Form Approved: OMB No. 0910-0025
Expiration Date: May 31, 2010

FORM FDA 3643 (7/07)

Microwave Oven Products Annual Report

Guide for Preparing Reports on Radiation Safety of Microwave Ovens

March 1985

This guide 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
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

GENERAL INFORMATION

The Guide for Preparing Reports on Radiation Safety of Microwave Ovens 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 guide supersedes the March 1974 version and incorporates the June 1983 Annual Report Guide. Most of the forms in this guide 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 GUIDE AND USE IT FOR PHOTOCOPYING. You should duplicate the forms in this guide 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:

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

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.

GENERAL INSTRUCTIONS

For ease of photocopying, all instructions are on the left-hand pages while the corresponding forms are on the right-hand pages. You need only submit the completed forms and any information you have provided on separate sheets. If you use separate sheets or additional copies of the forms, label each page with sequential lettering after the page number.

Example: Page 3a, Page 3b, Page 3c.

The forms provide blanks to be filled in, boxes to be checked, and tables or graphs to be completed. You may use a typewriter or hand print in black ink.

This guide is divided into the following main Parts:

REPORT IDENTIFICATION

Part A - Product Report

Part B - Quality Control Report

Part C - Annual Report

Part D - Supplement to Product Reports, Quality Control Report or Annual Report

PRODUCT REPORT

Part 1.0 - Model Design and Specifications

Part 2.0 - Label Requirements, Radiation Warnings and Instructions

Part 3.0 - Special Tests on Pre-Production Ovens

QUALITY CONTROL REPORT

Part 4.0 - Incoming Inspection and Subassembly Testing

Part 5.0 - Production Line and Final Tests

Part 6.0 - Quality Audit

Part 7.0 - Life and Endurance Testing

Part 8.0 - Instrumentation and Calibration Checks

Part 9.0 - Recordkeeping

ANNUAL REPORT

Part 10.0 - Yearly Summary

Part 11.0 - Quarterly Update of New Selling Models

The following chart briefly summarizes those Parts which are required for various types of submittals.

TYPE OF SUBMITTAL	PARTS OF REPORT REQUIRED
INITIAL REPORT BY NEW MANUFACTURER (First product line and quality control information)	Part A and Part B, plus Parts 1.0 through 9.0
NEW MODEL DESIGN FAMILY (No change in quality control program)	Part A, plus Parts 1.0 through 3.0 as needed
NEW MODEL DESIGN FAMILY (Changes in quality control program)	Part A and Part D, plus Parts 1.0 through 9.0 as needed
NEW SELLING MODELS (Change in model numbers, brand names, selling companies, cosmetic features, etc., but no change in radiation safety design)	Part D, plus Part 11.0
ADDENDA, NEW MODEL DESIGNS WITHIN AN EXISTING FAMILY, CHANGES TO REPORTS PREVIOUSLY FILED, OR QUALITY CONTROL PROGRAM CHANGES	Part D, plus Parts 1.0 through 9.0 as needed
ANNUAL REPORT (Due September 1 of each year)	Part C, plus Part 10.0

INSTRUCTIONS: PART A - PRODUCT REPORT

Part A of the Product Report is used to identify the manufacturer and/or importer and date of submittal, as well as to confirm that the required Parts have been completed and are enclosed. Check the boxes in Section A.4 to confirm that you have completed and enclosed the required Parts 1.0 through 3.0. In Section A.5 of this form you are asked to review your current quality control and testing procedures for assessing and controlling radiation safety and confirm that the procedures are applicable to the new models listed in Part 1.1. If you have determined that the current quality control and testing procedures are not applicable to the new models, then a supplement to the Quality Control Report, containing the updated written quality control and testing procedures, must be filed (see Instructions: Part D).

Note that Parts 4.0 through 9.0 (Quality Control Report) of this guide are not required for the completion of the Product Report. Any changes in Parts 4.0 through 9.0 should only be reported as a supplement to your Quality Control Report.

Microwave Ovens
Product Code 01

PART A - PRODUCT REPORT

A.1 MANUFACTURER

Company Name:_____

Address:_____

_____

Corresponding Official:_____
(Signature)

_____ _____ (___)_____
(Name) (Title) (Telephone)

A.2 IMPORTER (if applicable)

Company Name:_____

Address:_____

_____

Corresponding Official:_____
(Signature)

_____ _____ (___)_____
(Name) (Title) (Telephone)

A.3 DATE OF THIS PRODUCT REPORT:_____

A.4 PRODUCT REPORT ENCLOSURES (Boxes are checked for those Parts submitted.)

	1.0	2.0	3.0
Parts	☐	☐	☐

A.5 Current quality control and testing information submitted in the Quality Control Report (CDRH Accession Number:_____) is applicable to the new models listed in Part 1.1:

☐ Yes

☐ No. Part D - Supplement to Product Reports, Quality Control Report or Annual Report is attached, as well as Parts 4.0 through 9.0 as needed to show the updated quality control information.

INSTRUCTIONS: PART B - QUALITY CONTROL REPORT

Manufacturers are required to certify that their products comply with the Radiation Control for Health and Safety Act of 1968 and applicable provisions of the Federal Performance Standard for Microwave Ovens, 21 CFR 1030.10. The certification process involves the implementation of a sound quality control and testing program which ensures that the finished product complies with the Federal standard. To meet the requirements for a Quality Control Report, it is necessary to complete Form B as well as Parts 4.0 through 9.0 of the Quality Control Report, as follows: Part 4.0 Incoming Inspection and Subassembly Testing; Part 5.0 Production Line and Final Tests; Part 6.0 Quality Audit; Part 7.0 Life and Endurance Testing; Part 8.0 Instrumentation and Calibration Checks; and Part 9.0 Recordkeeping.

Upon receipt of the Quality Control Report, CDRH will assign a unique Accession Number, different from that assigned to the Product Report.

If a manufacturer has to report to CDRH any significant changes in the quality control and testing program because of the introduction of a new or markedly changed microwave oven model design, or for any other reason, the manufacturer can update the Quality Control Report by submitting Part D - Supplement to Product Reports, Quality Control Report or Annual Report and attaching any Part(s) containing addenda or changes. This will allow consolidation of all quality control and testing procedures into one document which is separate from the Product Report.

Fill in the requested information and sign where indicated. Check the boxes to confirm completion and enclosure of the required Parts 4.0 through 9.0.

PART B - QUALITY CONTROL REPORT

B.1 MANUFACTURER

Company Name: _____

Address: _____

_____

Corresponding Official: _____
(Signature)

_____ _____ (___) _____
(Name) (Title) (Telephone)

B.2 IMPORTER (if applicable)

Company Name: _____

Address: _____

_____

Corresponding Official: _____
(Signature)

_____ _____ (___) _____
(Name) (Title) (Telephone)

B.3 DATE OF THIS QUALITY CONTROL REPORT: _____

B.4 QUALITY CONTROL REPORT ENCLOSURES (Boxes are checked for those Parts submitted.)

	4.0	5.0	6.0	7.0	8.0	9.0
Parts	☐	☐	☐	☐	☐	☐

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 on September 1, 1985, should cover the reporting year July 1, 1984, through June 30, 1985.

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.

C.5 ANNUAL REPORT ENCLOSURE

Check the box to confirm that you have completed and enclosed the required Part 10.0. If no microwave products were manufactured during this period, check the other box to confirm that you have completed and enclosed Part 10.4 only.

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)

C.2 IMPORTER (if applicable)

Company Name: _____

Address: _____

_____

Corresponding Official: _____
(Signature)

_____ _____ (___)_____
(Name) (Title) (Telephone)

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.

C.5 ANNUAL REPORT ENCLOSURE (Box is checked for the Part submitted.)

Part	All of 10.0	10.4 only
	☐	☐

INSTRUCTIONS: PART D - SUPPLEMENT TO PRODUCT REPORTS, QUALITY CONTROL REPORT OR ANNUAL REPORT

Part D is used for reporting corrections, changes or addenda to a Product Report, Quality Control Report, or Annual Report; changes to new or current models; or the addition of new selling models to an existing model family.

D.1 SUBMITTER

Check the appropriate box, fill in the requested information, and sign where indicated.

D.3 SUPPLEMENT TYPE AND PURPOSE

Check the appropriate boxes. Complete and enclose the indicated Parts.

D.3.1 - Fill in the Accession Number of the current Annual Report. Also, complete Part 11.0 and submit it as an attachment to this form.

