

Specific Instructions for Microwave Oven Product Inspections

Background

The Microwave Oven Product Performance Standard (the standard) was designed to protect the public from unnecessary emissions from microwave ovens. A minimal, but risk-based and continued presence by FDA is needed in the microwave oven industry to ensure continued compliance with radiation safety standards. This presence is limited to for-cause manufacturer inspection and laboratory inspection. No field tests are conducted on microwave oven products.

Specific Instructions

Microwave oven product manufacturers should be inspected or tested at CDRH direction. Microwave oven product manufacturers are all located overseas, and all inspections will require foreign travel. Reasons for manufacturer inspection include:

- Manufacturers with known or suspected problems based on previous inspection or complaints
- New manufacturers not yet inspected
- Manufacturers introducing new technology to the US market
- Manufacturers with a large portion of the US market share.

WEAC laboratory analysts have knowledge of general EPRC requirements and also have specialized training in the microwave oven product performance standard. These analysts have experience planning and conducting foreign microwave oven manufacturer inspections. WEAC analysts should perform these inspections and field tests and may train additional field staff.

CDRH is responsible for review of microwave oven manufacturer inspection observations and initiating administrative or regulatory follow-up.

References

Performance Standard-Microwave Oven Products

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1030&showFR=1>

Guide for Preparing Reports on Radiation Safety of Microwave Ovens

<http://www.fda.gov/cdrh/radhlth/pdf/mworptgd.pdf>

Refer to the microwave oven products main page for guidance documents and additional information:

<http://www.fda.gov/cdrh/radhealth/products/microwave.html>

Microwave Oven Product Codes

Translation of 2-Digit Code	Product Name	Product Code		CFR	Definition
Microwave Ovens (Food Prep)	Microwave Oven, Consumer (Food Prep)	96	RCR	1030.10	A machine that utilizes microwave radiation for food preparation, designed for home use.
Microwave Ovens (Food Prep)	Microwave Oven, Commercial (Food Prep)	96	RCS	1030.10	A machine that utilizes microwave radiation for food preparation, designed for commercial establishments
Microwave Ovens (Food Prep)	Tunnel/Conveyor, Microwave Ovens (Food Prep)	96	RCT	1030.10	A machine that utilizes microwave radiation for food preparation using a conveyORIZED or tunnel microwave waveguide.
Microwave Ovens (Food Prep)	Vending Machine, Microwave Ovens (Food Prep)	96	RCU	1030.10	A machine that utilizes microwave radiation for dispensing heated foods in public areas.
Microwave Ovens (Food Prep)	Other	96	RZZ	Unknown	A machine that utilizes microwave radiation for food preparation not previously specified.

Classification of Non-compliant Items

Power density limit requirements			
1030.10(c)(1)	Leakage from door, vents, other seams > 6mW/cm ²	Major	Class A
1030.10(c)(1)	Leakage from door, vents, other seams >1.25mW/cm ² , < 6mW/cm ²	Minor	Class B
1030.10(c)(1)	Leakage from door, vents, etc. < 6mW/cm ² after purchase	Concern	Class C
Safety interlocks			
1030.10(c)(2)(i), (iv)	Does not incorporate two (2) independent safety interlocks or monitor	Major	Class A
1030.10(c)(2)(i)	No concealed or inaccessible interlock	Major	Class A
1030.10(c)(2)(ii)	Single mechanical/electrical failure disables interlocks	Major	Class A
1030.10(c)(2)(iii)	Secondary interlock allows leakage > 6mW/cm ²	Major	Class A
1030.10(c)(2)(iii)	Primary interlock allows excess leakage > 6mW/cm ²		
1030.10(c)(2)(iv)	Insulating wire is accessible to energy-containing space Opening is obvious to user Opening is not obvious or readily accessible	Major Minor	Class A Class B
User instructions			
1030.10(c)(4)(ii)	Precaution statement unclear, not located to elicit attention, not legible or durable, etc.	Minor	Class B
1030.10(c)(4)(iii)	User manual or cookbook has no precaution statement	Minor	Class B
Service instructions			
1030.10(c)(5)(ii)	Safety information or precaution statement unclear, not located to elicit attention not legible or durable, etc.	Minor	Class B
1030.10(c)(5)(iii)	Service instructions have non precaution statement	Minor	Class B
1030.10(c)(5)(iv)	Service instructions have insufficient safety information	Major	Class A
Warning labels			
1030.10(c)(6)(i), (ii)	No user warning label or service caution label	Major	Class A

