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FORM FDA 3646 (7/07)

Mercury Vapor Lamp Products Radiation Safety Report

REPORTING GUIDE
FOR PRODUCT REPORTS ON
HIGH INTENSITY MERCURY VAPOR DISCHARGE LAMPS

(21 CFR 1002)

Compiled by:
Office of Compliance

September 1995

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

The Office of Compliance, 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].

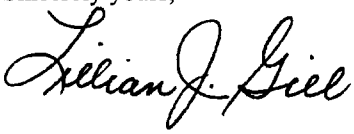
Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7). If the report does not follow an applicable guide it must contain a sufficient justification for any deviations. The submitter of the report will receive an acknowledgment letter with the accession number we assign to the report. Please reference this accession number in the future when providing additional information about this model family in either a supplement or the annual report. 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 mail your reports to the address below (FDA can not process electronic submissions at this time). Provide the original report with appropriate signature(s) (no facsimiles, please). Provide extra copies only if this guide specifically requires them. 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 report in your records.

We are making our reporting guides and other regulatory information available on the Internet under http://www.fda.gov/cdrh. 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. If you need additional regulations for electronic products or medical devices, you should contact the Division of Small Manufacturers Assistance by telephone at 1-800-638-2041 or 301-443-6597, or by facsimile at 301-443-8818.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance

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

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF COMPLIANCE (HFZ-307)
ATTN: ELECTRONIC PRODUCT REPORTS
2098 GAITHER ROAD
ROCKVILLE MD 20850

[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 Director of the Office of Compliance (HFZ-300).

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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 product reports concerning high intensity mercury vapor discharge lamps which are designed, intended, or promoted for illumination purposes, as required by paragraph 1002.10 and 1002.11 of Title 21 CFR (Code of Federal Regulations).

Mercury Vapor Lamp Product Reports, Supplemental Reports, and Abbreviated Reports must be submitted to CDRH at the address below prior to the introduction of the reported products into commerce. (This includes products imported into the U.S.)

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.

A complete Product Report is required for each mercury vapor lamp model or model family. Product Reports were formerly called Initial or Model Change Reports. Since these reports contain essentially the same information, the single term, Product Report, is now used. CDRH suggests that a complete report on one model of a family be submitted, with a separate Supplemental Report for each of the other models in the family. The Supplemental Report should respond in detail to the parts of the guide where there are differences to report, referencing the number of the affected item. Items that are unchanged need only be referenced to the original report.

A Product Report is required in Section 1002.10 to be submitted to the Director, Center for Devices and Radiological Health within 90 days following the effective date of listing the product under Section 1002.61 of the Regulations or prior to the introduction of the product into commerce, whichever is later. A new or modified model belonging to a previously reported model family must be reported in a Supplemental Report on that model family prior to its introduction into commerce.

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. Mercury vapor 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. Therefore, a complete report on one model of a model family shall be submitted with a separate supplemental report for each of the other models in that family. Supplemental reports should respond to the appropriate parts of the guide. The supplemental reports must clearly indicate all items of the part of the previous product reports that have not been changed, and must also report all changes in detail with reference to the affected items.

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 non-self-extinguishing, "R" type mercury vapor lamps. For such lamps, completion of Parts 1, 2, 3, 4, and 5 of this report will serve as the abbreviated report.

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. Rather, the manufacturer is only required to identify them in the annual report, or in quarterly updates to the annual report. Quarterly updates to annual reports should be clearly marked as such and be submitted prior to December 1, March 1, and/or June 1 when required. [See 21 CFR 1002.13(c).]

All symbols, units, and unusual terms in the report must be adequately defined and consistently used. Please use the terms as defined in Section 1040.20(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:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF COMPLIANCE (HFZ-307)
ATTN: ELECTRONIC PRODUCT REPORTS
2098 GAITHER ROAD
ROCKVILLE MD 20850

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 the submitter will be advised of the results. Report supplements should be clearly identified with accession number of the original product report.

The Product Reporting Guides and Annual Reporting Guides are available from the Division of Small Manufacturer's Assistance (DSMA) in

Rockville, Maryland at 1-800-638-2041. DSMA should be contacted for requests of any current documents and the reporting guides mentioned here.

If you have specific questions regarding regulations or filling out these reports, call the Nonmedical Radiological Devices Branch at (301) 594-4654.

DEFINITIONS

NOTE: These definitions have been revised.

Product Report (21 CFR 1002.10) - A Product Report is a report submitted by a manufacturer of a regulated product, e.g., mercury vapor lamps, sunlamps, laser products, TV. The Product Report describes the product, details how the product complies with the standard, and explains the quality control program to assure compliance. A Product Report can be used for families of products as well as for individual products.