Check "new selling models" if you are adding new selling models to a previously reported model family for which there are only changes in the model numbers and/or brand names.

Check "electrical and/or mechanical changes" if you are reporting electrical, cosmetic, or mechanical changes to new or current models that COULD NOT affect the RF leakage characteristics or function of the safety interlocks and monitor.

D.3.2 - Check the appropriate box, "Product Report" or "Quality Control Report," and fill in the Accession Number of the current Product Report or Quality Control Report, as appropriate. Fill in the number(s) of the Parts containing the addenda or changes, and attach the copies to the form.

D.3.3 - Check this box if you are answering a letter from CDRH. Your reply should be attached. Provide the date of the CDRH letter and the Accession Number of your report on the blank lines.

D.3.4 - Check this box if you want to write a brief explanation of any other submission. If applicable, please provide an Accession Number.

D.4 MODELS OR MODEL FAMILIES AFFECTED BY THIS SUPPLEMENT

List any models or model families that will be affected by this supplement.

PART D - SUPPLEMENT TO PRODUCT REPORTS, QUALITY CONTROL REPORT OR ANNUAL REPORT

D.1 SUBMITTER

☐ Manufacturer ☐ Importer

Company Name:_____

Address:_____

_____

Corresponding Official:_____
(Signature)

_____ _____ (___) _____
(Name) (Title) (Telephone)

D.2 DATE OF THIS SUBMITTAL:_____

D.3 SUPPLEMENT TYPE AND PURPOSE

D.3.1 Update of CURRENT ANNUAL REPORT (Part 11.0 is enclosed.)

Accession Number of Current Annual Report:_____

☐ new selling models

☐ electrical and/or mechanical changes

D.3.2 Update of the ☐ PRODUCT REPORT (Parts 1.0 through 3.0, as needed)

☐ QUALITY CONTROL REPORT (Parts 4.0 through 9.0, as needed)

Accession Number: _____

The Part(s) containing the addenda or changes are attached behind this form and include Part(s)_____

D.3.3 ☐ To answer letter from CDRH dated: _____

Accession Number: _____

D.3.4 ☐ Other: (Explain)_____

_____

D.4 Models or model families affected by this Supplement:_____

_____

_____

INSTRUCTIONS: Page 1

PRODUCT REPORT

PART 1.0 - MODEL DESIGN AND SPECIFICATIONS

Part 1.0 must be completed in its entirety for the first model of each Model Family. If there are any questions concerning what design variations necessitate completing Part 1.0, please contact the Microwave/Acoustic Products Section at the Center for Devices and Radiological Health, telephone (301) 427-7187.

Note that Part 1.0 contains nine subparts:

1.1 Identification of Model Family

1.2 Magnetron and Wave Guide

1.3 Mode Stirrer or Equivalent Devices

1.4 Insertion

1.5 Exposed Welds or Seams of the Cavity

1.6 Oven Door

1.7 Safety Interlocks System and Function

1.1 - Provide an identification of a Model Family using numbers, letters or symbols (i.e. "AB" family) known by your quality control personnel that would represent the model(s) listed below.

"Brand Names": 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 the codes used. Label the sheet Part 1.1.

"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).

After submitting the Product Report for the Model Family, other models to be reported in the future which are similar in design to the basic Model Family should be reported as a supplement to the Current Annual Report (see Instructions: Part D - Supplement to Product Reports, Quality Control Report or Annual Report).

NOTE: A separate Product Report must be completed for each Model Family (see Definitions: Model Change, page iii).

1.2.1 through 1.3.2 Fill in the information requested, check the appropriate boxes and provide attachments where indicated. If a certain subsection is not applicable to the model design, then use the notation "N.A." for not applicable.

PRODUCT REPORT - Page 1

PART 1.0 - MODEL DESIGN AND SPECIFICATIONS

1.1 IDENTIFICATION OF MODEL FAMILY (Identify by numbers, letters, symbols, or any generic family name that would represent the models listed below)

MODEL FAMILY: _____

MODEL NUMBERS	BRAND NAMES	OVEN TYPE	CAVITY SIZE (CU. FT.)	POWER OUTPUT (WATTS)

1.2 MAGNETRON AND WAVEGUIDE

1.2.1 The power source for the above model family is a:

☐ magnetron ☐ other (explain):_____

1.2.2 ☐ A photograph or engineering diagram of the waveguide is enclosed behind this page and labeled Attachment 1.2.2.

☐ The description is on a photograph or engineering diagram enclosed in another part of this report and labeled Attachment: _____.

1.3 MODE STIRRER OR EQUIVALENT DEVICES

1.3.1 ☐ The mode stirrer or equivalent device (e.g., turntable) is described below. All variations of the stirrer within the same family are clearly detailed.

☐ The mode stirrer cannot be satisfactorily explained in the format below. A full explanation is enclosed behind this page and labeled Attachment 1.3.1.

MODEL NUMBER OR FAMILY	SPEED (RPM) OF: STIRRER	SPEED (RPM) OF: TURNTABLE	NUMBER OF BLADES	METHOD OF DRIVE

1.3.2 ☐ Photograph(s) or engineering diagram(s) of mode stirrer is (are) enclosed behind this page and labeled Attachment 1.3.2.

☐ The description is on a photograph or engineering diagram enclosed in another part of this report and labeled Attachment:_____.

INSTRUCTIONS: Page 2

PRODUCT REPORT

PART 1.0 - MODEL DESIGN AND SPECIFICATIONS

Model Family identification - See the instructions Part 1.1 for explanation.

1.4.1 through 1.5.1 - Fill in the information requested, check the appropriate boxes and provide attachments where indicated. If a certain subsection is not applicable to the model design, then use the notation "N.A." for not applicable.

PART 1.0 - MODEL DESIGN AND SPECIFICATIONS

Model Family (Identify by numbers, letters or symbols):

1.4 INSERTION (21 CFR 1030.10(c)(2)(iv))

1.4.1 Can an insulated wire be inserted through any opening in the external surface of the oven into the cavity, waveguide, or other microwave energy containing spaces while the door is closed, provided the wire, when inserted, would consist of two straight segments forming an obtuse angle of not less than 170 degrees?

☐ Yes ☐ No

1.4.2 ☐ Clearly labeled photographs or engineering diagrams which show all external surfaces of a fully assembled oven are enclosed behind this page and are labeled Attachment 1.4.2. Adequate illustrations are provided to demonstrate that it is not possible to insert an insulated wire through any opening in the external surface into the cavity, waveguide, or other microwave energy containing spaces.

☐ The description is on a photograph or engineering diagram enclosed in another part of this report and labeled Attachment:_____.

1.5 EXPOSED WELDS OR SEAMS OF THE CAVITY

1.5.1 Are there any exposed welds or seams of the cavity on the fully assembled oven (e.g., bottom of oven)?

☐ Yes. Clearly labeled photographs or engineering diagrams which show the exposed welds or seams are enclosed behind this page and labeled Attachment 1.5.1.

☐ Yes. The description is on a photograph or engineering diagram enclosed in another part of this report and labeled Attachment:_____.

☐ No

PRODUCT REPORT

PART 1.0 - MODEL DESIGN AND SPECIFICATIONS

Model Family identification - See the instructions Part 1.1 for explanation.

1.6 OVEN DOOR

1.6.1 - Explain how the oven door is attached to the main frame by components such as hinge plates or piano hinges.

1.6.2 - Provide description of the means by which further adjustment or loosening of the door is prevented.

1.6.3 and 1.6.4 - Use the check boxes to describe the door seal design on the oven.

1.6.5 - Specify what type(s) of door latches are used (e.g., latch pawls, blades) to actuate any of the required safety interlocks or monitor. You should confirm that the latching mechanism is not removable from the oven door without disassembly of the oven or the oven door.

1.6.6 - Provide adequate explanation of the means by which microwave emission through the viewing window is controlled.

1.6.7 - For each model or model family, submit clearly labeled photographs, mechanical diagrams, and/or engineering sketches which show the door features (e.g., hinges, gasket, viewing screen, choke, door sealing system, door latches).

