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TITLE 21--FOOD AND DRUGS

SERVICES--(Continued)

PART 1030--PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS--Table of Contents

Sec. 1030.10 Microwave ovens.

(a) Applicability. The provisions of this standard are applicable to microwave ovens manufactured after October 6, 1971.

(b) Definitions. (1) Microwave oven means a device designed to heat, cook, or dry food through the application of electromagnetic energy at frequencies assigned by the Federal Communications Commission in the normal ISM heating bands ranging from 890 megahertz to 6,000 megahertz. As defined in this standard, ``microwave ovens'' are limited to those manufactured for use in homes, restaurants, food vending, or service establishments, on interstate carriers, and in similar facilities.

(2) Cavity means that portion of the microwave oven in which food may be heated, cooked, or dried.

(3) Door means the movable barrier which prevents access to the cavity during operation and whose function is to prevent emission of microwave energy from the passage or opening which provides access to the cavity.

(4) Safety interlock means a device or system of devices which is intended to prevent generation of microwave energy when access to the cavity is possible.

(5) Service adjustments or service procedures means those servicing methods prescribed by the manufacturer for a specific product model.

(6) Stirrer means that feature of a microwave oven which is intended to provide uniform heating of the load by constantly changing the standing wave pattern within the cavity or moving the load.

(7) External surface means the outside surface of the cabinet or enclosure provided by the manufacturer as part of the microwave oven, including doors, door handles, latches, and control knobs.

(8) Equivalent plane-wave power density means the square of the root-mean-square (rms) electric field strength divided by the impedance of free space (377 ohms).

(c) Requirements--(1) Power density limit. The equivalent plane-wave power density existing in the proximity of the external oven surface shall not exceed 1 milliwatt per square centimeter at any point 5 centimeters or more from the external surface of the oven, measured prior to acquisition by a purchaser, and, thereafter, 5 milliwatts per square centimeter at any such point.

(2) Safety interlocks. (i) Microwave ovens shall have a minimum of two operative safety interlocks. At least one operative safety interlock

on a fully assembled microwave oven shall not be operable by any part of the human body, or any object with a straight insertable length of 10 centimeters. Such interlock must also be concealed, unless its actuation is prevented when access to the interlock is possible. Any visible actuator or device to prevent actuation of this safety interlock must not be removable without disassembly of the oven or its door. A magnetically operated interlock is considered to be concealed, or its actuation is considered to be prevented, only if a test magnet held in place on the oven by gravity or its own attraction cannot operate the safety interlock. The test magnet shall be capable of lifting vertically at zero air gap at least 4.5 kilograms, and at 1 centimeter air gap at least 450 grams when the face of the magnet, which is toward the interlock when the magnet is in the test position, is pulling against one of the large faces of a mild steel armature having dimensions of 80 millimeters by 50 millimeters by 8 millimeters.

(ii) Failure of any single mechanical or electrical component of the microwave oven shall not cause all safety interlocks to be inoperative.

(iii) 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.

(iv) Microwave radiation emission in excess of the limits specified in paragraph (c)(1) of this section shall not be caused by insertion of an insulated wire through any opening in the external surfaces of a fully assembled oven into the cavity, waveguide, or other microwave-energy-containing spaces while the door is closed, provided the wire, when inserted, could consist of two straight segments forming an obtuse angle of not less than 170 degrees.

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(v) One (the primary) required safety interlock shall prevent microwave radiation emission in excess of the requirement of paragraph (c)(1) of this section; the other (secondary) required safety interlock shall prevent microwave radiation emission in excess of 5 milliwatts per square centimeter at any point 5 centimeters or more from the external surface of the oven. The two required safety interlocks shall be designated as primary or secondary in the service instructions for the oven.

(vi) A means of monitoring one or both of the required safety interlocks shall be provided which shall cause the oven to become inoperable and remain so until repaired if the required safety interlock(s) should fail to perform required functions as specified in this section. Interlock failures shall not disrupt the monitoring function.

(3) Measurement and test conditions. (i) Compliance with the power density limit in paragraph (c)(1) of this section shall be determined by measurement of the equivalent plane-wave power density made with an instrument which reaches 90 percent of its steady-state reading within 3 seconds, when the system is subjected to a step-function input signal. Tests for compliance shall account for all measurement errors and uncertainties to ensure that the equivalent plane-wave power density does not exceed the limit prescribed by paragraph (c)(1) of this section.

(ii) Microwave ovens shall be in compliance with the power density limits if the maximum reading obtained at the location of greatest

microwave radiation emission, taking into account all measurement errors and uncertainties, does not exceed the limit specified in paragraph (c)(1) of this section, when the emission is measured through at least one stirrer cycle. As provided in Sec. 1010.13 of this chapter, a manufacturer may request alternative test procedures if, as a result of the stirrer characteristics of a microwave oven, such oven is not susceptible to testing by the procedures described in this paragraph.

(iii) Measurements shall be made with the microwave oven operating at its maximum output and containing a load of 275<SUP>plus-minus15 milliliters of tap water initially at 20 deg.<SUP>plus-minus5 deg. centigrade placed within the cavity at the center of the load-carrying surface provided by the manufacturer. The water container shall be a low form 600-milliliter beaker having an inside diameter of approximately 8.5 centimeters and made of an electrically nonconductive material such as glass or plastic.

(iv) Measurements shall be made with the door fully closed as well as with the door fixed in any other position which allows the oven to operate.