Supplemental Report (21 CFR 1002.11) - A Supplemental Report provides information supplementary to a previously submitted Product Report. It is used to report a new model in a previously reported model family, a modification of a previously reported model, or other changes to a previous report (e.g., changes in testing programs, additions or changes in user or service manuals, responses to CDRH report review letters).

Supplemental Reports are also required for changes that:

a. affect actual or potential emission,

b. decrease the degree of compliance with the performance standard, or

c. result in a decreased probability of detecting product noncompliance or increased radiation emission.

Supplemental Reports should clearly reference the CDRH accession number of the Product Report and the appropriate sections of this guide.

Abbreviated Report (21 CFR 1002.12) - An abbreviated report is allowed for non-self-extinguishing or "R" type high intensity mercury vapor discharge lamps. Completing and submitting only Parts 1 through 5 of this report will fulfill the reporting requirements for the manufacturer of such products.

Annual Report (21 CFR 1002.13) - An Annual Report summarizing the required records must be submitted by September 1 for the 12 months ending on June 30 of the same year. In addition, the Annual Report is the appropriate vehicle for identifying new models for which Supplemental Reports are not required. If the new models do not involve changes in radiation emission or performance requirements, then the manufacturer need only identify them in their annual report, or in quarterly updates to the annual report. Copies of the annual report form to be followed are available from DSMA by calling 1-800-638-2041.

PART 1: MANUFACTURER, PRODUCT, AND REPORT IDENTIFICATION

1.1 Identification of Manufacturer

Prime contact/responsible person _____

Name of manufacturing firm _____

Address _____

_____

_____

Telephone _____

Importer (if applicable) _____

Address _____

_____

Telephone _____

Person preparing this report:

Signature _____

Name & Title _____

Telephone _____

1.2 Identification of Report

1.2.1 Is this report submitted pursuant to paragraph (c) of 21 CFR 1002.61?

YES _____ NO _____

1.2.2 Date of this Report _____

1.2.3 Is this a complete Product Report _____,

Supplemental Report _____, or Abbreviated Report _____?

1.2.4 If this is a Supplemental Report, give CDRH accession number and date of the Product Report that it supplements.

Accession Number _____

Date _____

1.3 Identification of Product

1.3.1 Specify the type of lamp being reported.

non-self-extinguishing _____,
self-extinguishing _____,
mercury vapor _____,
metal halide _____,
other (specify) _____

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).

_____

_____

1.3.4 Identify the model detailed in this report:

_____

1.3.5 List all other models in the model family and specify if supplements are attached. (If not, explain why not)

_____

_____

1.3.6 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

PART 2: DESCRIPTION OF THE REPORTED LAMP MODEL

2.1 Description of the product

2.1.1 Provide description of the exterior including information on the base or socket of the reported model. The descriptions may include the photographs or drawings with dimension reference scale.

_____

_____

_____

photographs or drawings attached _____

2.1.2 Provide description of the interior structures of the reported model. The description may consist of photographs or drawings of the interior structures with parts and component identification and with scale dimensions.

_____

_____

_____

photographs or drawings attached _____

2.2 Description of operation

2.2.1 Provide a brief general description of the theory and process of operation including the start, warmup, and the steady-state condition of the reported model.

_____

_____

_____

_____

2.2.2 Provide information on lamp starting voltage, and operating current of the reported model (reference may be made to ANSI standard).

2.2.3 Specify the type of ballast that meets the specifications of the reported model's ratings for starting and operation (reference may be made to ANSI standard).

2.2.4 Provide information on the life and warm-up time of the lamp.

2.2.5 If the reported model is a self-extinguishing lamp, provide descriptions in detail of the self- extinguishing mechanism including its functioning theory and the conditions under which it renders the lamp inoperable.

PART 3: COMPLIANCE WITH THE GENERAL LABELING REQUIREMENTS

3.1 Does the reported lamp model have a label certifying that the lamp conforms to the provisions of 21 CFR 1040.30 as required by 21 CFR 1010.2?

YES _____ NO _____

3.1.1 Where is the certification label? On the lamp _____, or on the lamp packaging _____.

3.1.2 Submit a sample of the required certification label for the reported model, or a facsimile of the label if the label is inscribed on the lamp.

Sample attached _____

Facsimile attached _____

3.2 Does the reported lamp model have an identification label that conforms to the provisions of 21 CFR 1010.3?

YES _____ NO _____

3.2.1 Where is the identification label? On the lamp _____, or on the lamp packaging _____.

3.2.2 Submit a sample of the required identification label for the reported model, or a facsimile of the label if the label is inscribed on the lamp.