PART 1.0 - MODEL DESIGN AND SPECIFICATIONS

Model Family (Identify by numbers, letters or symbols):

1.6 OVEN DOOR

1.6.1 The oven door is attached to the main frame by:

☐ hinge parts ☐ piano hinges ☐ other (explain):

_____

1.6.2 Further adjustment or loosening is prevented by (explain):

_____

1.6.3 The door seal type is:

☐ metal-to-metal contact ☐ capacitive ☐ choke

☐ other (explain):_____

1.6.4 Is part of the door sealing system a gasket: ☐ Yes ☐ No

If Yes, the gasket is: ☐ ferrite absorber ☐ metal mesh

☐ other (explain):_____

1.6.5 The type(s) of door latches are:

☐ pawl(s) ☐ blade(s) ☐ other (explain):

_____

1.6.6 If a viewing window is provided, describe its construction and size and the techniques used to control RF emission through it:

_____

_____

1.6.7 ☐ Photographs or engineering diagrams of microwave emission control door features, hinges, gasket, viewing screen, choke, door sealing system, door latches, etc. are enclosed behind this page and labeled Attachment 1.6.7.

PRODUCT REPORT

PART 1.0 - MODEL DESIGN AND SPECIFICATIONS

Model Family identification - See the instructions Part 1.1 for explanation.

1.7 SAFETY INTERLOCKS SYSTEM AND FUNCTION

For each model or model family, fill in the information requested inside the boxes for each of the safety components by answering the questions, or completing the statements, below.

1.7.1 - Location - Indicate location of each item.

1.7.2 - Concealment - Indicate whether interlock or actuator is hidden from view. (Yes or No)

1.7.3 - Wire Insertion - Can a straight wire or other small thin straight object (10 cm length or less) operate the interlock? (Yes or No)

1.7.4 - Finger Insertion - Can a small (child's) finger operate the interlock or actuator? (Yes or No)

1.7.5 - Interlock Adjustment - Can the switch (or bracket on which the switch is mounted) be adjusted to allow the interlock to remain in a "closed" position or the monitor to remain open? (Yes or No)

1.7.6 - Actuation Distance - How far can the door be opened before the interlock switch actuates? (fill in number and unit, e.g., 2 mm)

1.7.7 - Monitored - Is the safety interlock in the monitoring or crowbar circuit? (Yes or No)

1.7.8 - Door Motion - Is door motion required to operate this interlock? (Yes or No)

1.7.9 - Sequential Operation (Door Opening) - With door just opening, number the order of interlock actuation, e.g., primary interlock = first, secondary = second, interlock monitor = third.

1.7.10 through 1.7.12 - Check the boxes to answer specific questions related to 21 CFR 1030.10(c)(2)(ii) and (vi).

PART 1.0 - MODEL DESIGN AND SPECIFICATIONS

Model Family (Identify by numbers, letters or symbols):

1.7 SAFETY INTERLOCKS SYSTEM AND FUNCTION

	PRIMARY INTERLOCK	SECONDARY INTERLOCK	MONITOR SYSTEM	OTHER INTERLOCK (DESCRIBE) _____
1.7.1 Location				
1.7.2 Concealment				
1.7.3 Wire Insertion				
1.7.4 Finger Insertion				
1.7.5 Interlock Adjustment				
1.7.6 Actuation Distance				
1.7.7 Monitored				
1.7.8 Door Motion				
1.7.9 Sequential Operation				

1.7.10 Can a failure of any single mechanical or electrical component of the microwave oven cause all safety interlocks to be inoperative?

☐ Yes ☐ No

1.7.11 Is there any additional component in the monitor circuit, such as a relay, which can disrupt or prevent the function of the monitor system?

☐ Yes ☐ No

1.7.12 Can interlock failures disrupt the monitoring function?

☐ Yes ☐ No

INSTRUCTIONS: Page 5

PRODUCT REPORT

PART 1.0 - MODEL DESIGN AND SPECIFICATIONS

Model Family identification - See the instructions Part 1.1 for explanation.

1.7. SAFETY INTERLOCKS SYSTEM AND FUNCTION

For each model or model family, submit clearly labeled photographs, mechanical diagrams, and/or engineering sketches which show the door latch(es), the various elements of the interlock system including monitor, and features to prevent insertion of a small finger or straight wire. These photographs, diagrams and sketches must be of sufficient quality and show adequate detail to substantially assist in understanding and visualizing the safety interlocks system. Check the boxes on the form and provide the labeled attachments behind the form.

1.7.13 - Attachment - Photographs or engineering diagrams of safety interlocks, monitor and support brackets.

1.7.14 - Attachment - Photographs or diagrams of door latches (external and internal) in relation to safety interlocks and monitor.

1.7.15 - Attachment - Photographs or engineering diagrams of concealed safety interlock(s) to show how it (they) cannot be activated by a small finger or a straight wire (10 cm in length).

PART 1.0 - MODEL DESIGN AND SPECIFICATIONS

Model Family (Identify by numbers, letters or symbols):

1.7 SAFETY INTERLOCKS SYSTEM AND FUNCTION

1.7.13 ☐ Photographs or engineering diagrams of safety interlocks, monitor and support brackets are enclosed behind this page and labeled Attachment 1.7.13.

1.7.14 ☐ Photographs of latches (external and internal) in relation to safety interlocks and monitor are enclosed behind this page and labeled Attachment 1.7.14.

1.7.15 ☐ Photographs or engineering diagrams of concealed safety interlock(s) to show how it (they) cannot be activated by a small finger or a straight wire (10 cm in length) are enclosed behind this page and labeled Attachment 1.7.15.

PRODUCT REPORT

PART 1.0 - MODEL DESIGN AND SPECIFICATIONS

Model Family identification - See instructions Part 1.1 for explanation.

1.7 SAFETY INTERLOCKS SYSTEM AND FUNCTION

1.7.16 - For each model or Model Family, submit a complete schematic and wiring diagram. As required by 21 CFR 1030.10(c)(2)(v), identify the safety interlocks as "PRIMARY" and "SECONDARY." State the condition of the oven, e.g., door open, door closed, timer off. Label the test points on the schematics which are used on the production line to check the continuity of the safety interlock switches and monitor. These checks should include as much related wiring as possible. See Part 5.3 for providing complete description of the tests.

NOTE: ONLY ONE COPY SHOULD BE PROVIDED FOR EACH MODEL FAMILY UNLESS THERE ARE MAJOR DIFFERENCES BETWEEN MODELS.

1.7.17 - Provide an explanation of the function and sequence of the control circuitry, safety interlocks, monitor, relays and other related components. If the monitored safety interlock(s) fail(s) to perform its (their) required function(s), describe the sequence of operation that would cause the monitor switch to render the oven inoperable until repaired.

PART 1.0 - MODEL DESIGN AND SPECIFICATIONS

Model Family (Identify by numbers, letters or symbols):

1.7 SAFETY INTERLOCKS SYSTEM AND FUNCTION

1.7.16 ☐ Complete schematic and wiring diagram for each model or Model Family are enclosed behind this form and labeled Attachment 1.7.16.

1.7.17 If the monitored safety interlock(s) fail(s) to perform its (their) required function(s), the sequence of operation is:

_____

_____

_____

PRODUCT REPORT

PART 2.0 - LABEL REQUIREMENTS, RADIATION WARNINGS AND INSTRUCTIONS

Model Family identification - See the instructions Part 1.1 for explanation.

Part 2.0 must be completed in its entirety for the first model of each Model Family.

21 CFR 1010.2 requires that a legible certification label or tag be permanently affixed and accessible to view on a fully assembled oven. The following statements are given as examples which satisfy the requirements of 21 CFR 1010.2:

1 - "This oven complies with DHHS Radiation Performance Standards, 21 CFR Subchapter J," or;

2 - "This product complies with applicable DHHS standards under the Radiation Control for Health and Safety Act of 1968," or;

3 - "This oven complies with applicable sections of DHHS Federal Performance Standard 21 CFR 1030.10."

21 CFR 1010.3 requires that a legible identification label be permanently affixed and accessible to view on a fully assembled oven. The identification label should contain the full name and address of the manufacturer; and the date (month and year) of manufacture must be spelled out completely without abbreviation. The place of manufacture may be expressed in code provided the manufacturer has supplied the key to such code in Section 2.1.6.

21 CFR 1030.10(c)(6)(i) requires that a legible user warning label be permanently affixed and be readily viewable during normal oven use. This label must also have the title emphasized, and be so located as to elicit the attention of the user. The exact wording of the user warning label is specified in 21 CFR 1030.10(c)(6)(i).

