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# GUIDE for SUBMISSION of INFORMATION on INDUSTRIAL RADIOFREQUENCY DIELECTRIC HEATER and SEALER EQUIPMENT PURSUANT to 21 CFR 1002.10 and 1002.12

Compiled by
Division of Compliance
Division of Electronic Products

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland 20857

CONTENTS

## INTRODUCTION

This guide is to be used by manufacturers of industrial dielectric heaters, including radiofrequency (RF) sealers, and electromagnetic (EM) induction heating equipment, in the preparation of initial and model change reports to be filed with the Bureau of Radiological Health, as required by 21 CFR 1002.10 and 1002.12 issued under authority of the Radiation Control for Health and Safety Act of 1968.

These reports will be used by Bureau staff to assess the performance and radiation safety aspects of the products, and to evaluate trends in the design and manufacture of industrial dielectric heater and sealer equipment. Any questions regarding this guide should be directed to the Bureau's Division of Compliance.

## GENERAL INSTRUCTIONS

Initial and Model Change Reports. An initial report is required for the first of a class of products (e.g., industrial dielectric heater or sealer) that a manufacturer introduces into commerce. Subsequent products should be reported in a model change report. In either case, the report must be filed prior to introduction of the product into commerce. When filing an initial or model change report, all sections of this guide must be responded to individually.

Upon receipt of an initial or model change report, the Bureau will assign to the report a seven-digit accession number, which simply locates the report in the Bureau's file system. All subsequent correspondence concerning the report should include this accession number.

Report Supplement. Once an initial or model change report has been filed for a product, any modifications to the product that affect its performance or radiation safety aspects may be reported in a supplement to the original report. When filing a report supplement, all items in section 1.0 of this guide must be responded to individually; in the remainder of the supplement, only those items which are affected by the modification must be responded to individually. For those items which are unaffected by the modification, a reference to the original report is sufficient.

Model Families. When several products are sold as different models, but share similar or identical performance parameters, they may be considered a model family and reported in a single report. When reporting a model family, the differences between models must be clearly explained in section 1.5. If in doubt as to whether two or more models are sufficiently similar to constitute a family, the manufacturer should consult the Bureau's Division of Compliance.

Completed reports should be submitted to:

Director, Division of Compliance
HFX-400
Bureau of Radiological Health
5600 Fishers Lane
Rockville, Maryland 20857

## DEFINITIONS

(1) "Applicator" means that portion of the dielectric heater which is intended to emit the radiofrequency (RF)/electromagnetic (EM) fields.

(2) "Industrial dielectric heaters" means all industrial radiofrequency (RF) induction heating equipment that is used for the purpose of controllably heating dielectric materials with RF fields in the frequency range from 2 Megahertz to 500 Megahertz.

(3) "Safety interlock" means a device or system of devices which is intended to prevent generation of RF/EM energy when access to the RF/EM energy generator is possible.

(4) "Service adjustments or servicing instructions" mean those servicing methods prescribed by the manufacturers for a specific product model.

NOTE: FOR ALL SECTIONS OF THE REPORT WHICH REQUIRE A SEPARATE DESCRIPTIVE NARRATIVE, PHOTOGRAPHS, OR DRAWINGS, SUBMIT THE REQUESTED INFORMATION IN AN APPROPRIATE ATTACHMENT. IDENTIFY EACH ATTACHMENT BY LETTER (A, B, C, ETC.) ASSIGNED AT END OF EACH SECTION IN PARENTHESES.

## 1.0 IDENTIFICATION

1.1 Name and address of corporate headquarters of the manufacturer:

1.2 Place of manufacture, if other than above:

1.3 Name and address of importer, if product is imported. (If the manufacturer has a U.S. office, provide the address in this space):

1.4 Type of report being filed

- ☐ Initial report
- ☐ Model change report
- ☐ Report supplement to (give BRH accession no.) _____

1.5 Brand name and model designation of unit(s) being reported:

1.6 Describe the intended and known uses of each model.

1.7 Name, title, and signature of person submitting the report:

Name:
Title:
Signature:

1.8 Report date:

## 2.0 REPORT SUBMITTAL

2.1 Confirm that the report is submitted pursuant to paragraph (c) of section 1002.61 of the Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968.

