

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

(21 CFR 1002)

Compiled by:
Office of Compliance

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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

This guide was developed by the Office of Compliance, Center for Devices and Radiological Health (CDRH), to assist electronic product manufacturers in providing adequate reporting of radiation safety testing and compliance with performance standards. Reporting requirements are specified in Title 21 of the Code of Federal Regulations (CFR), Part 1002.

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7), or contain a justification why it was not followed. CDRH may reject an incomplete report and return it for completion. When the report is adequate for filing, it will be logged into the CDRH computer system and assigned an accession number. 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.

WE DO NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with the applicable standard (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. The manufacturer is required to submit the report (21 CFR 1002) and to comply with all applicable importation requirements (21 CFR 1005) prior to the shipment of products in interstate commerce. If there are deficiencies, we may disapprove the firm's quality control and testing program or determine that the product contains a radiation defect or fails to comply with a standard. We will notify the manufacturer if we make such a determination. Then the manufacturer may be required 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.

We are making our reporting guides available on the CDRH web site at <http://www.fda.gov/cdrh/comp/eprc.html>, for downloading and reproduction. They are not copyrighted and may be reproduced as needed.

Please mail your reports to the address below (electronic submissions cannot be processed yet). Provide one original IN ENGLISH (no facsimile, please) unless specified otherwise in the guide. Make a copy of the completed report for your records. If you would like to comment on the reporting guides or the electronic docket or future electronic submissions, you may direct the comments to the same address. If you need additional regulations for electronic products or medical devices, 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.

A handwritten signature in cursive script that reads "Lillian J. Gill".

Lillian J. Gill
Director
Office of Compliance

MAILING ADDRESS:

Center for Devices and Radiological Health
ATTN: Electronic Product Reports
Electronic Product Document Control (HFZ-309)
Office of Communication, Education, and Radiation Programs
9200 Corporate Blvd.
Rockville, MD 20850

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INTRODUCTION

Manufacturers of products subject to the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C, 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.

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 October 1, December 1, March 1, 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
ATTN: Electronic Product Reports
Electronic Product Document Control (HFZ-309)
Office of Communication, Education, and Radiation Programs
9200 Corporate Blvd.
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 Manufacturers, International, and Consumer Assistance (DSMICA) in Rockville, Maryland at 1-800-638-2041. DSMICA 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 Electronic Products Branch at 240-276-3332.

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 radiation emission,
- b. affect the manner of compliance with a standard or manner of testing for radiation safety.

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 DSMICA 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 21 CFR 1002?

() YES () NO

1.2.2 Date of this Report:

1.2.3 This is 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 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
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PART 2: DESCRIPTION OF THE REPORTED LAMP MODEL

2.1Description of the product

2.1.1Provide 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:
() Yes () No

2.1.2Provide 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:
() Yes () No

2.2Description of operation

2.2.1Provide 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, or
() other means of containment for the reported model (specify):

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, () other description or commercial brochure/literature for the reported model.

4.3.3 Submit copies of all advertisements containing the warning label as required 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 reported lamp model is designed to cease operation 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) within a cumulative operating time not to exceed _____ minutes.

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

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

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

() YES () NO

6.3.2Does 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

6.3.3The required warning statement for a self-extinguishing lamp appears on the

() lamp carton, () outer wrapping,
() other means of containment for the reported model (specify):

6.3.4Submit 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

6.3.5Describe 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.