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FORM FDA 3663 (09/26)

Abbreviated Reports on Radiation Safety for Microwave Products (Other than Microwave Ovens)

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paper Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please do NOT send your completed document to this PRA Staff email address.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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/.

Email your completed, signed report to: RadHealthCustomerService@fda.hhs.gov
or send your completed report 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.

ABBREVIATED REPORTS ON RADIATION SAFETY FOR MICROWAVE PRODUCTS (OTHER THAN MICROWAVE OVENS)

AUGUST 1995

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Silver Spring, MD 20993

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 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. If you need additional regulations for electronic products or medical devices, you should contact the Division of Industry and Consumer Education by telephone at 1-800-638-2041 or by facsimile at 301-847-8149.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance

Email your completed, signed report to: RadHealthCustomerService@fda.hhs.gov or send your completed report to:

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

[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.

ABBREVIATED REPORTS FOR MICROWAVE PRODUCTS (OTHER THAN MICROWAVE OVENS)

General Information and use of this Guide

This guide for preparing abbreviated report for microwave products (other than microwave ovens) is issued by the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) for manufacturers and importers of radiation emitting electronic products. Manufacturers and importers of microwave products (see example of products listed below) are subject to the requirements promulgated under Chapter V, Subchapter C - Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act. Applicable radiation reporting regulations are contained in Title 21 CFR, Part 1002.12. Further information regarding the reporting requirements can be obtained by calling the Division of Small Manufacturers Assistance at 1-800-638-2041.

Retain this guide for photocopying (or formatting for word processing) for use in filing all reports in the future. When the report is received by CDRH, an acknowledgement letter will be sent to the submitter identifying an Accession Number. A unique accession number will be assigned for each MODEL FAMILY; all additional models within that family or changes to a previously reported model will be assigned the same accession number with a unique supplement number. Please reference the accession number when additional information is submitted.

There are some foreign manufacturers that do not have a firm or a representative in the United States working on their behalf. Part 1005.25 requires foreign manufacturers to assign a manufacturer's U.S. Agent to act on their behalf. The U.S. Agent may be an individual, a firm, a domestic corporation or an importer.

Summary of requirements: An Abbreviated report must be filed for each model or chassis. Any major changes made to the product design affecting the radiation emission, transmission or leakage will require sending a new Abbreviated Report.

Email your completed, signed report to: RadHealthCustomerService@fda.hhs.gov or send your completed report to:

Electronic Product Reports
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Examples of Microwave Products Covered By This Abbreviated Report: microwave heating or drying, microwave security system, RF sealers, electromagnetic induction and heating equipment, dialectric heaters (2-500 MHz), and other microwave power generating devices.

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ABBREVIATED REPORT FOR MICROWAVE PRODUCTS (OTHER THAN MICROWAVE OVENS)

A. PRODUCT IDENTIFICATION (CHECK APPROPRIATE BOX):

[ ] Microwave Heating (02)

[ ] Microwave Diathermy (03)

[ ] Rf Sealers, Induction, Dielectric heaters (27)

[ ] Other (explain): _____

B. IDENTIFICATION OF FIRM:

B.1 Manufacturer Name: _____

Address: _____

_____

_____

Contact Official: _____

Title: _____

Signature: _____

Telephone: _____

Email address: _____

B.2 Importer or U.S. Agent Name: _____

Address: _____

_____

_____

Contact Official: _____

Title: _____

Signature: _____

Telephone: _____

Email address: _____

B.3 Factory Location(s): _____

_____

_____

B.4 Date of this Report: _____

ABBREVIATED REPORT FOR MICROWAVE PRODUCTS (OTHER THAN MICROWAVE OVENS)

C. IDENTIFICATION OF MODEL(S) BEING REPORTED

Brand Model Number

D. APPLICATIONS - USES (Describe the intended and known uses or applications of each model):

E. OPERATIONAL CHARACTERISTICS (Provide a brief description of operational characteristics that affect radiation emissions, transmission, or leakage or that control exposure):

F. RADIATION LEVELS (Fill in the answers or check where indicated)

F.1 The maximum amount of radiation output allowed by your design is: _____.

F.2 The frequency of the output radiation is: _____.

F.3 The product operates [ ] continuously or [ ] has a duty cycle of _____.

F.4 Does the product produce modulation of the output radiation? [ ] Yes [ ] No

If yes, describe all types of modulation and how it is produced: _____

_____

F.5 Does the product meets any know radiation standard? If yes, give the name of the performance or radiation standard:

F.5 Technical Information Attached - Attach technical information including the following: (a) operation and maintenance manual, (b) servicing manual, (c) performance or design data on the product, (d) wiring diagrams or schematics, and (e) appropriate warnings and labels with instruction to avoid unnecessary radiation exposure.