(4) User instructions. Manufacturers of microwave ovens to which this section is applicable shall provide, or cause to be provided, with each oven, radiation safety instructions which:

(i) Occupy a separate section and are an integral part of the regularly supplied users' manual and cookbook, if supplied separately, and are located so as to elicit the attention of the reader.

(ii) Are as legible and durable as other instructions with the title emphasized to elicit the attention of the reader by such means as bold-faced type, contrasting color, a heavy-lined border, or by similar means.

(iii) Contain the following wording:

Precautions To Avoid Possible Exposure To Excessive Microwave Energy

(a) Do not attempt to operate this oven with the door open since open-door operation can result in harmful exposure to microwave energy. It is important not to defeat or tamper with the safety interlocks.

(b) Do not place any object between the oven front face and the door or allow soil or cleaner residue to accumulate on sealing surfaces.

(c) Do not operate the oven if it is damaged. It is particularly important that the oven door close properly and that there is no damage to the: (1) Door (bent), (2) hinges and latches (broken or loosened), (3) door seals and sealing surfaces.

(d) The oven should not be adjusted or repaired by anyone except properly qualified service personnel.

(iv) Include additional radiation safety precautions or instructions which may be necessary for particular oven designs or models, as determined by the Director, Center for Devices and Radiological Health or the manufacturer.

(5) Service instructions. Manufacturers of microwave ovens to which this section is applicable shall provide or cause to be provided to servicing dealers and

distributors and to others upon request, for each oven model, adequate instructions for service adjustments and service procedures, and, in

addition, radiation safety instructions which:

(i) Occupy a separate section and are an integral part of the regularly supplied service manual and are located so as to elicit the attention of the reader.

(ii) Are as legible and durable as other instructions with the title emphasized so as to elicit the attention of the reader by such means as bold-faced type, contrasting color, a heavy-lined border, or by similar means.

(iii) Contain the following wording:

Precautions To Be Observed Before And During Servicing To Avoid Possible Exposure To Excessive Microwave Energy

(a) Do not operate or allow the oven to be operated with the door open.

(b) Make the following safety checks on all ovens to be serviced before activating the magnetron or other microwave source, and make repairs as necessary: (1) Interlock operation, (2) proper door closing, (3) seal and sealing surfaces (arcing, wear, and other damage), (4) damage to or loosening of hinges and latches, (5) evidence of dropping or abuse.

(c) Before turning on microwave power for any service test or inspection within the microwave generating compartments, check the magnetron, wave guide or transmission line, and cavity for proper alignment, integrity, and connections.

(d) Any defective or misadjusted components in the interlock, monitor, door seal, and microwave generation and transmission systems shall be repaired, replaced, or adjusted by procedures described in this manual before the oven is released to the owner.

(e) A Microwave leakage check to verify compliance with the Federal performance standard should be performed on each oven prior to release to the owner.

(iv) Include additional radiation safety precautions or instructions which may be necessary for particular oven designs or models, as determined by the Director, Center for Devices and Radiological Health or the manufacturer.

(6) Warning labels. Except as provided in paragraph (c)(6)(iv) of this section, microwave ovens shall have the following warning labels:

(i) A label, permanently attached to or inscribed on the oven, which shall be legible and readily viewable during normal oven use, and which shall have the title emphasized and be so located as to elicit the attention of the user. The label shall bear the following warning statement:

Precautions For Safe Use To Avoid Possible Exposure To Excessive Microwave Energy

DO NOT Attempt to Operate This Oven With:

(a) Object Caught in Door.

(b) Door That Does Not Close Properly.

(c) Damaged Door, Hinge, Latch, or Sealing Surface.

(ii) A label, permanently attached to or inscribed on the external surface of the oven, which shall be legible and readily viewable during servicing, and which shall have the word ``CAUTION'' emphasized and be

so located as to elicit the attention of service personnel. The label shall bear the following warning statement:

Caution: This Device is to be Serviced Only by Properly Qualified Service Personnel. Consult the Service Manual for Proper Service Procedures to Assure Continued Compliance with the Federal Performance Standard for Microwave Ovens and for Precautions to be Taken to Avoid Possible Exposure to Excessive Microwave Energy.

(iii) The labels provided in accordance with paragraphs (c)(6)(i) and (ii) of this section shall bear only the statements specified in that paragraph, except for additional radiation safety warnings or instructions which may be necessary for particular oven designs or models, as determined by the Director, Center for Devices and Radiological Health or the manufacturer.

(iv) Upon application by a manufacturer, the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant an exemption from one or more of the statements (radiation safety warnings) specified in paragraph (c)(6)(i) of this section. Such exemption shall be based upon a determination by the Director that the microwave oven model for which the exemption is sought should continue to comply with paragraphs (c) (1), (2), and (3) of this section under the adverse condition of use addressed by such precautionary statement(s). An original and two copies of applications shall be submitted to the Dockets Management Branch (HFA-305), Food and

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Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Copies of the written portion of the application, including supporting data and information, and the Director's action on the application will be maintained by the Branch for public review. The application shall include:

(a) The specific microwave oven model(s) for which the exemption is sought.

(b) The specific radiation safety warning(s) from which exemption is sought.

(c) Data and information which clearly establish that one or more of the radiation safety warnings in paragraph (c)(6)(i) of this section is not necessary for the specified microwave oven model(s).

(d) Such other information and a sample of the applicable product if required by regulation or by the Director, Center for Devices and Radiological Health, to evaluate and act on the application.

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