Submission Report

eRadHealth Menu

Introduction

Electronic Product Radiation Safety Reporting Form

This software application is intended to automate the hard copy product reporting forms in the effort of the Center for Devices and Radiological Health (CDRH) to become capable of accepting electronic submissions from industry and to improve our review process. This FDA Electronic Submission (eSub) software is the next version of the application developed to allow us to accept all Radiological Health reports and other submissions electronically and improve the ability of CDRH to accomplish its mandated product and industry evaluations in a timely and efficient manner.

All electronic reports and correspondence can either be transferred to CD and mailed to the address below, or can be sent via the FDA Electronic Submissions Gateway to CDRH. If you follow instructions to set up an account with the FDA Gateway, it currently may take several weeks,, but when you submit through it you will receive your acknowledgement email message with Accession Number within minutes! Or, in the interest of faster turn-around for a one-time urgent report of if you submit few reports, you may simply fill out this template creating the submission and then at 'Packaging' follow the instructions to transfer the files to a CD to mail in. This method of submitting your report will be acknowledged by an email with the Accession Number within several days.

Information about the FDA Electronic Submissions Gateway can be found at **www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm**. Please contact the Gateway Helpdesk with your questions about that system.

Electronic submissions on CD should be mailed directly to the Document Control Center at:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Attn: eSubmitter Team
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submissions received in the mail on CD will be processed within a few days of receipt.

Note about eSubmitter software:

Instructions provided in this software briefly summarize the requirements of the regulations under the Federal Food, Drug and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product

Radiation Control, that applies to manufacturers of electronic products that emit radiation. The software provides questions relevant to requirements in the performance standards and may include explanations or clarification about the performance, labeling, and informational requirements of the standard. It does not replace the regulations, however, and if there is any conflict between the software and the regulations, the regulations must prevail. Throughout this application, pertinent sections of Title 21, Code of Federal Regulations, Chapter I, Subchapter J, are cited in parentheses. Please consult them before making design or procedural decisions.

Regulatory requirements for radiological products can be found at **http://www.fda.gov/Radiation-EmittingProducts/default.htm** and for medical devices are located at **www.fda.gov/M/devaDvices/default.htm**. If you have specific questions about the regulations, please contact us at: **DSMICA@fda.hhs.gov**.

If you have specific questions regarding this software, please contact the eSub team by email at: **eSubmitter@fda.hhs.gov**.

Thank you for using our electronic product reporting software. Please communicate your comments and suggestions to the eSub team as often as you like.

Thank you for your continued support of the FDA Electronic Submission Program (eSub).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0025 (expires January 31, 2017).

Role

What is your role?	!*	Manufacturer

Information:	*The following screen provides several options for you to accurately define what type of eSubmission you intend to create for FDA. Below are explanations of your options. Please feel free to review this screen, advance to the next screen and view the picklists, but if you're confused, come back to read this screen again to be certain you are selecting the correct report or correspondence type you want to create.*

Submission Information

Step 1	**Use the radio buttons to identify the type of submission you are preparing. (Supplements should be prepared using the same document type as the original submission.)**

What Type of Submission is this? (Supplements should be submitted selecting the same document type as the original report.)	!*	(•) Radiation Safety Report (Product) Report (21 CFR 1002.10) ( ) Annual Report (21 CFR 1002.13) ( ) Laser Light Show Documents (all relevant documents) (21 CFR 1040.11(c)) ( ) Correspondence

	( ) Variance Request (General, not Laser Light Show) (21 CFR 1010.4) ( ) Laser Original Equipment/Component Manufacturer Registration (21 CFR 1040.10(a)(3)(ii)) ( ) Abbreviated Report (21 CFR 1002.12)

Step 2	**After answering the Submission Type question above, one of the questions below may become active and required (see the blue dot to the right of the question). If there is an active question, select the appropriate product area or document type from the question's pick list.**
What Type of Product is this Radiation Safety Report about? **!***	
Microwave Oven Products	
What Type of Product is this Annual Report about?	
What Laser Light Show Document are you filing?	
What Type of Correspondence is this?	
What Type of Product is this Variance Request about?	