Sample attached _____

Facsimile attached _____

3.2.3 How is the identification label permanently affixed, inscribed or marked on the lamp and/or the lamp packaging?

_____

_____

_____

3.3 Is the reported lamp model permanently labeled or marked in such a manner that the name of the manufacturer and the month and year of manufacture of the lamp can be determined on the intact lamp and after the outer envelope is broken or removed?

YES _____ NO _____

3.3.1 Submit a facsimile of the above identification label or mark for the reported model.

Facsimile attached _____

3.3.2 If the name of the manufacturer and month and year of manufacture are expressed in code or symbols, you must provide the following information.

code	key or explanation
____	_____
____	_____

The location of the coded information or symbols (please include picture, drawing, or diagram showing location).

_____

_____

3.3.3 How are the name of the manufacturer and the date of the manufacture permanently labeled or marked on the lamp?

_____

_____

_____

PART 4: COMPLIANCE WITH THE REQUIREMENTS FOR NON-SELF-EXTINGUISHING LAMPS

[This part should be completed when reporting non-self-extinguishing types of high intensity mercury vapor discharge lamp as defined in 21 CFR 1040.30(b)(1)].

4.1 Lamp Labeling (submit explanations for all "NO" answers as attachments)

4.1.1 Is the reported lamp model clearly marked with the letter "R" on the outer envelope?

YES _____ NO _____

4.1.2 Does the reported lamp model have the letter "R" also marked on another part of the lamp?

YES _____ NO _____

If yes:

(a) Identify the location of the letter "R" (include picture, drawing, or diagram showing location).

_____

_____

(b) How is the letter"R" marked on the lamp?

_____

_____

(c) Is the letter "R" visible after the outer envelope of the lamp is broken or removed?

YES _____ NO _____

4.2 Lamp packaging (submit explanations for all "NO" answers as attachments)

4.2.1 Does the lamp packaging for the reported lamp model clearly and prominently display the letter "R"?

YES _____ NO _____

4.2.2 Does the lamp packaging for the reported lamp model clearly and prominently display the words:

"WARNING: This lamp can cause serious skin burn and eye inflammation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Lamps* that will automatically extinguish when the outer envelope is broken or punctured are commercially available"?

YES _____ NO _____

*The words "certain types of" may be inserted before "lamps that will ...."

4.2.3 The required warning statement for a non-self-extinguishing lamp appears on the lamp carton _____, outer wrapping _____, and/or other means of containment (specify)_____ for the reported model.

4.2.4 Submit a sample or facsimile of the label on lamp packaging as required by 1040.30(e)(2) for the reported model.

Sample attached _____

Facsimile attached _____

4.2.5 Describe other radiation safety related information, if any, provided on or with the lamp packaging for the reported model and the reason for providing that information.

_____

_____

_____

4.3 Lamp advertisement (submit explanations for all "NO" answers as attachments)

4.3.1 Does the advertising for the reported model prominently display the words:

"WARNING: This lamp can cause serious skin burn and eye inflammation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Lamps* that will automatically extinguish when the outer envelope is broken or punctured are commercially available"?

YES _____ NO _____

*The words "certain types of" may be inserted before "lamps that will ...."

4.3.2 The required warning statement in advertisement for a non-self-extinguishing lamp is included in the catalog _____, specification sheet _____, price list _____, and other description or commercial brochure and literature _____ for the reported model.

4.3.3 Submit copies of all advertisements containing the warning label as requried by 1040.30(e)(3) for the reported model (Material may be submitted in draft form as long as it is marked as a draft and final copies are to be submitted as report supplements when available.)

Copies of finals attached _____

Copies of drafts attached _____

4.3.4 Describe other radiation safety-related information, if any, provided in advertisement for the reported model and the reason for providing that information.

_____

_____

_____

PART 5: QUALITY CONTROL TESTS FOR NON-SELF-EXTINGUISHING LAMPS

[This part should be completed by manufacturers of non-self-extinguishing types of high intensity mercury vapor discharge lamps as defined in 21 CFR 1040.30(b)(1).]

5.1 Quality control tests

What tests or checks are conducted to assure the presence of the required labels and markings prior to and after completion of the manufacturing process?

Information attached _____

If not, explain _____

_____

_____

_____

5.2 Action upon rejection

Describe actions to be taken for rejected units and rejected lots.

Information attached _____

If not, explain _____

_____

_____

_____

PART 6: COMPLIANCE WITH THE REQUIREMENTS FOR SELF-EXTINGUISHING LAMPS

[This part should be completed when reporting self-extinguishing types of high intensity mercury vapor discharge lamps as defined in 21 CFR 1040.30(b)(1) and (7).]