21 CFR 1030.10(c)(6)(ii) requires that a legible service caution label be permanently affixed and be readily viewable during servicing. This label must also have the title "CAUTION" emphasized and be so located as to elicit the attention of the service personnel. More than one service warning label may be needed if there is more than one access entry to the internal mechanism of the oven. The exact wording of the service warning label is specified in 21 CFR 1030.10(c)(6)(ii).

2.1 - State the location of each label and state whether the label will be secure and legible after being subjected to excess wear, humidity, cleaning, etc. (Yes or No).

2.2 - Verify that the date of manufacture is spelled out fully without abbreviation and with the month in capital letters.

2.3 - If place of manufacture is expressed in code, provide a key to such codes as an attachment.

2.4 through 2.7 - Provide facsimiles, engineering drawings or photographs of the required labels as attachments.

PART 2.0 - LABEL REQUIREMENTS, RADIATION WARNINGS AND INSTRUCTIONS

Model Family (Identify by numbers, letters or symbols):

2.1 LABEL ATTACHMENT

	Location	Is the label permanent and legible? (Yes or No)
2.1.1 Certification Label 21 CFR 1010.2		
2.1.2 Identification Label 21 CFR 1010.3		
2.1.3 User Warning Label 21 CFR 1030.10(c)(6)(i)		
2.1.4 Service Caution Label 21 CFR 1030.10(c)(6)(ii)		

2.2 Is the date of manufacture (month and year) spelled out fully without abbreviation, e.g., "Manufactured: FEBRUARY 1984"?

☐ Yes ☐ No

2.3 ☐ The place of manufacture is expressed in code. The key to the code is enclosed behind this page and labeled Attachment 2.3.

2.4 ☐ Certification label sample is enclosed behind this page and labeled Attachment 2.4.

2.5 ☐ Identification label sample is enclosed behind this page and labeled Attachment 2.5.

2.6 ☐ User Warning label sample is enclosed behind this page and labeled Attachment 2.6.

2.7 ☐ Service Caution label sample is enclosed behind this page and labeled Attachment 2.7.

PRODUCT REPORT

PART 2.0 - LABEL REQUIREMENTS, RADIATION WARNINGS AND INSTRUCTIONS

Model Family identification - See the instructions Part 1.1 for explanation.

2.8 - User Instruction or manual (21 CFR 1030.10(c)(4)) - For each model family, submit a representative draft copy or final sample of user instructions which will contain adequate instructions for safe use. These instructions must include the required clear warnings of the "PRECAUTIONS TO AVOID POSSIBLE EXPOSURE TO MICROWAVE ENERGY..." statements. The final version must be submitted to complete the filing of the Product Report.*

2.9 - Cookbook (21 CFR 1030.(c)(4) - For each model family, submit a draft copy or final sample of the pages in the cookbook which will contain adequate instructions for safe use including the required clear warnings of the "PRECAUTIONS TO AVOID POSSIBLE EXPOSURE TO MICROWAVE ENERGY..." statements.

2.10 - Service Instructions or Manual (21 CFR 1030.10(c)(5)) - For each model family, submit two copies of the final version of the service manual. If the final version is not yet available, submit a draft copy now, and two copies of the final version in a specified number of days, e.g., 120 days. These service manuals must contain adequate instructions for service adjustments and service procedures. These instructions must include the required clear warnings of the "PRECAUTIONS TO BE OBSERVED BEFORE AND DURING SERVICING TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY..." statements as specified by 21 CFR 1030.10(c)(5).

*NOTE: WHEN SUBMITTING A DRAFT OR FINAL COPY OF THE USER MANUAL AND/OR COOKBOOK, SEND US ONLY THE TABLE OF CONTENTS AND THE PAGE(S) ON WHICH THE USER PRECAUTION STATEMENTS APPEAR. WE DO NOT NEED A COPY OF THE ENTIRE COOKBOOK.

PART 2.0 - LABEL REQUIREMENTS, RADIATION WARNINGS AND INSTRUCTIONS

Model Family (Identify by numbers, letters or symbols):

2.8 ☐ A copy of the final user manual is attached.

☐ A draft copy of the user manual is attached. The final version will be submitted in _____ days.

2.9 ☐ A final copy of the cookbook Table of Contents and the cookbook page on which the user precaution statements appear is attached.

☐ A draft copy of the required cookbook pages is attached. The final version will be submitted in _____ days.

2.10 ☐ Two copies of the final service manual are attached.

☐ A draft copy of the service manual is attached. Two copies of the final version will be submitted in _____ days.

PRODUCT REPORT

PART 3.0 - SPECIAL TESTS ON PRE-PRODUCTION OVENS

Model Family identification - See the instructions Part 1.1 for explanation.

For each Model Family, provide results of any special or unique tests performed on preproduction ovens to assure compliance of subsequent production ovens with the Federal performance standard. The attachment of results of tests on the preproduction ovens should include the following:

1. Testing performed to evaluate effects of the environment (heat, humidity, etc.), sensitivity to cavity temperature, effects of abuse, and the effects of shipping and transporting the oven.

2. Testing to evaluate performance of safety interlocks and monitor switches, door-sealing system, door choke, and other radiation safety components through life and endurance testing.

3. Testing to evaluate microwave emission characteristics on the external surfaces (vents, door-sealing system, door choke, underneath the oven, etc.) prior to actuation of safety interlocks and monitor switches in both normal mode and worse case mode; RF emission sensitivity to load placement; and stirrer modulation effect on RF emission.

3.1 - Submit the results of any special or unique tests necessary to evaluate the performance of safety interlocks, monitor, RF emission characteristics, and life and endurance testing of all radiation safety components.

3.2 - Submit the results of testing performed on the monitor system or crowbar circuit. The summary of the results should include the conditions of the safety interlocks and monitor switch before and after the tests, and description of how the monitored safety interlock(s) was (were) defeated.

PART 3.0 - SPECIAL TESTS ON PRE-PRODUCTION OVENS

Model Family (Identify by numbers, letters or symbols):

3.1 ☐ Results of special or unique tests necessary to evaluate the performance of safety interlocks, monitor, microwave emission at all surface areas, and life and endurance of radiation safety components are enclosed behind this page and labeled Attachment 3.1.

3.2 Has a test been conducted of the monitor system (or crowbar) circuit to show that if one (or both) of the monitored safety interlock(s) is (are) defeated, the oven is disabled until it is serviced (i.e., the fuse blows)?

☐ Yes. The results of such tests are enclosed behind this page and labeled Attachment 3.2.

☐ No. Such a test has not been conducted for the following reasons(s):_____

_____

_____

_____

INSTRUCTIONS: Page 10

QUALITY CONTROL REPORT

PART 4.0 - INCOMING INSPECTION AND SUBASSEMBLY TESTING

Model Family identification - See the instructions Part 1.1 for explanation.

Part 4.0 must be completed in its entirety for the Quality Control Report only. Any addenda or changes to this Part should be reported as a supplement to the Quality Control Report using appropriate Part D - Supplement to Product Reports, Quality Control Report or Annual Report.

Part 4.0 addresses all applicable quality control and testing procedures for incoming inspection and subassembly testing of critical radiation safety components which you consider to be a vital and necessary part of your testing program to ensure compliance of your finished products with the Federal performance standard 21 CFR 1030.10. This shall include (but not be limited to) incoming inspection and/or subassembly testing of such items as safety interlocks and monitor switches, wire harnesses, magnetron gasket, waveguide and cavity assemblies, door and door assemblies, door sealing system, door viewing screen and noncertified microwave oven modules.

4.1 - For each critical safety component listed on the corresponding form, use as many of the keys to test parameters identified below as necessary to describe the parameters of each test conducted during incoming inspection or subassembly testing. In addition, use the notation (100) or (S) to describe whether the tests are done on a "100 percent basis" or "sampling basis." If no tests are done to the component, use the notation (NT) for "no test."

Keys to Test Parameters:

D = dimension check

E = electrical continuity or performance

F = function test

RF = microwave emission measurement

V = visual inspection

W = weld integrity (destructive or nondestructive)

Example:

Cavities and waveguides: V/S, W/S, D/S

Wire harnesses: NT , _____, _____

Magnetron gasket: V/100, _____, _____

Microwave oven modules: E/100, RF/S, F/100

4.2 and 4.3 - Check the boxes to answer specific questions.

