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FORM FDA 3643 (02/23)

Microwave Oven Products Annual Report

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:

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 report may be sent to the above address or may be discussed by calling 1-800-638-2041.

Microwave Oven Products
Annual Report

March 1985

This report replaces the March 1974 edition and incorporates the June 1983 Annual Report Guide.

The reporting and/or recordkeeping requirements contained herein have been approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1980 (OMB Approval No. 0910-0025).

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

GENERAL INFORMATION

The Microwave Oven Products Annual Report provides microwave oven manufacturers and importers with guidelines and uniform formats for submitting information on the certification of microwave ovens subject to the Federal performance standard under the Radiation Control for Health and Safety Act of 1968 (P.L. 90-602). Microwave oven manufacturers are required to submit Initial Reports, Model Change Reports, Annual Reports, and Report Supplements to the Center for Devices and Radiological Health (CDRH) as mandated by Title 21 CFR 1002.10, 1002.11, and 1002.12.

This new report supersedes the March 1974 version and incorporates the June 1983 Annual Report Guide. Most of the forms in this report have been revised and simplified from the March 1974 edition. The new format is intended to provide manufacturers and importers with a clear understanding of the specific information required by CDRH. These reporting forms will provide CDRH with product information and an adequate explanation of how manufacturers' quality control and testing programs are utilized to assure that the microwave ovens comply with all applicable sections of the Federal performance standard prior to introduction into United States commerce.

SAVE THIS REPORT AND USE IT FOR PHOTOCOPYING. You should duplicate the forms in this report for inclusion in your report and retain a copy of the completed report for your records. Proprietary information should be specifically and clearly marked. Information submitted in your report will be used to evaluate your quality control and testing program, identify potential safety problems, and make decisions on the level and type of monitoring programs to be conducted by FDA, such as product testing and factory inspections.

Upon receipt of your reports, the Center for Devices and Radiological Health (CDRH) will send you an acknowledgment letter with an Accession Number which you should reference when you submit additional information. You will receive further notification only if additional information or clarification is needed. Send your completed reports to:

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

REMINDER

ACCIDENTAL RADIATION OCCURRENCES

You are required by 21 CFR Subchapter J, Section 1002.20, to immediately report accidental radiation occurrences. Report to the Director, Center for Devices and Radiological Health, all accidental radiation occurrences reported or otherwise known to you and arising from the manufacture, testing, or use of any product you have introduced, or intend to introduce, into commerce.

DEFINITIONS

Initial Report: The first report submitted by a manufacturer in a regulated product area, e.g., microwave ovens. The Initial Report consists of a PRODUCT REPORT that describes the product and identifies its radiation safety features and a QUALITY CONTROL REPORT that explains the quality control and testing program to assure compliance (21 CFR 1002.10). Upon receipt of the PRODUCT REPORT and the QUALITY CONTROL REPORT, the Center for Devices and Radiological Health (CDRH) will assign each a seven-digit Accession Number which is used to locate the reports in the CDRH file system. CDRH will then send a letter to the corresponding official of the manufacturer or importer; this letter will acknowledge receipt of the reports and will list their Accession Numbers.

Model Family: A group of two or more microwave oven models that are basically similar in design and performance features, particularly those relating to radiation safety. Ovens within the same Model Family may have slight variations in such areas as power output, control panel features, or circuitry. Such ovens are manufactured under the same, or very similar, quality control and testing procedures. Each Model Family is described in a separate PRODUCT REPORT.

Model Change: When a microwave oven with a new model number is produced, it should be reported in one of the following ways:

A. If a new model is significantly different from all previously reported models in regard to radiation safety components or radiation safety performance (e.g., door-choke design, door-sealing system, cavity configuration, mode stirrer, location of safety interlocks or monitor switches), a new PRODUCT REPORT must be filed before the new model is introduced into commerce. This PRODUCT REPORT must describe that model, which will be the first in a new Model Family. If quality control and testing procedures for the new model are different from those previously described in the QUALITY CONTROL REPORT, the changes must be described in a REPORT SUPPLEMENT to the QUALITY CONTROL REPORT.