Sample Microwave Oven Product Inspection Checklist

Manufacturer Identification

Manufacturer Name : _____
 Plant Location: _____
 Date(s) of Visit: _____

F.D.A. Personnel

Name	Title	Organization

Manufacturer Personnel

Name	Title	Name	Title

LIST OF EXHIBITS

A -	C -	E -	G -
B -	D -	F -	

GENERAL INSPECTION OVERVIEW

SUMMARY OF FINDINGS (See the FDA483 in Exhibit A)

HISTORY OF BUSINESS

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITY

FIRM'S TRAINING PROGRAM

RAW MATERIALS AND COMPONENTS

MANUFACTURING PROCEDURES

SAMPLES COLLECTED

Y2K ISSUES

COMPLAINTS

REFUSALS

DISCUSSION WITH MANAGEMENT

1.0 Production Summary - Maximum number of production lines is:

Line Name	Model #	Brand	Type*	Rate	Shift/Hours	Comments

* **CTD** = Countertop/Domestic **CTC** = Countertop/Commercial **UTC** = Under-the-cabinet **WHO** = Wall hanging
COM = Common cavity **MOD** = Module for High/Low **HLO** = High/Lo **BDO** = Built-in-double
BSO = Built-in single

2.0 Component Inspection

	<u>Components</u>		<u>Test Parameters*/Sampling Rate</u>	
2.1 Cavities and Waveguides	/	/	/	/
2.2 Interlock & Monitor Switches	/	/	/	/
2.3 Wire Harnesses	/	/	/	/
2.4 Door Structure, Hinges, Latches	/	/	/	/
2.5 Door Chokes and Seals	/	/	/	/
2.6 Door Screen Perforations	/	/	/	/
2.7 Noncertified MWO Modules	/	/	/	/

*Test Parameter Keys: **D** = dimension check, **E** = electrical continuity or performance, **F** = function check, **RF** = RF emission check, **V** = visual inspection, **W** = weld integrity

3.0 Component Control

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

Yes No (Explain) _____

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

Yes No (Explain) _____

4.0 Production Line and Final Tests**General Tests**

Line Names /All Lines

Door installation & adjust. checks _____

Safety interlocks & monitor continuity checks _____

RF emission hazard waveguide, cavity seams, etc. _____

Check door travel before sec. interlock actuation _____

Open door (shut off-restart) operation test _____

Presence and content of required labels _____

RF Emission Tests

Door viewing screen _____

Door perimeter _____

Door perimeter ~ door pulled & all interlocks operating _____

Door perimeter ~ door pulled & only Secondary interlock operating _____

Door hinge _____

Control panel _____

Vents and Louvers _____

Underneath the oven (bottomless or exposed cavity) _____

Automated Microwave Scanner _____

NP = Not performed, B = Before final assembly, A = After final assembly NA = Not applicable, ND = Not determined

4.1 Are the written procedures or diagrams available or posted in the working area for the operator performing Q.C. checks?

Yes No (Explain) _____

4.2 Are repaired ovens returned to the assembly line at a point prior to the test that caused their rejection?

Yes No (Explain) _____

4.3 Are all repaired ovens, regardless of the nature of the repair, returned to the assembly line for the open door operation test and final RF emission test?

Yes No (Explain) _____

5.0 Final Test Records (Check information permanently retained)

<input type="checkbox"/> Final and highest RF value	<input type="checkbox"/> Serial no.
<input type="checkbox"/> Date of Test	<input type="checkbox"/> Secondary Interlock Only RF
<input type="checkbox"/> Safety Interlocks/Monitor Continuity	<input type="checkbox"/> Label check
<input type="checkbox"/> Scanner Start-up Test	<input type="checkbox"/> Open Door (Shut Off - Restart) Test

6.0 Automated Microwave Oven Scanner

Line Name	AMOS Brand/ Serial No.	Model Family	Model Exceptions	Qualified	RF Reject Limit

* User manual provided to person responsible for operation of AMOS?