6.1 Maximum cumulative operating time

6.1.1 The reporting lamp model is designed to cease operation within a cumulative operating time not to exceed _____ minutes, following complete breakage or removal of the outer envelope (with no fragment of the outer envelope extending more than 50 millimeters from the base shell).

6.1.2 The reported lamp model is designed to cease operation within a cumulative operating time not to exceed _____ minutes, following breakage or removal of at least 3 square centimeters of continguous surface of the outer envelope. Not applicable? _____

6.2 Lamp labeling (submit explanations for all "NO" answers as attachments)

6.2.1 Is the reported lamp model clearly marked with the letter "T" on the outer envelope?

YES _____ NO _____

6.2.2 Does the reported lamp model have the letter "T" on another part of the lamp?

YES _____ NO _____

If yes:

(a) Identify the location of the letter "T" (include picture, drawing, or diagram showing location).

_____

_____

(b) How is the letter "T" marked on the lamp?

_____

_____

(c) Is the letter "T" visible after the outer envelope of the lamp is broken or removed?

YES _____ NO _____

6.3 Lamp packaging (submit explanations for all "NO" answers as attachments)

6.3.1 Does the lamp packaging for the reported lamp model clearly and prominently display the letter "T"?

YES _____ NO _____

6.3.2 Does the lamp packaging for the reported lamp model clearly and prominently display the words:

"This lamp should self-extinguish within 15 minutes after the outer envelope is broken or punctured. If such damage occurs, TURN OFF AND REMOVE LAMP to avoid possible injury from hazardous shortwave ultraviolet radiation"?

YES _____ NO _____

6.3.3 The required warning statement for a self-extinguishing lamp appears on the lamp carton _____, outer wrapping _____, and/or other means of containment (specify) _____ for the reported model.

6.3.4 Submit a sample or a facsimile of the label on lamp packaging as required by 1040.30 (d)(3) for the reported model.

Sample attached _____

Facsimile attached _____

6.3.5 Describe other radiation safety related information, if any, provided on or with the lamp packaging for the reported model and the reason for providing that information.

_____

_____

PART 7: QUALITY CONTROL, LIFE, AND RELIABILITY TESTS FOR SELF-EXTINGUISHING LAMPS

[This part should be completed by manufacturers of self-extinguishing type of high intensity mercury vapor discharge lamp as defined in 21 CFR 1040.30(b)(7). Wherever appropriate, information attached should include quality control procedures for the tests performed, parameters measured, physical conditions under which tests are conducted, measurement instrumentation and techniques, uncertainty evaluations of the measurements, sampling plans, the rejection criteria or confidence limits used, and the justification for the particular choice of such limits, methods of data analysis, etc.]

7.1 Quality control tests conducted before the lamp is manufactured.

7.1.1 What tests were conducted on preproduction or prototype models prior to initiation of manufacturing to assure that the lamp was adequately designed for compliance within the performance standard.

Information attached _____

If not, explain _____

_____

_____

_____

7.1.2 What tests are conducted on the components of the self-extinguishing mechanism of the lamp prior to their incorporation into the lamp?

Information attached _____

If not, explain _____

_____

_____

_____

_____

7.2 Quality control tests done during and after manufacture of the lamp.

7.2.1 What tests or checks are conducted on the components of the self-extinguishing mechanism of the lamp prior to their incorporation into the lamp?

Information attached _____

If not, explain _____

_____

_____

_____

7.2.2 What tests or checks are conducted to assure proper functioning of the self-extinguishing mechanism after completion of the manufacturing process?

Information attached _____

If not, explain _____

_____

_____

_____

7.2.3 What tests or checks are conducted to assure the presence of the required labels and markings prior to and after completion of the manufacturing process?

Information attached _____

If not, explain _____

_____

_____

_____

7.3 Action upon rejection

Describe actions to be taken for rejected units and rejected lots if they have been rejected for problems concerning compliance with 21 CFR 1040.30. If retesting is required, state the criteria and procedures for retesting.

Information attached _____

If not, explain _____

_____

_____

_____

7.4 Life and reliability tests

Provide descriptions of the life and reliability tests of the self-extinguishing mechanism of reported model, including testing procedures, accept or reject criteria, lot and sample size and action following rejection.

Information attached _____

If not, explain _____

_____

_____

_____

7.5 Results of tests

7.5.1 Identify the type of tests related to compliance with 21 CFR 1040.30 for which results are presented including reference to applicable portions of this part of the report as appropriate.

_____

_____

_____

7.5.2 Identify the time period represented by results presented for each test.

_____

_____

_____

7.5.3 Provide information on the total number of units manufactured or received in the case of components, the number of units tested, and the number of units that initially failed to meet the quality control acceptance criteria for each test related to compliance with 21 CFR 1040.30.

_____

_____

_____

_____