Manufacturer Data

Manufacturer Responsible for Product Compliance

Note:	*This is the firm that takes responsibility for certification that the product meets the performance standard. This firm develops and maintains the quality control and testing program that is the basis for the certification of this product. Additionally, this firm usually is the owner of the product design and manufacturing process design.* *Be sure to enter address information for each tab below:*

Select the Manufacturer's address from the Establishment Address book: *	
Establishment Information:	
Establishment Name	
Division Name	
Home Page	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	

Responsible Individual

Note:	*The responsible individual is the highest level and most responsible individual affiliated with this establishment.*

Select the Responsible Individual from the Contact Address book: *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	

Mailing Location:	
Address	
Telephone Number	
Fax Number	

Manufacturer's Reporting Official

Note:	*This is the person at the manufacturing facility that is knowledgeable and responsible for addressing all aspects of the testing and quality control procedures for certification as reported to FDA in the product report. Documentation of changes intesting and quality control procedures submitted to FDA must be signed by this individual.*

Select the Reporting Official from Contact Address book: *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	

Report Submitter

Note:	*The submitter may be a consulting individual or firm providing assistance in report preparation and maintenance. Documents or submissions such as this one that are prepared by the submitter must have an accompanying authorization letter from the manufacturer's reporting official for authenticity.*

Select the Submitter from the Contact Address book: *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	

Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	
Comments:	

Internal Reference Number:	

Parent Establishment

Is there a parent establishment? *	

Select the Parent Establishment and Contact from the Contact Address book:	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	

Manufacturer Designated United States Agent

Note:	*Manufacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005.25.*

Is there a United States agent that has been designated by the manufacturer? *	

Importer

Additional Manufacturing Locations

Product Data

Product and Model Identification

Attention - Information about this section

In this section you'll be asked to identify several required or optional things which will help FDA/CDRH staff to prioritize their reviews. You'll be asked to consider the following aspects:

(1) Identify your product's radiation type and the CDRH Product Code.

(2) Enter an Accession number if this will be a report supplment. If you are preparing a supplement, you'll see that after entering a valid 7-digit Accession number many questions will no longer be required (they will either be disabled or will be optional, meaning they will no longer have the blue dot).

(3) You will also have several questions that are of high significance for FDA/CDRH - why you might be submitting this report or correspondence. Please read these questions carefully, referring to the 21 CFR regulations on the website www.FDA.gov if you are unsure if the question is relevant to your firm's situation.

(4) If you find that you have more information that you want the FDA/CDRH to read but it doesn't seem to fit under other questions, we have a final "***Additional Information***" question in this section which invites you to add comments and/or attach a file that provides further information from your firm about this submission. This is the place to add that extra information.

Product Type Reported

What is the product code? *

To select the three letter product code,

- Click the plus sign. You will see a product code filter dialog box.
- Select the appropriate category name from the pick list. You will be provided a list of product codes from which to choose.
- Select the best match to your product.
- The remaining fields will be filled in for you when you select your product code.

Category	
Product Code	
Performance Standard	

If Other, provide a category name for this specific product.

Report Information

Is this the first time you've submitted a report on the particular type of product selected in the Product Type Reported section? *	
Since this is not the first time you've reported on this type of product, then is this a report supplement to a previously reported model family?	
Provide the Accession Number of the original report for which this is a supplement: (Note: Do not enter any Device Premarket Application or Notification document number here, such as PMAs, 510(k)s, IDEs, etc. See Accession number description below.)	

Are you requesting a new variance, a renewal, extension or amendment to a previous variance? *	
Stop:	*If you are requesting a new variance, renewal, extension, or amendment, you must file a Variance Request separate from this report. To do this, open a new report (File > New) and select either "Laser Light Show Variance Request" or "Variance Request (General, not Laser Light Show)" as your Type of Submission in the Submission Information Screen. If you select "Variance Request (General, not Laser Light Show)r" you must select the product for which you are requesting a variance with the pick list in the bottom section of the screen.*

Special Considerations

Information:	*If this product will require a formally approved Variance from a certain performance requirement, you will need to complete two Reports for FDA, both (1) this Radiation Safety Report (RSR) on this product, and (2) a Variance Request report. This eSubmitter software application package includes a general Variance Request form as well as the specific Laser Light Show Variance Request form. Both the Product RSR file and the appropriate Variance Request Correspondence file must be submitted to CDRH following the regular files packaging procedures in this application. Both may be transferred to the same CD or submitted via the FDA ESG to submit to the FDA/CDRH.* *In addition, any Variance Request form must be printed out and the signed hard-copy sent to FDA's Division of Dockets Management at:* *Division of Dockets Management (HFA-305)* *Food and Drug Administration* *5630 Fishers Lane* *Rockville, MD 20852* *NOTE: There is no need to send a copy of the CD to Division of Dockets Management.*