B. If a new model is basically the same as a previously reported model (i.e., the new model is part of the same Model Family), the PRODUCT REPORT for the previous model must be updated, before the new model is introduced into commerce, by a REPORT SUPPLEMENT which details the differences. Any changes in quality control or testing procedures resulting from the new model must be described in a REPORT SUPPLEMENT to the QUALITY CONTROL REPORT.

C. If a new model is the same as a previously reported model in all aspects of radiation safety (i.e., only the selling model number has changed), the ANNUAL REPORT must be updated in a quarterly REPORT SUPPLEMENT.

Annual Report: A summary of records covering the 1-year period July 1 to June 30, to be submitted to CDRH on or before September 1 of each year. Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, requires that manufacturers of electronic products establish and maintain records, and provide performance data, on radiation safety and provide information on their quality control and testing programs.

Report Supplement: Additions, deletions, corrections, or changes to information previously submitted in a PRODUCT REPORT, QUALITY CONTROL REPORT, or ANNUAL REPORT. REPORT SUPPLEMENTS reference the CDRH Accession Number and submission date of the previous report.

INSTRUCTIONS: PART C - ANNUAL REPORT

C.1 AND C.2 MANUFACTURER/IMPORTER IDENTIFICATION

Fill in the requested information and sign where indicated. Fill in the years in the reporting period. Example: The report due every September 1 should cover the reporting year July 1, 20__, through June 30, 20__.

C.4 PRODUCTION STATUS

Check the statement that applies to your firm. Complete all of Part 10.0, or Part 10.4 only, as indicated after the statement you have checked.

PART C - ANNUAL REPORT

C.1 MANUFACTURER

Company Name: _____

Address: _____

_____

This Annual Report is submitted in accordance with 21 CFR 1002.11 for the period July 1, 19__ through June 30, 19__.

Corresponding Official: _____
(Signature)

_____ _____
(Name) (Title)

( ) _____ _____
(Telephone) Email

C.2 IMPORTER (if applicable)

Company Name: _____

Address: _____

_____

Corresponding Official: _____
(Signature)

_____ _____
(Name) (Title)

( ) _____ _____
(Telephone) Email

C.3 DATE OF THIS ANNUAL REPORT: _____

C.4 PRODUCTION STATUS

☐ Products were manufactured during this period, and the firm is still in business. All of Part 10.0 has been completed.

☐ No products were manufactured during this period, but the firm is still in business and expects to manufacture in the future. Only Part 10.4 has been completed.

☐ No products were manufactured during this period, and the firm is now out of business. Only Part 10.4 has been completed.

☐ Products were manufactured during this period, but the firm is now out of business. All of Part 10.0 has been completed.

INSTRUCTIONS

ANNUAL REPORT

PART 10.0 - YEARLY SUMMARY

10.1 CURRENT PRODUCTION TABULATION

Provide production data, using the form or a comparable tabulation. If additional space is needed, use another copy of the form and label it Part 10.la, 10.1b, etc., on each page.

"Accession Number": For previously reported models, CDRH will have assigned this number and reported it to you.

"Brand": You may use a code for each brand in the chart. On a separate sheet, provide the complete address for each importer or distributor of each brand and identify any codes. Label the sheet Part 10.1.

"Oven Type": Indicate whether the model is common cavity (COM), countertop commercial (CTC), countertop domestic/household (CTD), high/low or over/under (HLO), module (MOD), wall hanging oven (WHO), built-in single oven (BSO), built-in double oven (BDO), or under-the-cabinet oven (UTC).

"Plant Location": Codes may be used. On a separate sheet, provide the complete address for each manufacturing location and identify any codes. Label the sheet Part 10.1.

"Discontinued (mo/yr)": Provide discontinuation date for any model that is no longer in production but was produced at some time during the reporting period.

ANNUAL REPORT

PART 10.0 - YEARLY SUMMARY

10.1 CURRENT PRODUCTION TABULATION

Accession No.	Model No.	Brand	Oven Type	Plant Location	No. of Units Produced	Intro. Into Com-merce (mo/yr)	Discon-tinued (mo/yr)

Total:

INSTRUCTIONS

ANNUAL REPORT

PART 10.0 - YEARLY SUMMARY

10.2 PROCEDURES FOR QUALITY CONTROL AND TESTING

You are required by 21 CFR 1002.30(a) (1) and (2) to maintain written procedures for quality control and testing. The procedures in use and those submitted in the Quality Control Report should be reviewed and updated.