PART 4.0 - INCOMING INSPECTION AND SUBASSEMBLY TESTING

Model Family (Identify by numbers, letters or symbols):

4.1 COMPONENT TESTS

COMPONENTS	TEST PARAMETER/SAMPLING RATE
4.1 1 Magnetron gasket	___/___, ___/___, ___/___, ___/___
4.1.2 Cavities and waveguides	___/___, ___/___, ___/___, ___/___
4.1.3 Safety interlocks and monitor switches	___/___, ___/___, ___/___, ___/___
4.1.4 Wire harnesses	___/___, ___/___, ___/___, ___/___
4.1.5 Door structure, hinges, latches	___/___, ___/___, ___/___, ___/___
4.1.6 Door chokes and seals	___/___, ___/___, ___/___, ___/___
4.1.7 Door viewing screen perforations	___/___, ___/___, ___/___, ___/___
4.1.8 Noncertified microwave oven modules	___/___, ___/___, ___/___, ___/___

4.2 Are the incoming components adequately controlled to prevent their use until quality control tests are completed and lot acceptability is determined?

☐ Yes ☐ No

4.3 Are the rejected lots of components adequately marked or secured so the rejected parts are not used in production unless reworked?

☐ Yes ☐ No

INSTRUCTIONS: Page 11

QUALITY CONTROL REPORT

PART 5.0 - PRODUCTION LINE AND FINAL TESTS

Model Family identification - See the instructions Part 1.1 for explanation.

Part 5.0 must be completed in its entirety for the Quality Control Report only. Any addenda or changes to this Part must be reported as a supplement to the Quality Control Report using the appropriate Part D - Supplement to Product Reports, Quality Control Report or Annual Report.

In Part 5.0, you should summarize quality control and testing procedures necessary to assure compliance of your finished products with the Federal regulations and performance standard 21 CFR 1030.10. DO NOT SUBMIT PROCEDURES FOR NON-RADIATION TESTS.

5.1 - Provide the answer to verify whether the quality control procedures are done.

Use the following codes to indicate where the tests are performed:

NP = not performed,

B = before final assembly, or

A = after final assembly.

"Final" tests are those conducted after assembly is complete. Note: If the procedures in Part 5.1 vary between models or Model Families, provide an attachment labeled 5.1 (behind the form) to explain that certain procedures are done on some models or Model Families and not on others.

5.2 through 5.2.2 - Check the appropriate boxes to answer specific questions concerning the quality control and testing procedures.

PART 5.0 - PRODUCTION LINE AND FINAL TESTS

Model Family (Identify by numbers, letters or symbols):

5.1 QUALITY CONTROL PROCEDURES

General Tests

Door installation and adjustment checks ..... _____

Safety interlocks and monitor continuity functions checks ... _____

RF emission hazard test over waveguide, cavity seams, and magnetron area prior to installing cabinet ..... _____

Amount of door travel before secondary interlock actuation (See 5.5 for details)..... _____

Open door (shut off) operation tests (See 5.4 for details) ... _____

Presence and content of required labels (e.g., certification, identification, service, user)..... _____

RF Emission Tests

Door viewing screen ..... _____

Door perimeter ..... _____

Door perimeter with door pulled out and all safety interlocks operating ..... _____

Door perimeter with door pulled and only secondary interlock operating (See 5.5 for details)..... _____

Door hinge..... _____

Control panel..... _____

Vents and louvers..... _____

Underneath the oven (bottomless or exposed cavity)..... _____

Automated Microwave Oven Scanner (See 5.7 for details)..... _____

5.2 Are the written procedures or diagrams available or posted in the working area for the individual performing the quality control checks?

☐ Yes ☐ No

5.2.1 Are repaired or adjusted units returned to the assembly line at a point prior to the test that caused their rejection?

☐ Yes ☐ No

5.2.2 Are all repaired or adjusted units, regardless of the nature of the repair, returned to the assembly line for the open door operation test and the final RF leakage tests?

☐ Yes ☐ No

QUALITY CONTROL REPORT

PART 5.0 - PRODUCTION LINE AND FINAL TESTS

Model Family identification - See the instructions Part 1.1 for explanation.

5.3 - Submit copies of written quality control test procedures for testing continuity of safety interlocks and monitor switches and all associated wiring. These should include the following:

A - A brief outline of the procedures for function tests of each interlock switch (primary and secondary) and monitor. Also describe electrical continuity checks of each switch along with as much related wiring as possible.
B - A sample schematic with test points identified.
C - A list of instruments and test equipment and a description of preoperational checks. Describe any special testing apparatus or devices.

5.4 - Submit a copy of the written quality control test procedures for performing open door tests on every fully assembled oven. An open door operation test procedure is an excellent quality control test to prevent any oven that will operate with the door open from being introduced into commerce. The test should include a check that operation ceases when the door is opened and an attempt to restart the oven while the door is unlatched. Any signs of microwave power can be monitored by either an ammeter or RF emission. The restart check should be done with the oven both programmed, and not programmed, for operation for electronic controller ovens; with and without time on the timer for electromechanical timer ovens.

NOTE: ONLY ONE COPY OF THESE WRITTEN QUALITY CONTROL PROCEDURES REQUESTED IN PARTS 5.4 AND 5.5 SHOULD BE FILED IN THE QUALITY CONTROL REPORT. IF DIFFERENT TEST POINTS ARE USED FOR CONTINUITY CHECK OF SUBSEQUENT PRODUCTION MODELS, THESE NEW TEST POINTS ON THE SCHEMATIC CAN BE REPORTED IN PART 1.7.16.

5.5 - This part requests written quality control procedures for assessing the performance of secondary interlock designs that interrupt power to the oven (interlock actuates) <u>after</u> the door starts to move. These quality control tests assure that this secondary safety interlock will "prevent microwave radiation in excess of 5 milliwatts per square centimeter at any point 5 centimeters or more from the external surface of the oven," as stated in 21 CFR 1030.10(c)(2)(v). If the oven design employs a latch-actuated secondary interlock that interrupts power to the oven before there is outward door movement, this part is not required.

5.6 - Provide any internal quality control documents that describe procedures for the repair and retesting of defective ovens. These should include at least the following information:

A - A description of all quality control checks done on the repaired or adjusted ovens, e.g., hazard RF emission, electrical continuity of safety interlocks and monitor, and tests of any other radiation safety components required to confirm proper operation.
B - A description of how all ovens set aside for repair and/or adjustment re-enter the production line.
C - A sample of the record or form used to retain the model, serial number, nature of defect and repair, and the results of all retesting conducted.

PART 5.0 - PRODUCTION LINE AND FINAL TESTS

Model Family (Identify by numbers, letters or symbols):

5.3 ☐ Written quality control test procedures for testing continuity of safety interlocks and monitor switches are enclosed behind this page and labeled Attachment 5.3.

5.4 ☐ Written quality control test procedures for performing open door restart operation are enclosed behind this page and labeled Attachment 5.4.

5.5 ☐ (If applicable) Written quality control procedures for assessing the performance of the secondary interlock are enclosed behind this page and labeled Attachment 5.5.

5.6 ☐ Written internal quality control documents that describe the procedures for repair and retesting of defective ovens found during production are enclosed behind this page and labeled Attachment 5.6.

QUALITY CONTROL REPORT

PART 5.0 - PRODUCTION LINE AND FINAL TESTS

Part 5.7 requests copies of procedures and forms for recording final RF emission testing of fully assembled microwave ovens. If tests are conducted on a 100 percent basis, so state. If the tests are based on a sampling plan, provide a description of the sampling plan.

Provide the identification of the Model Family (i.e., numbers, letters, or symbols known by your quality control personnel). If more than one Model Family is tested using exactly the same final RF emission testing procedures, use one form and list or identify all such Model Families. If other Model Families use different final RF emission testing procedures, additional forms must be completed.

5.7.1 - Submit an attachment of written final RF emission measurement procedures (both hand-held and automated), including at least the following information:

5.7.1 - A: Physical and electrical conditions under which tests are made (e.g., line voltage, test load, test load placement, test load temperature, turntable rotation, power on/off, full power setting, door open, door pulled, door closed, secondary interlock only RF emission test).

5.7.1 - B: Adjustments, if any, made during the test and specific procedures and criteria for making adjustments.

5.7.1 - C: Instruments and test equipment used to make each test, including preoperational instrument checks and descriptions of any special testing apparatus or devices such as door shims or door pull device.