Noncompliances or Defects

Does this document or any of its attachments contain:	
A notification of noncompliance or defect? *	
You may provide an explanation and/or attach a document here:	
Details	

Responses to Noncompliances or Defects

Does this document or any of its attachments contain any of these responses concerning noncompliances or defects?	
A refutation of noncompliances or defects identified to your firm? *	
A request for an exemption from notification to purchasers (see 21 CFR 1003.21 and 1003.30)? *	
Corrective action plans you intend to implement to correct noncompliances or defects discovered in past or current production? *	
Note:	*If you are submitting a Corrective Action Plan (CAP) following 21 CFR 1004 and information on design changes for future production, the design change information must be submitted in a Radiation Safety (Product) Report or supplemental report. Both the proposed CAP and the design changes may be submitted in one document if you prepare a product report and choose to include the CAP in it as a file attachment. Alternatively, you may create a separate eSubmission for the CAP using the "Correspondence" type template and selecting "Follow-up correspondence to FDA."*
A description of any design changes that correct noncompliances for future production? *	
Note:	*If you are submitting information on product design changes for future production due to a discovery of noncompliances or defects in current production, you must use the Radiation Safety (Product) Report template to create the report . Correspondence templates may be used to submit other information such as a proposed corrective action plan pertaining to a noncompliance or defect.*
You may add an explanation and/or attach a document here:	
Details	

Exemption Requests

Does this document or any of its attachments contain:	
Exemption of a product for government use from a standard (21 CFR 1010.5)? *	
Exemption for products for government use from reporting and recordkeeping (21 CFR 1002.51)? *	
Special exemption of products from reporting and/or recordkeeping (21 CFR 1002.50)? *	
Request for approval of alternate labeling? *	
Application for alternate test procedures (21 CFR 1010.13)? *	
You may provide an explanation and/or attach any relevant documents here:	

Variance Requests

Information:	*Please note: in addition to responding to these questions below, a separate General Variance Request or Laser Light Show Variance Request form must be completed and submitted to CDRH, with a hard copy sent to FDA's Division of Dockets Management as instructed below for any variance request. The information requested on this screen does not constitute the full structured content of the variance request. The 2 types of Variance forms can be created in eSubmitter by selecting the appropriate Variance submission type under the eRad Health Menu section of this application.*

Message:	*Click the plus sign to list the requirements from which you are requesting a variance.*
This submission includes an application for a variance from certain requirements.	
Item	No Information Provided.
Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.	
Details	
Stop:	*For all Variance requests, two submissions must be made to the FDA.* *The electronic version should be submitted following the Packaging Files for Submission instructions located under Output in the Menu bar, and explained in subsection 4.3 of the User Manual. If sending a CD & submittal letter, please mail to:* *U.S. Food and Drug Administration* *Center for Devices and Radiological Health* *Attn: eSubmitter Team* *Document Mail Center - WO66-0609* *10903 New Hampshire Avenue* *Silver Spring, MD 20993-0002* *Additionally, a paper version (hard-copy) of the signed Variance request document should be submitted to:* *Food and Drug Administration* *Division of Dockets Management (HFA-305)* *5630 Fishers Lane, Room 1061* *Rockville, MD 20857*

Responses to Communications from FDA

Does this document or any of its attachments contain:		
A response to an FDA inspection?	*	
What was the date of the inspection?		
A response to a Warning letter or a Notification of Noncompliance or Defect from the FDA?	*	
What was the date of the Warning Letter or other notification letter?		
A response to a report review inquiry from the CDRH (the inquiry may have been in the form of a letter, email, or phone call)?	*	
What was the date of the inquiry?		
A response to any other communication from FDA?	*	
What was the date of the communication?		
Provide an explanation:		

Additional Information

Here's your opportunity to add anything else to this submission that you want to tell the FDA!

Is there any other relevant information or additional comments that would help expedite the review of this submission? Click the plus sign below to attach any supporting files.	
Details	

Private Labeling

Is the product sold by other companies under different brand names? *	

Medical Devices

Provide the premarket 510(k), IDE, HDE, PDP, or PMA filing numbers related to this medical product, if one of these numbers has been assigned by FDA yet.