Compare your current procedures with those submitted in your Quality Control Report. Check the appropriate answers and take any indicated action.

10.3 SUMMARY OF TEST RESULTS

You are required by 21 CFR 1002.30(a)(2) to maintain results of quality control tests. For each microwave oven product introduced into commerce, you should evaluate test results to be certain that the total program is adequate to assure radiation safety and compliance with the standard (21 CFR 1030.10).

10.3.1 - Results of Audit Tests

Complete the table or provide comparable data on a separate sheet and label it Part 10.3.1.

"Door Condition": Indicate the door condition during tests, using these codes:

(C) = door in the normal closed position with all interlocks operating;

(P) = door pulled against any mechanical stops with all interlocks operating;

(S) = door pulled against any mechanical stops with only the secondary interlock operating.

The interlock design of some models requires that leakage measurements be made under more than one door condition. Provide data for measurements made under each door condition.

"No. of Interlock Failures": Provide identification of failed switches and a description of the failure. (Use a separate sheet and label it Part 10.3.1.)

"No. of Units Rejected": For each unit rejected in audit testing because of failure to conform to microwave radiation safety specifications, describe the reason for rejection and the actions taken to determine if other units in that lot or in other lots had the same problem. (Use a separate sheet and label it Part 10.3.1.)

ANNUAL REPORT

PART 10.0 - YEARLY SUMMARY

10.2 PROCEDURES FOR QUALITY CONTROL AND TESTING

The internal quality control written procedures for assessing and controlling radiation safety have been reviewed. (These include prototype testing, incoming materials testing, assembly testing, retesting after repair, and service testing.) The procedures for maintaining quality control testing equipment have also been reviewed. All procedures are up-to-date, complete, and accurate.

☐ Yes ☐ No

Are the written quality control procedures you have submitted to CDRH up-to-date, complete, and accurate?

☐ Yes ☐ No

If either question is answered No, provide the current procedures in a supplement to the appropriate quality control report.

10.3. SUMMARY OF TEST RESULTS

10.3.1 Results of Audit Tests

Model No.	No. of Units Produced	No. of Units Sampled	Door Condition	Leakage Measure-ments Mean (mW/cm^2)	Leakage Measure-ments Std. Dev. (mW/cm^2)	No. of Interlock Failures Primary	No. of Interlock Failures Secondary	No. of Interlock Failures Monitor	No. of Units Rejected

INSTRUCTIONS

ANNUAL REPORT

PART 10.0 - YEARLY SUMMARY

10.3.2 - Distribution of Microwave Leakage Audit Data

Analyze microwave leakage audit data. Use bar graphs to summarize the maximum levels; include only one model family (with a common accession number) in each graph.

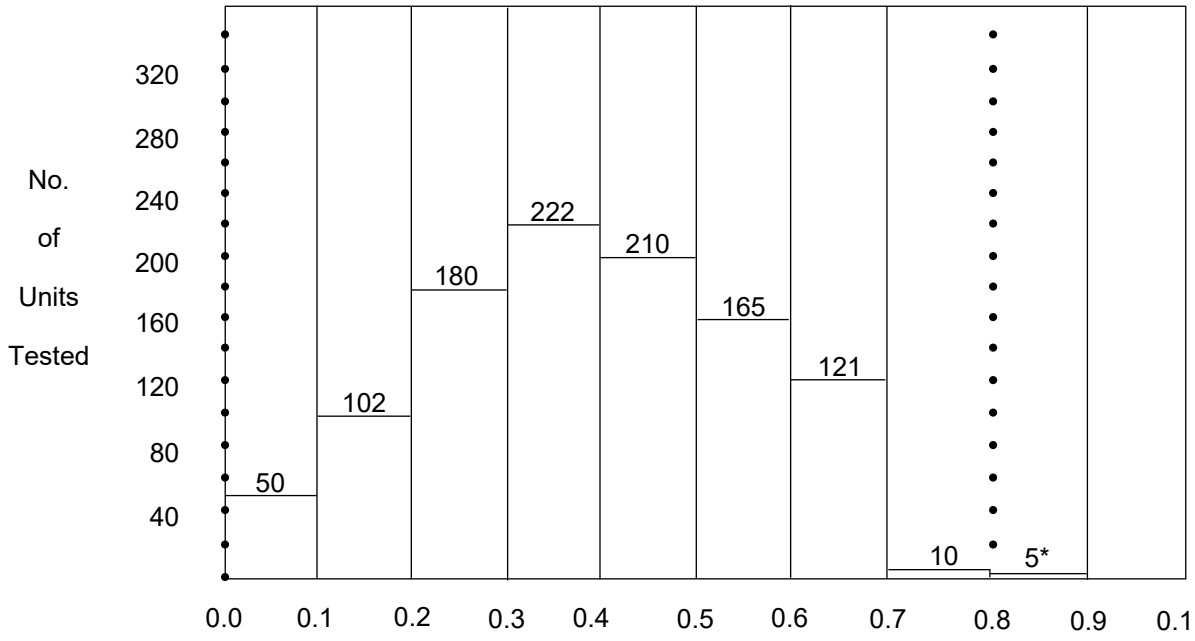
Above each graph, check the appropriate door condition; at the bottom, indicate the model family designation. Label the side of the graph to show the number of units tested; label the bottom to show the upper limit of each range of measurement. Then draw in the bars to represent the distribution of measurements, and mark the reject limit with a dotted line.

