preparation of abbreviated reports concerning high-intensity mercury vapor discharge lamps which are designed, intended, or promoted for illumination purposes (21 CFR 1040.30(a)), as required by paragraph 1002.12 of Title 21 CFR (Code of Federal Regulations).

The material submitted in the report is expected to be concise and to-the-point. As required in 21 CFR 1002.7(b), the material submitted shall conform to the guide to the extent that it is possible or appropriate to do so.

High-intensity mercury vapor discharge lamps Abbreviated Reports must be submitted to CDRH at the address on the previous "Foreword" page prior to the introduction of the reported products into commerce. (This includes products imported into the U.S.). Alternatively, high-intensity mercury vapor discharge lamps Abbreviated Reports may now be submitted to CDRH by email to the RadHealthCustomerService@fda.hhs.gov mailbox.

An Abbreviated Report is required for each high-intensity mercury vapor discharge lamp model or model family.

To avoid any unnecessary burden of reporting, the concept of model family is emphasized. You are requested to group your products into as small a number of model families as possible. A model family is a group of one or more mercury vapor lamp models having basically similar design with regard to the performance requirements in the standard, and which are manufactured using the same or very similar quality control and testing procedures. High-intensity mercury vapor discharge lamp models within the same model family may have different wattage values, different shapes, and different sizes of sockets. The information reported for any model within a model family will be largely the same as the information for every other model within the same family.

The manufacturer must be sure that referenced information is accurate, current, and applicable to the reported models. Information that is applicable to more than one model family, but cannot be referenced in accordance with the above guidance, should be duplicated and included in each report.

An Abbreviated Report is acceptable for both "R" and "T" type high-intensity mercury vapor discharge lamps.

When new models of a lamp are introduced, if the models do not involve changes in radiation emission or performance requirements, then the manufacturer need not report the models prior to introduction into commerce.

All symbols, units, and unusual terms in the report must be adequately defined and consistently used. Please use the terms as defined in Section 1040.30(b) and in the IEEE Standard Dictionary of Electrical and Electronic Terms (IEEE Std. 1001972 and ANSI C42.1001972).

Your reports and correspondence are to be submitted to either:

RadHealthCustomerService@FDA.HHS.GOV

Or by mail to:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER − WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS

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10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

When a report is received at CDRH, an accession number will be assigned to the report. The submitter will be informed of the accession number in a letter acknowledging receipt of the report. The acknowledgement letter is not a technical review of the report. The report will be reviewed by CDRH technical staff as soon as possible and if the report is incomplete or inadequate, the submitter will be advised of the results. Report supplements should be clearly identified with accession number of the original report.

If you have specific questions regarding regulations or filling out this report, call the Division of Industry and Consumer Education (DICE) at 1-800-638-2041.

DEFINITIONS

NOTE: These definitions have been revised.

Abbreviated Report (21 CFR 1002.12) - An Abbreviated Report is allowed for “R” and “T ” type high-intensity mercury vapor discharge lamps. Completing and submitting only the applicable Parts of this report based on the non-self-extinguishing or self-extinguishing design will fulfill the reporting requirements for the manufacturer of such products.

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PART 1: MANUFACTURER, PRODUCT, AND REPORT IDENTIFICATION

1.1. IDENTIFICATION OF MANUFACTURER

PRIME CONTACT/RESPONSIBLE PERSON

NAME OF MANUFACTURING FIRM

ADDRESS

TELEPHONE	EMAIL

IMPORTER OR U.S. AGENT NAME (IF APPLICABLE)

ADDRESS

TELEPHONE	EMAIL

Person preparing this report:

SIGNATURE

NAME & TITLE

TELEPHONE	EMAIL

1.2. IDENTIFICATION OF REPORT

1.2.1. DATE OF THIS REPORT

1.3. IDENTIFICATION OF PRODUCT

1.3.1. SPECIFY THE TYPE OF LAMP BEING REPORTED.

non-self-extinguishing (Type T) ☐,

self-extinguishing (Type R) ☐

1.3.2. PROVIDE THE MODEL FAMILY DESIGNATION.

1.3.3. DESCRIBE THE MODEL DESIGNATION SYSTEM WITHIN THE FAMILY *(ANSI designation system may be used).*

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1.3.4. IDENTIFY THE MODEL DETAILED IN THIS REPORT:

1.3.5. SUPPLY THE FOLLOWING INFORMATION IF THE REPORTED LAMP IS MANUFACTURED FOR AND/OR SOLD TO OTHER MANUFACTURERS OR SUPPLIERS FOR SALE UNDER A DIFFERENT NAME. PROVIDE A COPY OF EACH LABEL AND LAMP PACKAGING LABEL.

Brand name	Model number	Name & address of firm under whose name the lamp is sold

1.3.6. DOES THE PRODUCT MEET ANY KNOWN RADIATION STANDARD? IF YES, GIVE THE NAME OF THE PERFORMANCE OR RADIATION STANDARD:

PART 2: DESCRIPTION OF THE REPORTED LAMP MODEL

2.1. DESCRIPTION OF THE PRODUCT

2.1.1. PROVIDE A BRIEF DESCRIPTION OF OPERATIONAL CHARACTERISTICS THAT AFFECT RADIATION EMISSIONS, TRANSMISSION, LEAKAGE, OR THAT CONTROL EXPOSURE. ATTACH ANY SUPPORTING FILES.

2.1.2. PROVIDE A LIST OF APPLICATIONS OR USES. ATTACH ANY SUPPORTING FILES.

2.1.3. PROVIDE A DESCRIPTION OF THE RADIATION EMISSION, TRANSMISSION, OR LEAKAGE. ATTACH ANY SUPPORTING FILES.