If it has not been submitted yet, or if your device is exempt from premarket clearance or approval, please provide an explanation. The device regulations can be found in 21 CFR 807 - device manufacturer registration and device listing.

Microwave Oven Product

Part 1.0 Model Designation and Specifications

1.1 Identification of Model Family

Provide an identification of a Model Family (Identify by numbers, letters, symbols, or any generic family name that would represent the models to be listed). *	
Enter Model designation. *	
Item	No Information Provided.
If you use code for the brand name, please attach a list providing the complete address for each importer or distributor of each brand and identify the codes used.	
Details	

1.2 Magnetron and Waveguide

Please provide photographs and/or engineering diagrams of the waveguide. *	
Details	

1.3 Mode Stirrer or Equivalent Devices

1.4 Insertion

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? *	
Warning:	*If you answered yes, your product does not comply with the wire insertion requirement. Please review the requirement in 21 CFR 1030.10(c)(2)(iv).*
Attach clearly labeled photographs or engineering diagrams which show all external surfaces of a fully assembled oven. Adequate illustrations should 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. *	
Details	

1.5 Exposed Welds or Seams of the Cavity

Are there any exposed welds or seams of the cavity on the fully assembled oven (such as bottom of oven)? *	
Attach clearly labeled photographs or engineering diagrams which show the entire surface of the fully assembled oven (including underneath). *	
Details	

1.6 Oven Door

1.7 Safety Interlocks and Monitor System

1.8 Other Requirements

Can a failure of any single mechanical or electrical component of the microwave oven cause all safety interlocks to be inoperative? [21 CFR 1030.10(c)(2)(ii)]	*	
is there any additional component in the monitor circuit, such as a relay which can disrupt or prevent the function of the monitor system? [21 CFR 1030.10(c)(2)(v)]	*	
Can interlock failures distrupt the monitoring functions? [21 CFR 1030.10(c)(2)(v)]	*	

Attach schematic and wiring diagram for each model or Model Family. Be sure the required safety interlocks and monitor are clearly labeled or identified in the schematic or wiring diagram. *	
Details	

Attach an explanation of how the monitor system works when the safety interlock(s) fail(s) to perform its (their) required function(s). Be sure to explain the sequence of operation when safety interlock(s) fail(s). *	
Details	

1.9 Attachments

Attach photographs or engineering diagrams of safety interlocks, monitor and support brackets. *	
Details	

Attach photographs or engineering diagram of latches (external and internal) in relation to the safety interlocks and monitor. Be sure to show dimensions of access areas where the latches enter to actuate the safety intelocks and monitor. *	
Details	

Attach photographs or engineering diagrams of concealed safety interlock(s) to show how it (they) cannot be activated by a small child's finger or a straight wire (10 cm in length). Please include dimensions. *	
Details	

Part 2.0 Labeling Requirements

Information:	*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 Subchapter J," or* *2. "This product 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 to CDRH (as a supplement to the annual report).* *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 elecit 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 elecit 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 working of the service caution label is specified in 21 CFR 1030.10(c)(6)(ii)* *21 CFR 1030.10(c)(4) - User instructions or manual - For each model family, submit a representative draft 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 specified in 21 CFR 1030.10(c)(4).* *21 CFR 1030.10(c)(5) - Service Instructions or manual - For each model family, submit a representative draft or final sample of the service manual. The service manual 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 in 21 CFR 1030.10(c)(5).*

2.1 Labels and Radiation Warnings

Certification label [21 CFR 1010.2]: Describe location of the certification label on the product *	
Is the label permanent and legible? *	

Identification label [21 CFR 1010.3] : Describe location of the identification label on the product *	
Is the label permanent and legible? *	
Is the place of manufacture expressed in code?	
Provide addresses for each code.	
Details	

User Warning label [21 CFR 1030.10(c)(6)(i) : Describe location of the User Warning label on the product *

Is the label permanent and legible? *	

Service Caution label [21 CFR 1030.10(c)(6)(ii)] : Describe location of the Service Caution label on the product *
Is the label permanent and legible? *

2.2 Label Attachments

Attach a copy of each of the following labels: *
a. Certification label b. Identification label c. User warning label d. Service caution label
Details