If more than 2 graphs are needed, use additional photocopies of the form and label them Part 10.3.2a, 10.3.2b, etc., on each page.

If any measurements exceed the reject limit, identify them with asterisks (*) and indicate beneath the graph the area of the oven where the leakage was found and the reason for the leakage. On a separate sheet labeled Part 10.3.2, provide: (1) an analysis of the problem; (2) a description of the actions taken to correct the problem; and (3) a summary of the data from any additional testing.

Example:

DOOR CONDITION: ☐ Door closed, ☐ Door pulled, ☐ Secondary interlock only



Microwave Leakage (mW/cm^2) for model family AB

*Reject limit exceeded by measurement at top edge of door frame because of excessive tolerance in new switch bracket

ANNUAL REPORT
PART 10.0 - YEARLY SUMMARY

10.3.2 Distribution of Microwave Leakage Audit Data

DOOR CONDITION: ☐ Door closed, ☐ Door pulled, ☐ Secondary interlock only

No. of Units Tested

Microwave Leakage (mW/cm^2) for model family _____

*Reject limit exceeded by measurement at _____

_____

DOOR CONDITION: ☐ Door closed, ☐ Door pulled, ☐ Secondary interlock only

No. of Units Tested

Microwave Leakage (mW/cm^2) for model family _____

*Reject limit exceeded by measurement at _____

_____

INSTRUCTIONS

ANNUAL REPORT

PART 10.0 - YEARLY SUMMARY

10.3.3 - Results of Endurance Testing

You are required by 21 CFR 1002.30(a)(3) to maintain results of endurance testing. Summarize tests on prototypes and on final products to show how extended use can affect radiation safety, or provide comparable data on a separate sheet and label it Part 10.3.3.

"Door Condition": Indicate if door was closed (C), in a pulled position with all interlocks operating (P), or open to the position where only the secondary interlock is operating (S). If a model number is tested under more than one door condition, be sure to enter data in each column for each condition.

On a separate sheet labeled Part 10.3.3, identify each component that failed or required readjustment as a result of life or endurance testing and that could affect the quality or distribution of microwave leakage. Include interlock and monitor switch failures, and the means employed to correct each failure.

10.4 CORRESPONDENCE CONCERNING RADIATION SAFETY

You are required by 21 CFR 1002.30(a)(4) to maintain copies of communication to or from dealers, distributors, and purchasers concerning radiation safety. Correspondence should be reviewed if it involves any of the following: complaints or concerns about radiation exposure; difficulties with safety components in use or servicing of the product; investigations made or instructions issued concerning use, adjustment, and repair.

Fill in the number of documents sent or received and attach the copies, summaries, or samples as indicated.

NOTE: This summary does not replace the notification requirements for potential defects or noncompliances under 21 CFR 1003.10 or for suspected accidental radiation occurrences under 21 CFR 1002.20.

10.5 DISTRIBUTION RECORDS

You are required by 21 CFR 1002.30(b)(1) and (2) to maintain distribution records. Such records must allow tracing of products to the dealer and, if possible, to the user.