## 3.0 PRODUCT INFORMATION

3.1 Describe the physical characteristics, dimensions, etc. of the product and provide photographs showing physical characteristics and clearly identifying the applicator, access door to inside of machine, shielding, transmission lines, etc. (attachment A).

3.2 For each model submit a copy of any sales brochures which describe the product (attachment B).

3.3 State the source of the RF generator used in the dielectric heater:

Built in-house ☐ Yes ☐ No

Purchased from vendor ☐ Yes ☐ No

Vendor's name _____

_____

Address _____

_____

Phone number _____

RF generator model no.(s) _____

_____

3.4 Submit an estimate of the number of units of each different model dielectric heater you have sold to date. List this information by model number and production year. Note the year that each model was introduced and, if applicable, when it was discontinued (attachment C).

## 4.0 SPECIFICATIONS AND CHARACTERISTICS

4.1 Describe the functional and operational characteristics for each model manufactured.

4.1.1 State the frequency of operation

4.1.1.1 Nominal operating frequency fixed at _____ MHz; or step/tunable between _____MHz and _____MHz.

4.1.1.2 With regard to the raw dielectric material being sealed, state the resultant frequency shift (i.e., from ___MHz to MHz), as the material is worked (i.e., heated, sealed, molded, etc.). Material used was_____

4.1.2 State the maximum RF power output of the RF generator versus frequency. If this power is adjustable, state the range of adjustment.

4.1.3 State the maximum and minimum duty cycles.

$$Max_{DC} = \frac{t_{RF\ max}}{(t_{RF\ max} + t_{OFF\ min})}$$

$$Min_{DC} = \frac{t_{RF\ min}}{(t_{RF\ min} + t_{OFF\ max})}$$

where:

$Max_{DC}$ = Maximum duty cycle
$Min_{DC}$ = Minimum duty cycle
$t_{RF\ max}$ = Maximum length of time RF source can be energized (i.e., one operational cycle) in seconds or minutes
$t_{RF\ min}$ = Minimum length of time RF source can be energized in seconds or minutes

$t_{OFF\ min}$ = Minimum length of time between RF on cycles in seconds or minutes

$$Max_{DC} = \frac{(\quad\quad)}{(\quad) + (\quad)} = \_\_\_\_\_ cycles$$

$$Min_{DC} = \frac{(\quad\quad)}{(\quad) + (\quad)} = \_\_\_\_\_ cycles$$

NOTE: Time must be converted to same units (e.g., all in seconds or minutes)

4.1.4 State the number of people needed to operate each different model (attachment D).

4.2 State the maximum amount of RF leakage allowed, by your design specifications, to be emitted from a fully assembled product. For each model list the accept/reject limits used in production and quality control testing (attachment E).

4.3 State the design specifications for level of allowable leakage present during servicing of the equipment (attachment F).

4.4 Describe the mechanical and operational characteristics of the electrode and dies (attachment G).

## 5.0 LABELING, WARNINGS, AND INSTRUCTIONS

5.1 Describe any system of labeling which will allow the date and place of manufacture to be determined. If this information is coded, provide the key to the code (attachment H, to include 5.1.1, 5.1.2).

5.1.1 State the location of the label.

5.1.2 Submit a sample of the label or a facsimile if the label is not available at the time of reporting or is inscribed on the product.

5.2 Describe the type(s) of radiation warning labels that are affixed to the product (attachment I, to include 5.2.1, 5.2.2).

5.2.1 State the location of each label.

5.2.2 Submit a sample of the label(s) or a facsimile

5.3 Submit a copy of the user's and service instructions provided with each model. In particular, include all instructions related to radiation safety (attachment J).

## 6.0 SAFETY FEATURES

6.1 This section asks for information relating to the physical and/or electrical characteristics of the product (e.g., shielding, electrical circuitry, etc.) which ensure that the product meets the standards and specifications reported in section 4.2 (attachment K, to include 6.1.1 - 6.1.11).

6.1.1 Fully describe any shielding that is incorporated into the product, including the location and construction materials used. In particular, describe the shielding around the applicator.

6.1.2 State whether or not the shielding is a standard or optional part of the equipment.

6.1.3 To supplement the description requested in section 6.1.1, submit clearly labeled photographs, mechanical diagrams and/or engineering drawings which show the shielding location(s).