2.3 Attach User and Service manuals

Attach a copy of the draft or final user manual and service manual. *	
Details	

Technical Data

Part 3.0 Special Tests on Pre-Production Ovens

Information:	*For each model family, provide the 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; microwave emission sensitivity to load placement; and stirrer modulation effects on microwave emission.* *The special test should also include 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 system before and after the tests and description of how the monitored safety interlock(s) was (were) defeated. The monitor system should render the oven inoperable (such as fuse blowing) and servicing is required.*

3.1Special Tests on Pre-Production Ovens

Attach the results of special or unique tests necessary to evaluate the performance of the safety interlocks, monitor, microwave emission at all surfaces, transportation testing, life and endurance testing of radiation safety components. *	
Details	

3.2 Testing of the Monitor System

Attach a description of how the monitor system works when one or both safety interlocks failed, and how the oven is rendered inoperable. *	
Details	

Quality Control

Part 4.0 Incoming Inspection and Subassembly Testing

Message:	*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 andlor 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 non-destructive)* *Example:* *Cavities and waveguides: VIS, W/S, DIS* *Wire harnesses:NT* *Magnetron gasket: V/l00* *Microwave oven modules: E/l00, RF/S, F/l00*

4.1 Incoming Inspection and Component Tests

4.2 Control of components

Are the incoming components adequately controlled to prevent their use until quality control tests are completed and lot acceptability is determined?	*	
Are the rejected lots of components adequately marked or secured so the rejected parts are not used in production unless reworked?	*	

Part 5.0 Production Line and Final Tests

5.1 General Tests and Microwave Emission Tests

When are the following tests performed?		
Door installation and adjustment checks	*	
Safety interlocks and monitor continuity function checks	*	
Microwave emission hazard test over waveguide, cavity seams and magnetron area prior to installing cabinent	*	
Amount of door travel before secondary safety interlock actuation	*	
Open door (shut off) operation tests	*	
Presence and content of required labels (such as certification, identification, service and user caution labels)	*	
Microwave emission test of door viewing screen	*	
Microwave emission test of door perimeter	*	
Microwave emission test of door perimeter with door pullled out and all safety interlocks operating	*	
Microwave emission test of door perimeter with door pulled out and only secondary safety interlocks operating	*	
Microwave emission test of door hinge, control panel, vents and louvers	*	
Microwave emission test of underneath the oven (if there is exposed cavity under the oven)	*	
Microwave emission tests performed by an automated microwave oven scanner	*	

5.2 Description of Quality Control Checks

Are the written procedures or diagrams available or posted in the working area for the individual performing the quality control checks?	*	
Are repaired or adjusted ovens returned to the assembly line at a point prior to the test that caused their rejection?	*	
Are all repaired or adjusted ovens, regardless of the nature of the repair, returned to the assembly line for the open door operation test and final microwave emission tests?	*	

5.3 Test Procedures

Section 5.3.1. Attach written quality control test procedures for testing continuity of safety interlocks and monitor switches. You may attach the entire quality control and testing procedures but please indicate where the specific test procedures are located. These procedures should include the following: A) A brief outline of the procedures for function tests of each safety 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 schematci with test points identified.	*

C) A list of instruments and test equipment and description of preoperational checks. Describe any special testing apparatus or devices.	
Details	

Section 5.3.2. Attach written quality control test procedures for performing open door restart operation. You may attach the entire quality control and testing procedures but please indicate where the specific test procedures are located. This open door restart operation test procedure must be performed 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 incude 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 electromechnanical timer ovens.	*
Details	

Section 5.3.3. Attach written quality control test procedures for assesing the performance of the secondary safety interlock. You may attach the entire quality control and testing procedures but please indicate where the specific test procedures are located. This section requests written quality control procedures for assessing the performance of secondary interlock design that interrupt power to the oven (interlock actuates) after 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 safety interlock that interrupts power to the oven before there is outward door movement, this part is not required.	*
Details	

Section 5.3.4. Attach written quality control test procedures for repair and retesting of defective ovens found on the production line. You can attached the entire quality control and testing procedures but please indicate where the specific test procedures are located. You should describe the following information: A) A description of all quality control checks done on the repaired or adjusted ovens, such as 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.	*
Details	

5.4 Final RF Emission Testing of Fully Assembled Ovens

Information:	*Attach written quality control test procedures for testing continuity of safety interlocks and monitor switches. You may attach the entire quality control and testing procedures but please indicate where the specific test procedures are located.*
	*

Section 5.4.1 (A) - Physical and electrical conditions under which tests are made (such as 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.