10.3.3 Results of Endurance Testing

Model No.	Door Condition	Before Test Maximum Leakage (mW/cm^2)	During Test Maximum Leakage (mW/cm^2)	During Test No. of Cycles	After Test Maximum Leakage (mW/cm^2)	After Test No. of Cycles	After Test No. of Cycles at Failure

10.4 CORRESPONDENCE CONCERNING RADIATION SAFETY

The number of letters received from users, dealers, or others about possible radiation exposure or interlock failures during use of the product was _____ .

☐ If the complaint did not clearly result from steam or a hot utensil, a copy of each letter is attached behind this page and labeled Attachment 10.4.

The number of letters received from dealers, distributors, or others concerning the need for repair, adjustment, or replacement of a part to maintain radiation safety of the product was _____ .

☐ A summary of correspondence, or a sample, is attached behind this page and labeled Attachment 10.4. Any trends in failed components or adjustments needed during servicing are identified.

The number of notices or brochures sent to users, dealers, or service personnel on precautions or actions to be taken to maintain radiation safety of the product was _____ .

☐ A summary of correspondence, or a sample, is attached behind this page and labeled Attachment 10.4.

10.5 DISTRIBUTION RECORDS

Production facility shipping records and dealer records (when returned) are maintained at: _____ .

INSTRUCTIONS

ANNUAL REPORT

PART 11.0 - QUARTERLY UPDATE OF NEW SELLING MODELS

New model numbers added to a previously reported model family may be reported in a supplement to the current Annual Report if the information in the Product Report is still applicable. If you are reporting new or modified ovens with new electrical, cosmetic or mechanical changes that COULD NOT affect the RF leakage characteristics or function of the safety interlocks and monitor, this form can be used in the same manner. It is recommended that these new models be reported on a quarterly basis. Changes that may be reported in a new model report supplement include:

(a) = cosmetic changes

(b) = new brand names

(c) = control panel changes

(d) = addition of a temperature probe feature

(e) = changes in areas of the circuitry that could not affect the RF characteristics or the function of the safety interlock(s).

Note: If the current written quality control and testing procedures are not applicable to the new models, then a supplement to the Quality Control Report, containing updated quality control and testing information, must be submitted (see Instructions: Part D - Supplement to Product Reports, Quality Control Report or Annual Report).

Use the accompanying form or a comparable tabulation. If additional space is needed, use another copy of the form or attach a separate sheet and label it 10.6a, 10.6b, etc.

Check the appropriate answer to the question and check the reporting period for which the report supplement is being filed.

"Accession Number": Provide the accession number of the Product Report for the basic oven design family that closely resembles the new models.

"Brand": You may use a code for each brand in the chart. On a separate sheet, provide the complete address for each importer or distributor of each brand and identify any codes. Label the sheet 11.1.

"Oven Type": Indicate whether the model is common cavity (COM), countertop commercial (CTC), countertop domestic/household (CTD), high/low or over/under (HLO), module (MOD), wall hanging oven (WHO), built-in single oven (BSO), built-in double oven (BDO), or under-the-cabinet oven (UTC).

"Plant Location": Codes may be used. On a separate sheet, provide the complete address for each manufacturing location and identify any codes. Label the sheet 11.2.

"Changes": State the model number of the old model that is most similar to the new model. Using codes (a) through (e) for the changes listed above, indicate the changes made in the new model.

"Explanation": Additional space is given to allow explanation for brand names, oven types, or other pertinent information.

NOTE: If the new models contain any changes that could affect the RF leakage characteristics or the function of the safety interlock(s), which could result in the evolution of a new model family, the new model number(s) and the details of the change(s) must be submitted as a Product Report. If there are any questions in this regard, please contact CDRH prior to reporting.

ANNUAL REPORT

PART 11.0 - QUARTERLY UPDATE OF NEW SELLING MODELS

The current written quality control and testing procedures for assessing and controlling radiation safety have been reviewed and are applicable to the new models listed below.

☐ Yes ☐ No

Reporting Period	Submit not later than
☐ Jan., Feb., March	January 1
☐ April, May, June	April 1
☐ July, Aug., Sept.	July 1
☐ Oct., Nov., Dec.	October 1

Accession No.	New Model No.	Brand	Oven Type	Plant Location	Planned Intro. Into Commerce (mo/yr)	Changes

Explanation: _____

_____