5.7.1 - D: Description of microwave emission measurement procedures, including survey meter scanning techniques, surfaces and areas surveyed for RF leakage, scanning speed and type of spacer probes used to maintain constant distance from oven surface.

5.7.1 - E: RF reject limit and its basis, such as instrument manufacturer's assessment of calibration error, stirrer modulation effects, turntable modulation effects, scan speed.

5.7.2 - Provide a sample copy of the record used to retain the results of final emission tests. If automated microwave oven scanners (AMOS) are used, include samples for both hand-held testing and AMOS testing for each brand of AMOS.

5.7.3 - This part allows the attachment of a flowchart diagram of the production line(s) describing the quality control stations, final test areas, repair bays and audit testing areas.

PART 5.0 - PRODUCTION LINE AND FINAL TESTS

5.7 FINAL RF EMISSION TESTING OF FULLY ASSEMBLED MICROWAVE OVENS

Model Family (Identify by numbers, letters or symbols):

5.7.1 ☐ Written final RF emission test procedures are enclosed behind this page and labeled Attachments 5.7.1 A through E.

- A - Physical/Electrical Conditions
- B - Adjustments
- C - Instruments
- D - Measurement Procedures
- E - Reject Limit

5.7.2 ☐ A sample copy of the record(s) used to retain the results of final RF emission tests is enclosed behind this page and labeled Attachment 5.7.2.

5.7.3 ☐ A diagram of the flow chart of production line(s) describing the quality control stations, final test areas, repair bays and audit testing area is enclosed behind this page and labeled Attachment 5.7.3.

QUALITY CONTROL REPORT

PART 5.0 - PRODUCTION LINE AND FINAL TESTS

5.7 FINAL RF EMISSION TESTING OF FULLY ASSEMBLED MICROWAVE OVENS

5.7.4 If applicable, identify each Model Family whose RF emission levels are evaluated by an automated microwave oven scanner.

Example:

Model Family	AMOS Brand and Serial Number
AB	XYZ, #1
CD	XYZ, #1 JKL, #256

5.7.5 - The engineering and statistical analysis report(s) required to qualify each AMOS for use are submitted in a separate instrumentation report which is not part of the Guide for Preparing Reports on Radiation Safety of Microwave Ovens. List the Accession Number(s) of the report(s) for reference purposes only.

5.7.6 - Provide a copy of the user manual for each AMOS brand. Also, provide a copy of the service manual and any additional maintenance instructions and records needed to maintain the scanner in proper working order.

5.7.7 - Other quality control information on each AMOS brand is needed in Parts 5.7.1, 5.7.2, 6.3, 6.4, 6.5, 8.2, and 8.3.

PART 5.0 - PRODUCTION LINE AND FINAL TESTS

5.7 FINAL RF EMISSION TESTING OF FULLY ASSEMBLED MICROWAVE OVENS

5.7.4 Automated Microwave Oven Scanner (AMOS) Testing

Model Family (Identify by numbers, letters or symbols)	AMOS Brand and Serial Number

5.7.5 Accession Number(s) of the automated microwave oven scanner engineering and statistical analysis report(s) filed with CDRH: _____, _____.

5.7.6 ☐ Attachment 5.7.6 - Information on the use and maintenance of the AMOS is enclosed behind this page and labeled Attachment 5.7.6.

5.7.7 Is the quality control information provided to CDRH current for each AMOS brand?

☐ Yes

☐ No. Updated information is provided in Parts 5.7.1, 5.7.2, 6.3, 6.4, 6.5, 8.2, and 8.3.

QUALITY CONTROL REPORT

PART 6.0 - QUALITY AUDIT

Model Family identification - See the instructions Part 1.1 for explanation.

Part 6.0 must be completed in its entirety for the Quality Control Report only. Any addendums or changes to this Part must be reported as a supplement to the Quality Control Report using the appropriate Part D - Supplement to Product Reports, Quality Control Report or Annual Report.

Summarize all applicable quality control and testing procedures conducted on a sampling basis or audit basis after the completion of final quality control checks on the production line.

6.1 - For each quality control procedure listed, fill in the appropriate sampling rate, or use the notation, "NP" to indicate that this procedure is not performed in audit. Your sampling rate answer can be similar to any of the following examples: (units per lot), e.g., "20/1000;" (percentage of today's production), e.g., "10%;" (units per quarter), e.g., "5/quarter;" (units per year), e.g., "4/year;" or (not performed), i.e., "NP."

6.2 - Check the appropriate box to indicate the availability of the written quality control procedures to the audit personnel.

6.3 - Provide a sample copy of the oven audit record used to retain the results of the quality control checks in audit including the reject limit value for RF emission. If an AMOS (See Part 5.7) is used, include the scanner audit record also.

6.4 - Provide a sample copy of the internal quality control document that contains all oven and scanner audit procedures. Include all the equivalent information requested in Part 5.7.1.

6.5 - Provide a sample copy of the internal quality control document that contains the audit corrective action plan that would be followed should any ovens selected for oven audit testing fail to meet the audit test criteria. If an AMOS (See Part 5.7) is used, also provide a copy of the scanner audit reaction plan. The description of the audit reaction plans should include at least the following information:

A. Classification of radiation safety and compliance defects such as excessive RF emission, safety interlocks and monitor not performing their intended functions, open door operation, absence of required labels, etc., and their rejection criteria.

B. Plan of action following audit failure, including any resampling.

C. Sample of document, or record used, to retain test results from corrective action plan including: type of compliance related defect, sample size, selection, and corrective action or decision taken by supervisory audit personnel.

PART 6.0 - QUALITY AUDIT

Model Family: (Identify by numbers, letters or symbols):

6.1 QUALITY CONTROL PROCEDURES CONDUCTED IN AUDIT

	SAMPLING RATE
Safety interlocks and monitor continuity function checks.	_____
RF emission hazard test over waveguide, cavity seams, and magnetron area prior to installing cabinet.....	_____
Check for amount of door travel before secondary interlock actuation (See 5.5 for details).....	_____
Open door (restart) operation test (See 5.4 for details)..	_____
Insertion test by finger or wire into concealed safety interlock(s) and cavity.....	_____
Check for presence of required labels (e.g. certification, identification, service caution).....	_____
Check for required precaution statements in user and service manuals.....	_____

RF EMISSION TESTS

Door viewing screen.....	_____
Door perimeter.....	_____
Door perimeter with door pulled and all safety interlocks operating.....	_____
Door perimeter with door pulled and only secondary interlock operating (See 5.5 for details).....	_____
Door hinge.....	_____
Control panel.....	_____
Vents and louvers.....	_____
Underneath the oven (bottomless or exposed cavity).....	_____
Automated Microwave Oven Scanner (See 5.7 for details)....	_____

6.2 Are the written procedures or diagrams available or posted in the working area for the individuals performing the quality control checks?

☐ Yes ☐ No

6.3 ☐ A sample copy of the record used to retain the results of the quality control checks in audit is enclosed behind this page and labeled Attachment 6.3.

6.4 ☐ Quality control documents containing the audit program are enclosed behind this page and labeled Attachment 6.4.

6.5 ☐ Quality control documents containing the audit corrective action plan are enclosed behind this page and labeled Attachment 6.5.

INSTRUCTIONS: Page 16

QUALITY CONTROL REPORT

PART 7.0 - LIFE AND ENDURANCE TESTING

Model Family identification - See the instructions Part 1.1 for explanation.

Part 7.0 must be completed in its entirety for the Quality Control Report only. Any addenda or changes to this Part must be reported as a supplement to the Quality Control Report using the appropriate Part D - Supplement to Product Reports, Quality Control Report or Annual Report.

This Part relates to all applicable life and endurance test procedures to determine the ability of the oven and its subsequent model family to comply with the Federal performance standard throughout its normal useful life.

7.1 - Fill in and check off blank spaces where indicated to summarize the life and endurance test procedures conducted on domestic and commercial ovens. If no such procedure is performed, use the notation "NP."

7.2 - Provide a sample of the record used to retain results of life and endurance tests.

