



OCT 3 | 1988

Food and Drug Administration 8757 Georgia Avenue Silver Spring MD 20910

TO: ALL MANUFACTURERS AND IMPORTERS OF MICROWAVE OVENS

.SUBJECT: INFORMATIONAL REQUIREMENTS FOR COOKBOOKS AND USER AND SERVICE MANUALS

This notice is issued by the Center for Devices and Radiological Health (CDRH) to serve as guidance to manufacturers, importers, and assemblers of microwave oven products in the preparation of cookbooks and user and service manuals for their products. The outline below summarizes the specific requirements developed by CDRH for use in reviewing submissions. All microwave oven cookbooks and user and service manuals must meet these requirements to be considered acceptable.

# USER MANUALS AND COOKBOOKS

- The user manual must contain the required wording of the user precaution statements specified in 21 CFR 1030.10(c)(4)(iii). The required wording is specified by the regulations and cannot be changed. The Director of CDRH may also decide, if additional radiation safety precautions or instructions are necessary.
- 2. The PRECAUTIONS title must be emphasized to elicit the attention of the reader. This can be accomplished by the use of bold print, contrasting color, or a heavy-lined border. The print size of the title should be at least as large as that of any other title that appears on the same page as the user instructions. The print size of the precaution statements should be at least as large as that of any other statements (excluding titles) that appear on the same page.
- 3. The user precaution statements must be printed near the front of the user manual and before the operating instructions.
- 4. Additional precaution statements are permitted so long as they do not detract from the required warnings.
- 5. If the user precaution statements do not appear on the inside front cover of the manual or on a page prior to the table of contents, then the precaution statements should be referenced by page number in the table of contents. The table of contents should contain the wording "PRECAUTIONS TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY" and the page number on which the user precaution statements appear.
- 6. Supplements to the user manual or cookbook, such as recipe booklets or quick reference cards or guides, may or may not require user precaution statements. In general, any supplements which include operational information for the oven should include the precaution statements or reference the location of the caution statements in the user manual or cookbook.

### SERVICE MANUALS

### REQUIRED STATEMENTS

- 1. The service manual must contain the required wording of the service precaution statements as specified in 21 CFR 1030.10(c)(5). The required wording is specified by the regulations and cannot be changed. The Director of CDRH may decide that additional radiation safety precautions or instructions are necessary for particular oven designs.
- The PRECAUTIONS title must be emphasized to elicit the attention of the reader. This can be accomplished by the use of bold print, contrasting color, or a heavy-lined border. The print size of the title should be at least as large as that of any other title that appears on the same page as the user instructions. The print size of the precaution statements should be at least as large as that of any other statements (excluding titles) that appear on the same page.
- 3. The service precaution statements must be printed near the front of the service manual and before the servicing instructions.
- 4. Additional precaution statements are permitted so long as they do not detract from the required warnings.
- 5. If the service precaution statements do not appear on the inside front cover of the manual or on a page prior to the table of contents then these statements should be referenced by page number in the table of contents. The table of contents should contain the wording:

  "PRECAUTIONS TO BE OBSERVED BEFORE AND DURING SERVICING TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY," and the page number on which the service precaution statements appear.

### SCHEMATICS

- 1. 21 CFR 1030.10(c)(2)(v) states that the two required safety interlocks shall be designated as "PRIMARY" or "SECONDARY" in the manual for the oven. This designation should be shown on the schematic or wiring diagram or it may appear in the body of the service manual.
- 2. Although not required by the regulations, we recommend that the monitor be identified on the schematic or in the manual as "MONITOR" or "SHORT SWITCH" or other similar wording.
- 3. There should be no discrepancies between oven wiring diagrams and the schematic diagrams.
- 4. The monitor circuit (system) may contain a maximum of two safety interlocks. One interlock system may be made up of a switch and a relay.

- 5. Additional timers, fuses, and thermal protectors in the monitor circuit (system) are acceptable. Other components such as relays, triac, etc. may not be acceptable.
- 6. If a relay or other unusual component is present in the monitor circuit (system), it must not be able to disrupt the monitoring function if any electrical or mechanical failure occurred. If it is able to, then the circuit is noncompliant and cannot be used. We recommend active testing of the monitor circuit (system) by simulating a failure and then checking to see that the oven will not operate with the door open.

### SERVICING PROCEDURES

# 21 CFR 1030.10(c)(2)(iii) states that:

"Service adjustments or service procedures on the microwave oven shall not cause the safety interlocks to become inoperative or the microwave radiation emission to exceed the power density limits of this section as a result of such service adjustments or procedures."

Manufacturers, importers, and assemblers should incorporate review procedures for the following requirements in their quality control and testing programs to ensure that user and service instructions will not violate this standard.

## A. General:

- Adherence to the servicing instructions listed in the service manual, including adjustment and replacement procedures, should result in proper operation of the oven.
- 2. The service manual should advise the reader that if the oven is operative prior to servicing, a microwave emission check should be performed prior to servicing the oven.
- 3. The service manual should direct the reader to inform the manufacturer, importer, or assembler of any certified oven unit found to have a microwave emission level in excess of 5 mW/cm. The manufacturer, importer, or assembler should instruct the service person to repair any unit found to have excessive emission levels at no cost to the owner (see 21 CFR 1004.2) and should attempt to ascertain the cause of the excessive leakage. The owner of the unit should be instructed not to use the unit until the oven has been brought into compliance.
- 4. If the oven operates with the door open, the manual should instruct the service person to: 1) tell the user not to operate the oven and 2) contact the manufacturer and CDRH immediately.

## B. Electrical Continuity Test:

- 1. Review the continuity test procedures for accuracy and completeness. Check that the test should correlate with the wiring diagram and schematic in the manual.
- 2. All page references in trouble-shooting sections should refer to the correct test procedures.

# C. Safety Interlocks/Monitor Replacement and Adjustment:

- 1. The procedures listed in the service manual should be adequate to ensure that replacement and adjustment of the safety interlocks, monitor, mounting bracket, and/or latch mechanism will not result in excessive microwave emission.
- 2. If the oven has been rendered inoperative due to the failure of the monitored safety interlock(s) then the manual should instruct the service person to replace all of the monitored safety interlock switches and the monitor switch.
- The procedures listed for changing the safety interlocks and monitor should correlate with the wiring diagram.
- The procedures listed should remind the serviceman to connect the monitor switch after replacement and to check interlock/monitor continuity.
- 5. For non-zero motion door model designs, the procedures listed should include a check to ensure that the safety interlocks and monitor switches will actuate within a specified distance recommended by the manufacturer.

# D. Magnetron, Door and Hinge Replacement and Microwave Emissions Test:

- There should be adequate instructions provided in the service manual to allow the correct replacement of the magnetron, including a check for the presence of the wire mesh gasket.
- 2. There should be adequate instructions provided to allow the correct replacement of the door, including a check for correct alignment with the hinge and cavity front face.
- 3. Microwave emission testing procedures provided in the manual should be adequate. Instructions for testing should include: the correct water load (275 ml.), the correct emission limit (no greater than 4 mW/cm2 to allow for measurement uncertainty), the correct scan speed (no faster than one inch per second), instructions to check all surface and vent openings, etc.

Questions regarding this guidance should be directed to the Microwave/Acoustics Products Section of CDRH at (301) 427-7187.

Ann B. Holt, DVM

Que B. Holf

Acting Director Office of Compliance Center for Devices and

Radiological Health