Section 5.4.1 (B) - Adjustment, if any, made during the test and specific procedures and criteria for making adjustments.

Section 5.4.1 (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 devices.

Section 5.4.1 (D) - Description of microwave emission measurement procedures, including survery meter scanning procedures, surface and areas surveyed for RF leakage, scanning speed, and type of spacer probes used to maintain constatn distance from oven surface.

Section 5.4.1 (E) - RF reject limit and its basis, such as instrument manufacturer's assessment of calibration error, stirrer modulation effects, turntable modulation effects, scan speed.

Details	

Section 5.4.2 Provide a sample copy of the record used to retain the results of final emission tests. If an automated microwave oven scanner (AMOS) is used, inlcude samples for both hand-held testing and AMOS testing. *	
Details	

Section 5.4.3 Attach a flowchart diagram of the production lines describing the quality control stations, final test areas, repair bays and audit testing stations. *	
Details	

Part 6.0 Quality Audit

For each quality control procedures 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: (ovens per lot), e.g., "20/1000"; (percentage of today's production), e.g. "10%"; (ovens per quarter), e.g., "5/quarter"; (ovens per year), e.g., "4/year"; or (not performed), e.g., "NP".

Safety interlocks and monitor continuity function checks	*	
Microwave emission hazard test over waveguide, cavity seams and magnetron area prior to installing cabinet	*	
Microwave emission hazard test over waveguide, cavity seams and magnetron area prior to installing cabinet	*	
Amount of door travel before secondary safety interlock actuation.	*	
Open door (shut off) operation tests.	*	
Insertion test by finger or wire into concealed safety interlock(s) and cavity	*	
Presence and content of required labels (such as certification, identification, service and user caution labels)	*	
Check for required precaution statements in user and service manuals	*	

RF EMISSION TESTS		
Microwave emission test of door viewing screen	*	
Microwave emission test of door perimeter	*	
Microwave emission test of door perimeter with door pullled out and all safety interlocks operating	*	
Microwave emission test of door perimeter with door pulled out and only secondary safety interlocks operating	*	
Microwave emission test of door hinge, control panel, vents and louvers	*	
Microwave emission test of underneath the oven (if there is exposed cavity under the oven)	*	
Microwave emission tests performed by an automated microwave oven scanner	*	

Part 6.1 Quality Control Procedures Conducted in Audit

Attach a copy of the written quality control test procedures for testing continuity of safety interlocks and monitor switches and their related wiring.		*
Details		
Attach copy of written quality control test procedures for performing open door restart operation.		*
Details		
Attach copy of written quality control procedures for assessing the performance of the secondary safety interlock.		*
Details		
Are the written procedures or diagrams available or posted in the working area for the individuals performing the quality control checks?		*
Please explain how the firm can ensure that the proper quality control testing procedures are being followed.		
Attach a sample copy of the record used to retain the results of the quality control checks in audit.		*
Details		

Part 6.2 Audit Program

Attach a sample copy of the audit record used to retain the results of the quallity control checks in audit, including the reject limit value for RF emission.		*
Details		
Attach an internal quality control audit document that contains all oven audit procedures. Include all the equivalent information requested in Part 5.4.		*
Details		
Attach a copy of the internal quality control document that contains the audit corrective action plan that would be followed should any ovens selected for audit testing fail to meet the audit test criteria. The description of the audit plan should include at least the following information:		*

A. Classification of radisation safety and compliance defects such as excessive RF emission, safety interlocks and monitor not performing their intended functions, failure of the open door operation check, absence of the 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 responsible or supervisory audit personnel.