PART 7.0 - LIFE AND ENDURANCE TESTING

Model Family (Identify by numbers, letters or symbols):

7.1 TEST CRITERIA

	SHORT TERM	LONG TERM
Selection Criteria (Check all applicable)	_____ Model Family	_____ Model Family
	_____ Model Number	_____ Model Number
Number Tested (Fill in quantity)	_____ Per Week	_____ Per Week
	_____ Per Month	_____ Per Month
	_____ Per Quarter	_____ Per Quarter
Test Length (Fill in quantity)	_____ Cycles	_____ Cycles
RF Leakage Tests	_____ Start of test	_____ Start of test
(Check and fill in quantity)	_____ Every _____ cycles	____ Every ____ cycles
	_____ End of test	_____ End of test
RF Emission Reject Limit	_____ mW/cm^2	_____ mW/cm^2
Interlock/Monitor Continuity Checks (Check and fill in quantity)	_____ Start of test	_____ Start of test
	_____ Every ____ cycles	_____ Every ____ cycles
	_____ End of test	_____ End of test
Active Monitor Check at End of Test (Check)	_____ Yes	_____ Yes
	_____ No	_____ No

7.2 ☐ A sample of the record used to retain results of life and endurance tests is enclosed behind this page and labeled Attachment 7.2.

INSTRUCTIONS: Page 17

QUALITY CONTROL REPORT

PART 8.0 - INSTRUMENTATION AND CALIBRATION CHECKS

Part 8.0 must be completed in its entirety for the Quality Control Report only. Any addenda or changes to this Section should be reported as a supplement to the Quality Control Report using the appropriate Part D - Supplement to Product Reports, Quality Control Report or Annual Report.

Part 8.0 contains corresponding forms with fill in the blanks and check boxes concerning the microwave test instrumentation and calibration constancy program. Manufacturers must use properly calibrated microwave leakage measurement instruments in their production and audit testing, and quality control programs to assure compliance with the Federal Performance Standard for Microwave Ovens, 21 CFR 1030.10. This Part is divided into 6 major segments as follows:

1. Type of microwave test instruments and their measurement errors
2. Daily checks and recordkeeping
3. Thirty-day calibration constancy checks and recordkeeping
4. Repair of survey instruments and calibration instruments
5. Annual calibration and periodic calibration

8.1 through 8.2.4 - Fill in the information requested, check the appropriate boxes, and provide attachments where indicated. If certain subsections cannot be answered or are not applicable to the manufacturer's instrumentation program, use the notation "N.A." for not applicable.

PART 8.0 - INSTRUMENTATION AND CALIBRATION CHECKS

8.1 MICROWAVE TEST INSTRUMENTS (Type and quantity):

	Manufacturer Name/Model Number	Quantity
8.1.1 Production department	_____	_____
	_____	_____
	_____	_____
	_____	_____
8.1.2 Engineering department	_____	_____
	_____	_____
8.1.3 Audit department	_____	_____
	_____	_____

8.2 DAILY CHECK

8.2.1 Is a preoperational check made on each RF survey instrument in accordance with the instrument manufacturer's recommendation?

☐ Yes ☐ No

8.2.2 Is a polarization ellipse check performed on each instrument each day the instrument is used for compliance measurement?

☐ Yes ☐ No

8.2.3 Is the following formula used to calculate the percent of polarization ellipticity of each instrument?

$$\frac{\text{MAXIMUM - MINIMUM}}{\text{MEAN}} \times 100 = \_\_\_\_\_ \text{ (\%) total}$$

☐ Yes ☐ No

If No, what formula is used?: _____

8.2.4 For the daily check, specify the maximum allowable polarization ellipticity for each type of compliance instrument:

Survey meter type	Total polarization ellipticity allowed (%)
_____	± % or % total or _____
_____	± % or % total or _____
_____	± % or % total or _____
_____	± % or % total or _____

QUALITY CONTROL REPORT

PART 8.0 - INSTRUMENTATION AND CALIBRATION CHECKS

8.2.5 through 8.3.2 - Fill in the information requested, check the appropriate boxes, and provide attachments where indicated. If certain subsections cannot be answered or are not applicable to the manufacturer's instrumentation program, use the notation "N.A." for not applicable.

If an AMOS is used (see Part 5.7), include in Attachment 8.2.10 a copy of the supervisor test procedure and sample record for each scanner brand.

PART 8.0 - INSTRUMENTATION AND CALIBRATION CHECKS

8.2.5 Is each instrument that is found to exceed the maximum polarization ellipticity limit rejected until the instrument is repaired and recalibrated?

☐ Yes ☐ No

8.2.6 During the daily check, is the spacer cone checked on each survey instrument and replaced if it is worn or dirty?

☐ Yes ☐ No

8.2.7 What type of microwave source instrument (or electrical source, for an AMOS)is used for performing the daily check?

_____

_____

8.2.8 Is the probe holding fixture on the daily check instrument designed to prevent any horizontal, vertical and transverse motion while the probe is being rotated?

☐ Yes ☐ No

8.2.9 Is a daily record used to retain the model number, serial number, probe serial number, date of check, percent polarization ellipticity, entry for accept/reject criteria, and any information on the corrective action to any instrument that exceeds the limit?

☐ Yes ☐ No

8.2.10 ☐ A sample of the daily check record (and a copy of the AMOS procedure, if applicable) is enclosed behind this page and labeled Attachment 8.2.10.

8.3 THIRTY-DAY CONSTANCY CHECK

8.3.1 Instrument Intercomparison System

Manufacturer name and model number: _____

RF source frequency and frequency stability: _____ MHz, ± _____ MHz

RF source amplitude modulation: _____%

Local calibration reference (LCR): (Manufacturer name(s) and model number(s))_____

Radiated power monitor (RPM): (Manufacturer name(s) and model number(s))_____

8.3.2 ☐ The Instrument Intercomparison System is not a commercially available system. Details of the apparatus and procedures used to perform the thirty-day constancy check are enclosed behind this page and labeled Attachment 8.3.2.

QUALITY CONTROL REPORT

PART 8.0 - INSTRUMENTATION AND CALIBRATION CHECKS

8.3.3 through 8.3.9 - Fill in the information requested, check the appropriate boxes, and provide attachments where indicated. If certain subsections cannot be answered or are not applicable to the manufacturer's instrumentation program, use the notation "N.A." for not applicable.

PART 8.0 - INSTRUMENTATION AND CALIBRATION CHECKS

8.3.3 Is a preoperational check made on the LCR in accordance with the instrument manufacturer's recommendation?

☐ Yes ☐ No

8.3.4 Is the initial reference RF field set by adjusting the RF power level (with the LCR probe positioned at the mean of its polarization ellipse) until the LCR is reading 1 mW/cm^2?

☐ Yes ☐ No

8.3.5 A. Which of the following is used to establish the initial reference field (1 mW/cm^2 or other values) within the 30-day constancy check system?

☐ LCR ☐ RPM

B. Which of the following is used to re-establish the reference field (1 mW/cm^2 or other values) for subsequent constancy checks?

☐ LCR ☐ RPM

8.3.6 After the initial reference field (1 mW/cm^2 or other values) is established, does the technician perform the polarization ellipticity of the LCR to determine that it does not exceed the maximum polarization limit specified by the instrument manufacturer?

☐ Yes ☐ No

8.3.7 Is a thirty-day operational log record used to retain the date of the check, LCR polarization ellipticity (minimum, maximum, mean and percentage deviation from mean) and RPM net power readings (RPM difference readings)?

☐ Yes ☐ No

8.3.8 ☐ A sample of the thirty-day operational log record is enclosed behind this page and labeled Attachment 8.3.8.

8.3.9 For whichever instrument is used (LCR or RPM) to re-establish the reference field, are the previous readings for the other instrument compared with the present reading to ensure that they do not differ more than 10 percent (highest to lowest readings between annual LCR calibrations)?

☐ Yes ☐ No

INSTRUCTIONS: Page 20

QUALITY CONTROL REPORT

PART 8.0 - INSTRUMENTATION AND CALIBRATION CHECKS

8.3.10 through 8.3.15 - Fill in the information requested, check the appropriate boxes, and provide attachments where indicated. If certain subsections cannot be answered or are not applicable to the manufacturer's instrumentation program, use the notation "N.A." for not applicable.

If an AMOS is used (see Part 5.7), include in Attachment 8.3.13 a copy of the 30-day check procedures for each AMOS.

PART 8.0 - INSTRUMENTATION AND CALIBRATION CHECKS

8.3.10 After the reference field is reset, is the polarization ellipticity of each compliance instrument including the LCR shown not to exceed the maximum polarization ellipticity limit specified by the instrument manufacturer?