6.1.4 Fully describe the type(s) of safety interlock(s), if any, that the product is equipped with, its operation, any servicing procedures used, and which power connections are interrupted when it actuates.

6.1.5 State the location of each interlock.

6.1.6 To supplement the description requested in section 6.1.4, submit clearly labeled photographs, mechanical diagrams, and/or engineering drawings which show the safety interlock system circuitry and placement.

6.1.7 State the consequences of any interlock failure. State whether the interlock(s) automatically reset themselves after being manually defeated. State whether and how the interlocks can be manually defeated (e.g., pull to defeat, etc.).

6.1.8 Submit an estimate of the number of times per day interlocks would be electrically or mechanically cycled.

6.1.9 Describe the operation of any design feature which provides the operator with a clear indication (visually or audibly) that the RF/EM power is on.

6.1.10 Under normal operating conditions, is the operator grounded or ungrounded?

6.1.11 Submit any recommendations that are made to service personnel or users to ensure the continued proper performance and safety of the units (e.g., instructions on how to replace/adjust interlocks, RF generators, etc.).

## 7.0 INSTRUMENTATION AND CALIBRATION

7.1 Identify the instruments used to make RF radiation leakage measurements by manufacturer, model number and serial number. Submit a copy of the instrument manufacturer's technical specifications for each model (attachment L).

7.2 Procedures used for recalibration of the measuring instruments (attachments M, to include 7.2.1 - 7.2.2).

7.2.1 State how often the instruments are calibrated (e.g.,annually, semi-anually, etc.).

7.2.2 State the name and location of the calibration laboratory.

## 8.0 QUALITY CONTROL AND TESTING PROCEDURES

8.1 Describe, in complete detail, all test procedures used to locate and measure RF leakage radiation. Submit a copy of each test procedure used. The procedures should provide information on the following: which areas are checked for leakage and how (e.g., applicator, access doors, shielding, etc.); what type of dielectric materials are used; at what rate the instrument's sensor is moved; which leakage meter(s) was used; etc. (attachment N).

8.2 Provide actual test values for the parameters of sections 8.2.2 and 8.2.3. Reference the test procedures used to obtain these values, and submit a copy of each procedure with this report (see section 8.1, if procedures are the same just state so) (attachment O, to include 8.2.1 - 8.2.4).

The emission levels measured should all be for the worst case. That is, all parameters should be measured using that dielectric material which will create the maximum RF emissions during normal operation of the equipment.

8.2.1 State what the initial test conditions are prior to making any measurements. Include the following:

8.2.1.1 State whether the probe is hand held or placed in some type of holder (tripod). Describe the holder. Also, state if an operator is present during testing.

8.2.1.2 Describe the types of dielectric material used as a test load. Include the thickness of the test load and its initial temperature.

8.2.1.3 State what the press cycle is (i.e., time "on", time "off", time before next time "on", etc.).

8.2.1.4 State the frequency at which each power or field intensity reading was taken.

8.2.2 State what the maximum RF emission of the dielectric heater is when measured at a distance of 30 cm from any point on the machine. Express data values for magnetic field (H) in amps/meter and for electric field (E) in volts/meter; include diagrams and/or photographs which show the location of the maximum RF emissions.

8.2.3 State what the maximum RF emissions of the dielectric heater are when measured at the position(s) where the operator(s) normally stands. Emission levels should be measured at four points on the operator's body: head, chest, waist, and knees. State the height of the operator.

Express data values in amps/meter and volts/meter; include diagrams and/or photographs which show the location of the maximum RF emissions.

8.2.4 Submit clearly labeled photographs and/or drawings which show the test setup used.

8.3 Final radiation leakage testing plan of all fully assembled dielectric heating equipment (attachment P, to include 8.4.1 - 8.4.6).

8.3.1 State whether all fully assembled units undergo 100 percent final inspection or are inspected on a sampling basis. If sampled, describe how sampled units are chosen.

8.3.2 Describe the types of corrective actions taken after a unit is rejected.

8.3.3 Submit a copy of any applicable written quality control procedures.

8.4 Describe the types of inspection (e.g., incoming, on-line, etc.) tests performed on the RF generator with regard to RF leakage safety criteria. Detail the parameters and/or physical characteristics that are checked to ensure proper operation of the generator (e.g., power output, high voltage test, electromechanical operation, etc.) (attachment Q).