Yes No

* Maintenance record shows regular and adequate maintenance of the AMOS (cone checks, wires, RF absorbers, etc.)?

Yes No

7.0 *Microwave Emission - Final Test*

Line Name	Number of Testers	Scan Rate	Meter Type	Reject Limit	Comments on Scan Rate or Scan Pattern

general instrumentation : **warm-up, **reset zero, **dirty cones, **AC cover missing, **battery check, **voltage supply for AC powered meters, **barrel holding

8.0 Quality Audit**General Tests**

Line Names/ALL Lines/Lab Sampling Rate

8.4 Life and Endurance Testing (Check items observed & fill in units)

Magnetron/weld RF hazard test	_____	_____	_____	_____
Continuity check: interlocks, monitor, wiring	_____	_____	_____	_____
Check door travel before sec. interlock actuation	_____	_____	_____	_____
Open door (shut off-restart) operation test	_____	_____	_____	_____
Presence and content of required labels	_____	_____	_____	_____
Check for caution statements in User and Service manuals	_____	_____	_____	_____
Insertion by finger or wire into concealed safety interlock(s) and cavity	_____	_____	_____	_____

RF Emission Tests

Door viewing screen	_____	_____	_____	_____
Door perimeter	_____	_____	_____	_____
Door perimeter ~ door pulled & all interlocks operating	_____	_____	_____	_____
Door perimeter ~ door pulled & only Secondary interlock operating	_____	_____	_____	_____
Door hinge	_____	_____	_____	_____
Control panel	_____	_____	_____	_____
Vents and Louvers	_____	_____	_____	_____
Underneath the oven (bottomless or exposed cavity)	_____	_____	_____	_____
Automated Microwave Scanner (Audit rate - manual rescan)	_____	_____	_____	_____

NP = Not performed, NA = Not applicable, ND = Not determined

8.1 Audit Test Records (Circle information permanently retained)

_____ Final and Highest RF Value	_____ Serial No.
_____ Date of Test	_____ Secondary Interlock Only RF
_____ Safety Interlocks/Monitor Continuity	_____ Label check
_____ Daily Scanner Audit	_____ Open Door (Shut Off - Restart) Test

8.2 Audit Size and Reaction Plan (review any actual instances of audit failures)

Critical Defects	Reaction Plan	Failures?	Documented?
_____ Excess Emission	_____ Test Entire Lot	_____ Yes	_____ Yes
_____ Interlock/Monitor	_____ Test Days Production	_____ No	_____ No
_____ Open Door Operation	_____ Tighten Sampling		
_____ Missing Labels/statements			

8.3 Scanner Audit Reaction Plan

Has there been a failure in the scanner audit? (document adequate audit response)

_____ No _____ Yes (Explain) _____

9.3 Annual Calibration**Yes****No****Comments**Annual calibration of LCR is performed by:
-----Absolute calibration of LCR is performed annually?
-----Document shows annual calibration of LCR?
-----All records restarted after annual calibration of LCR?
-----Are they using JMI calibration data correctly?
-----Do they perform absolute. cal. of survey meters every 3 yrs.?
-----**9.4 Repair****Yes****No****Comments**Disposition of defective instruments clearly documented?
-----Are broken meters segregated and labeled?
-----If the Narda probe is replaced, are the meter and new probe calibrated together?
-----**10.0 Record keeping****Yes****No****Comments**Are the results of the quality control tests conducted on the production line kept for a minimum of 1 year after filing the annual report for these records?
-----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?
-----Is a file maintained of all written communications from all sources concerning radiation safety including complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintenance or testing?
-----Is a file maintained of records necessary for the tracing of microwave ovens to distributors, dealers and purchasers?
-----Have all the dealers and distributors been informed of their obligations to obtain the purchaser information?

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

____ Model Number

____ Serial No.

____ Date of Manufacture

____ Other (Specify): _____