Details	

Part 7.0 Life and Endurance Testing

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 life. Attach the internal quality control document and a sample of the test results including the following information: *

A. Frequency of life testing (weekly, monthly, or quarterly).

B. Test length (short term and long term).

C. Rf leakage tests (start of test, every fixed cycles, and end of test).

D. Rf emission reject limit.

E. Safety interlocks and monitor continuity checks (start of test, every fixed cycles, and end of test).

F. Active Monitor check at end of endurance test.

G. Sample of actual record used to retain the results of life and endurance test.

Details	

Part 8.0 Instrumentation and Calibration Checks

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 5 major segments. 1. Type of microwave survey instruments aand their measurement errors (total polarization ellipticity allowed) 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 Identification of Compliance Test Instruments

Attach document which provides the name of the compliance survey instrument, model number, and how many are used in the production department, engineering department and audit department. You can attach a copy of an operation manual of the compliance survey instrument. *

Details	

8.2 Daily Check

Is a preoperational check made on each microwave survey instrument in accordance with the instrument manufacturer's recommendation? *	
Is a polarization ellipse check performed on each instrument each day the instrument is used for compliance instrument? *	
Is the following formula used to calculate the percent of polarization ellipticity of each instrument? * (MAXIMUM - MINIMUM) / MEAN x 100 = _____(%) TOTAL	
What formula is used (type in formula below)? If you prefer, you may attach a file showing the formula for calculating the percentage of polarization ellipticity of each instrument.	
Details	
Is each instrument that is found to exceed the maximum polarization ellipticity limit rejected until the instrument is repaired and recalibrated? *	
During the daily check, is the spacer cone checked on each survey meter and replaced if it is worn or dirty? *	
What type of microwave source instrument is used for performing the daily check? *	
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 during ellipticity check? *	
Is a daily record used to retain the model number, serial number, probe serial number, date of check, percent of polarization ellipticity, entry for accept/reject criteria, and any other information on the corrective action to to any instrument that exceeds the limit?	
Attach a sample copy of the sample daily check record for the daily check *	
Details	

8.3 Thirty Day Constancy Check

Please provide the manufacturer name and model number of the instrument intercomparison system that is used to perform the thirty-day constancy check. Please attach a copy of the user operating manual. *	
Details	
Is a preoperational check made on the LCR in accordance with the instrument manufacturer's recommendation? *	
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 ? *	
Which of the following is used to establish the initial reference field (1 mW/cm^2) within the 30 day constancy check system? *	
Which of the following is used to re-establish the reference field (1 mW/cm^2) for subsequent constancy checks? *	
After the initial reference field (1 mW/cm^2) 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? *	
*	

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)?	
Please attach a sample copy of the thirty-day operational log record with data filled out. *	
Details	
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 readings to ensure that they do not differ more than 10 percent (highest to lowest readings between annual LCR calibration)? *	
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 specificed by the instrument manufacturer? *	
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 mimimum reading does not differ from the HIGHEST maximum reading by more than 2 dB? *	
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? *	
Please provide a copy of the 30-day record, with data filled out. *	
Details	
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 percent of its historical mean average values? *	
Please provide a sample graph or table used to record the instrument's historical mean average values. *	
Details	

8.4 Repair and Calibration of Compliance Test Instruments

Repair and re-calibration of the microwave survey compliance instruments are performed by the following firm(s): *
Please provide a copy of the written procedures for having instruments repaired and re-calibrated. *
Details
Repair and re-calibration of the LCR, RPM, and any other 30-day calibration instruments are performed by the following firm(s): *
Each time the LCR or RPM is sent out for calibration or repair, do you begin all of your instrumentation records again? *

8.5 Annual Calibration and Periodic Calibration

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

How often are the compliance survey instruments returned to the instrument manufacturer or other qualified calibration facility for periodic calibration (at least once every year) unless they have been sent out for repair and re-calibration? *

Part 9.0 Recordkeeping

Information:	*This part 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 purchases concerning radiation safety* *E - Dealer, distributor, purchaser shipment records.*

Are records maintained for the results of tests for the electronic product radiation safety, including control of unnecessatry secondary or product leakage radiation, the methods, devices and procedures used in such tests, and the basis for selecting such methods, devices and procedures? *	
Are the records maintained of tests for durability and stability of the product? *	
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? *	
Are the quality control audit records, documentation of defective ovens found in audit and the results of audit reaction plan kept for minimum of five years? *	
Is a file maintained of all written communications between 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? *	
Where is the file located? *	
Is a file maintained of records necessary for tracing of microwave ovens to distributors, dealers and purchasers? *	
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? *	
Manufacturer can trace shipment to dealers/distributors or purchasers by: *	[ ] Model number [ ] Serial number [ ] Date of manufacture [ ] Other:
Please specify other methods	
Stop:	*You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are correctly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Check to make sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirmed that there is no*

	missing data and all your files are attached, click on the Package Submission icon on the tool bar.