This guidance was written prior to the February 27, 1997 implementation of FDA’s Good Guidance Practices, GGP’s. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP’s.
To: All Manufacturers and Importers of Microwave Ovens

Subject: Open Door Operation of Microwave Ovens as a Result of Oven Miswiring

Recently there have been three incidents in consumer locations in which the microwave oven operated with the door open due to oven miswiring. These incidents have resulted in expensive oven retesting and recall programs. It has also been learned that several workers at one manufacturing location had accidentally been exposed to microwave radiation in several instances during oven testing, due to oven miswiring that resulted in the continued operation of the oven after the door was opened.

The Bureau is greatly concerned that future incidents such as these could occur and result in the exposure of individuals to high levels of microwave energy. To reduce the potential for such open door operation, due to miswiring of the oven circuitry, the Bureau strongly recommends that all manufacturers consider instituting design features that will, (1) preclude analogous accidental miswiring of microwave ovens, or (2) if miswiring occurred, prevent the unit from operating with the door open.

It is recommended that all manufacturers consider:

1. Locating one safety interlock on the neutral side of the line and another on the high side of the line.

2. Locating the monitor circuit as the last circuit branch in parallel with the high voltage transformer, or making the "hot" A.C. line connection to the monitor circuit the last connection prior to connection with the primary of the power transformer.

3. Performing a failure mode effects analysis on each unique design to identify critical connections and wires where the accidental interchange would result in electrically by-passing all safety interlocks and the monitor.

4. Designing critical wire terminal connect points so as to mechanically preclude accidental interchange of these wires to any unsafe configuration.

5. Covering the terminals of critical wires with insulation to prevent any loose wire from being able to contact another point that might result in by-passing the safety interlock or monitor circuit.

6. Using wire ties to limit the degree of movement of any wire that could become disconnected.
7. Instituting other design features that would prevent the miswiring of units or prevent units that are miswired from operating with the door open.

Manufacturers must be careful not to introduce design changes that could result in noncompliance with the Federal performance standard. It is requested that proposed changes be submitted to the Bureau for review prior to incorporating the changes on production models. It may also be appropriate to submit prototype units to the Bureau for evaluation.

It is equally important that certain good quality control practices be observed to help prevent these undesirable conditions. The Bureau is hereby requesting that all manufacturers now institute, if not already a part of their quality control and testing program, a specific test of each unit to determine that the unit will cease operating when the door is opened, and that it cannot be restarted, when the door is open. Any test that provides positive indication of magnetron shutdown upon latch release or door opening will be acceptable.

The test must also include an attempt to restart the unit while the door is unlatched. This should be attempted both with the unit programmed and not programmed (for operation) for digital units, and with and without time on the timer for nondigital units, if the status of these controls could alter the possibility of starting with the door open.

We recognize that these tests require care in order to prevent the exposure of the operator to high levels of microwave energy. In each case the door should be unlatched slowly and the operator instructed to terminate the test immediately if a problem is noted. Also a mechanical stop is recommended that would allow the door to be unlatched and opened slightly but which would prevent the door from opening to a position that would allow hazardous levels of microwave energy to leak from the oven.

Regardless of the type of test performed the test must be conducted at a point on the production that is subsequent to any assembly, adjustment or repair of the unit that could alter the oven wiring. All operators must be instructed to immediately report any findings of open door operation to the proper quality control person so that the defective unit can be analyzed to determine the cause of the failure. Manufacturers should take corrective action to prevent future incidents.

Since the failure could be the result of a defective wiring component that is assembled in-house or purchased from a vendor, it is recommended that the assemblers of such components receive additional training and assembly aids that will help prevent defective wiring components. Units of the components should be inspected on a sampling or 100% basis prior
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to being sent to the production line. If a defective component is found in a lot, then that lot should be rejected or 100 per cent tested prior to allowing the components to be sent to the assembly line. Where sampling is used, lots received after a rejected lot should be tested under a tightened sampling schedule until the results allow for return to a normal sampling schedule.

Please institute any design and testing program changes necessary to prevent open door operation. The Bureau would welcome other suggestions which could help prevent such incidents.

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