☐ Yes ☐ No

8.3.11 After all the compliance instruments have been checked, does the calibration technician perform a self-comparison check for all similar compliance instruments including the LCR by reviewing or plotting on a graph all of the minimum and maximum polarization readings since the last annual LCR calibration to ensure that the LOWEST minimum reading does not differ from the HIGHEST maximum reading by more than 2 dB?

☐ Yes ☐ No

8.3.12 Is a 30-day check record maintained including the model number, probe serial number, date of check, LCR and RPM readings, instrument polarization readings, accept/reject criteria, and repair history for each compliance survey instrument?

☐ Yes ☐ No

8.3.13 ☐ A copy of the 30-day record (and the AMOS procedure(s), if applicable) is enclosed behind this page and labeled Attachment 8.3.13.

8.3.14 Does the technician maintain a graph plotting the historical mean average values of each compliance instruments (including the LCR) to ensure that the instrument's mean values will be within ±5% of its historical mean average values?

☐ Yes ☐ No

8.3.15 ☐ Attachment 8.3.15 - A sample graph or form used to record the instrument's historical mean average values is enclosed behind this page and labeled Attachment 8.3.15.

INSTRUCTIONS: Page 21

QUALITY CONTROL REPORT

PART 8.0 - INSTRUMENTATION AND CALIBRATION CHECKS

8.4.1 through 8.5.2 - Fill in the information requested, check the appropriate boxes, and provide attachments where indicated. If certain subsections cannot be answered or are not applicable to the manufacturer's instrumentation program, use the notation "N.A." for not applicable.

PART 8.0 - INSTRUMENTATION AND CALIBRATION CHECKS

8.4 REPAIR OF SURVEY AND CALIBRATION INSTRUMENTS

8.4.1 Repair and re-calibration of the microwave survey compliance instruments are performed by the following firm(s):

_____

_____

8.4.2 ☐ A copy of written procedures for having instruments repaired and re-calibrated is enclosed behind this page and labeled Attachment 8.4.2.

8.4.3 Repair and re-calibration of the LCR, RPM, and any other 30-day calibration instruments are performed by the following firm(s):

_____

_____

8.4.4 Each time the LCR or RPM is sent out for calibration or repair, do you begin all of your instrumentation records anew?

☐ Yes ☐ No

8.5 ANNUAL CALIBRATION AND PERIODIC CALIBRATION

8.5.1 Are the LCR and RPM instruments returned to the instrument manufacturer or other qualified calibration facility for annual calibration?

☐ Yes ☐ No

8.5.2 Are the compliance survey instruments returned to the instrumentation manufacturer or other qualified calibration facility for calibration periodically (at least once every 3 years) unless they have been sent out for repair and calibration?

☐ Yes. The frequency of the periodic calibration is _____.

☐ No, for the following reason(s):_____

_____

_____

INSTRUCTIONS: Page 22

QUALITY CONTROL REPORT

PART 9.0 - RECORDKEEPING

Part 9.0 must be completed in its entirety for the Quality Control Report only. Any addenda or changes to this Part should be reported as a supplement to the Quality Control Report using the appropriate Part D - Supplement to Product Reports, Quality Control Report or Annual Report.

Part 9.0 requests confirmation that the manufacturer is maintaining records as required by 21 CFR 1002.30. These records basically consist of:

A - Written quality control procedures

B - Quality control test results

C - Life and endurance test results

D - Copies of written communication between the manufacturer and dealers, distributors and purchasers concerning radiation safety

E - Dealer, distributor, and purchaser shipment records

PART 9.0 - RECORDKEEPING

9.1 Are records maintained for the results of tests for the electronic product radiation safety, including: control of unnecessary secondary or product leakage radiation, the methods, devices, and procedures used in such tests, and the basis for selecting such methods, devices and procedures?

☐ Yes ☐ No

9.2 Are records maintained of tests for durability and stability of the product?

☐ Yes ☐ No

9.3 Are the results of quality control tests conducted on the production line kept for a minimum of one year after filing the annual report for these records?

☐ Yes ☐ No

9.4 Are the quality control audit records, documentation of defective ovens found in audit, and results of audit reaction plan kept for a minimum of five years?

☐ Yes ☐ No

9.5 Is a file maintained of all written communications between the manufacturer, dealers, distributors, and purchasers concerning radiation safety including complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintainence or testing of the microwave oven manufactured by your company?

☐ Yes. The file is located at:_____

☐ No

9.6 Is a file maintained of records necessary for the tracing of microwave ovens to distributors, dealers, and purchasers?

☐ Yes ☐ No

9.7 Have all the dealers and distributors been informed of their obligations or requirements to obtain the information required by 21 CFR 1002.4(b) (purchaser information) in order to permit tracing of specific products to specific purchasers?

☐ Yes ☐ No

9.8 Manufacturer can trace shipment to dealers/distributors or purchasers by:

☐ Model Number ☐ Serial Number ☐ Date of Manufacture

☐ Other; specify: _____

INSTRUCTIONS: Page 23

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 10.1a, 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.

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: Page 24

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.)

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		Door Condition	Leakage Measurements		No. of Interlock Failures			No. of Units Rejected
	Produced	Sampled		Mean	Std. Dev.	Primary	Secondary	Monitor	

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.

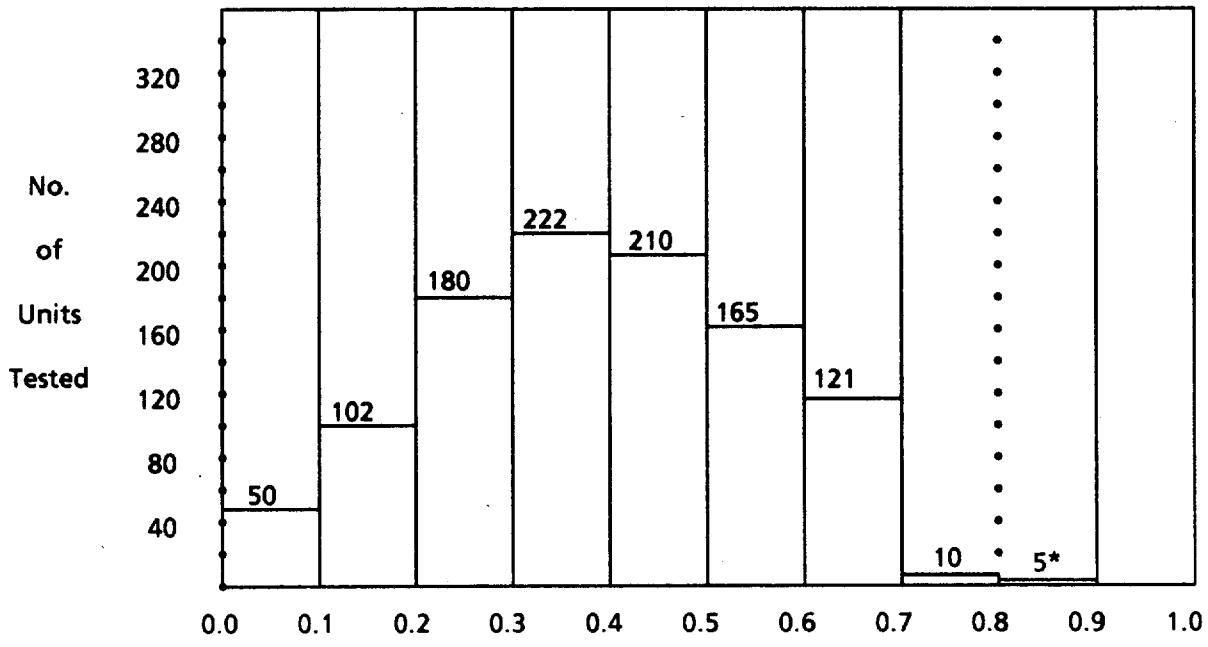
Above each graph, check the appropriate door condition; at the bottom, indicate the model family designation. Label the side of the graph to show the number of units tested; label the bottom to show the upper limit of each range of measurement. Then draw in the bars to represent the distribution of measurements,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

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 _____

_____

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 communications 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.

PART 10.0 - YEARLY SUMMARY

10.3.3 Results of Endurance Testing

Model No.	Door Condition	Before Test	During Test		After Test		No. of Cycles at Failure
		Maximum Leakage	Maximum Leakage	No. of Cycles	Maximum Leakage	No. of Cycles	

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:_____.

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 interlocks(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.

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, August, 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: _____

_____