

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE

NOTICE

DEPARTMENT OF LABOR

48385

Food and Drug Administration

48355

[Docket No. 79N-0314]

Radiofrequency Sealers, Heaters, and
Gluers; Open Workshop

AGENCIES: Food and Drug Administration; Occupational Safety and Health Administration.

ACTION: Notice.

SUMMARY: The Bureau of Radiological Health (BRH) of the Food and Drug Administration (FDA) and the Occupational Safety and Health Administration (OSHA) announce an open workshop to discuss potential hazards to persons involved in the use of radiofrequency (RF) sealers, heaters, and gluers. Techniques for the control or elimination of hazards from such RF-emitting devices are also being sought.

DATES: The workshop will be held September 12 and 13, 1979, and will convene at 9 a.m. each day.

ADDRESSES: The workshop will be held at the Department of Labor auditorium New Department of Labor Building, Second and Constitution Ave. NW., Washington, DC 20210.

Written supplemental comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Zory Glaser, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426; or

Frank Tipton, OSHA—OHP, Rm. N-3718, Department of Labor, Second and Constitution Ave., NW., Washington, DC 20210, 202-523-7174.

SUPPLEMENTARY INFORMATION: BRH and OSHA are concerned about potential adverse health effects on personnel exposed to RF energy emitted from RF sealers, heaters, and gluers. These RF-emitting devices are also known as: heat sealers, fusers, molders, fasteners or embossers; high frequency (HF) sealers or dryers; electronic or electromagnetic sealers or welders; and dielectric heaters. They are generally designed to operate at a frequency between 3 and 100 megahertz (MHz). Another class of electromagnetic radiation-emitting devices which operate at or near these frequencies include induction heating equipment.

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The open workshop is being scheduled to bring together users, manufacturers, Federal agency staff, employee representatives, trade associations, and others concerned with RF sealers, so that BRH and OSHA may benefit from their expertise, as well as to ensure that the present knowledge of the possible hazards of these devices is appreciated in the affected industries. Field measurements have confirmed that a significant number of personnel are exposed to high levels of RF radiation from these devices. Because the RF energy at these frequencies can penetrate deeply into the body without activating the heat sensors located in the skin, operators of such RF equipment may be unaware of exposures to the RF energy.

The workshop will cover topics important to the assessment and control of the possible hazards of RF energy from RF sealers, heaters, and gluers. The topics to be discussed are expected to include:

- a. Measurement of electric and magnetic field intensities generated by these devices;
- b. A brief review of biological effects at frequencies between 3 MHz and 100 MHz;
- c. Explanation of the near-field conditions that are a part of these exposures, and the difficulty posed under these conditions in exposure measurement and in predicting possible adverse effects to persons so exposed;
- d. A discussion of RF radiation measurement equipment and techniques;
- e. Procedures or techniques available for control of RF emissions;
- f. Possible initiatives of Federal agencies on the control of RF-emitting devices;
- g. Technical aspects related to the use or application of RF heater-type equipment, and the possible resultant effects upon intended functions and unnecessary radiation emission; and
- h. Other topics pertinent to the discussion of possible health hazards from RF equipment, particularly RF heaters, sealers, and gluers.

BRH and OSHA are anxious to gain information especially from users and manufacturers of RF sealers, heaters, and gluers, on the techniques for

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AdministrationRadiofrequency Sealers, Heaters, and
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Cross Reference: For a notice of open workshop issued by the Food and Drug Administration and the Occupational Safety and Health Administration to discuss potential hazards of using radiofrequency sealers, heaters, and gluers, see FR Doc. 79-25278 appearing in the Notices section of this issue.

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measurement of emissions of such RF energy assessment of operator exposure to the RF energy, and the techniques and procedures for the control or elimination of stray RF emission from sealers, heaters, and gluers. Other relevant information is also solicited.

Several speakers from the involved agencies are expected to make short presentations on the above topics. Opportunity will be provided for comments and questions by any interested person. Persons wishing to present brief prepared statements should contact Zory Glaser or Frank Tipton by September 5, 1979.

As time permits, other persons present will be given the opportunity to make brief statements. This will be an informal open workshop, but a transcript will be made so that the maximum benefit may be derived from the workshop. Anyone wishing to submit written statements or other information relevant to the subject of this workshop for inclusion in the permanent record may do so at the workshop, or by sending it to the FDA Hearing Clerk (address above) by October 12, 1979. Written submissions should be clearly identified with the words "BRH-OSHA open workshop on RF sealers."

Although this workshop is not a hearing, and is not a part of any formal rulemaking, all the information and opinion submitted in preparation for, during or in response to this workshop will become a part of a permanent file for any new or modified rules that may be issued by either agency concerning RF heaters, sealers, and gluers.

Dated: August 10, 1979.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

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