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NRC AMENDS REGULATIONS TO PROVIDE SPECIFIC  
REQUIREMENTS FOR IRRADIATORS

The Nuclear Regulatory Commission is changing its regulations to specify radiation safety and licensing requirements for licensees who use radioactive materials in irradiators.

There are over 70 irradiators currently licensed in the United States. Their primary use (85 percent) is to sterilize disposable medical products and supplies, such as rubber gloves and syringes. Most of the remaining irradiations are for chemical processing--mainly to change the chemical characteristics of plastics.

Irradiation of food, for the purpose of destroying pests or bacteria or prolonging shelf-life, is being conducted on a limited scale. NRC regulates irradiators for radiation protection purposes and does not specify types of products that may be irradiated, or evaluate the quality of irradiated products or the technical or economic feasibility of product irradiation. Food safety is regulated by the Food and Drug Administration and the Department of Agriculture.

Irradiators covered by the NRC's rule change are of three types:

(1) Panoramic, wet-source-storage irradiators--Sealed "sources" containing radioactive materials are submerged in a water storage pool and are fully shielded when not in use. Irradiations occur by moving the sources out of water and into the air, and then moving products to be irradiated past the sources.

(2) Underwater irradiators--The sealed sources are in a water storage pool at all times, and the products to be irradiated are lowered into the water.

(3) Panoramic, dry-source-storage irradiators--The sealed sources are stored in a shield constructed of solid materials and are fully shielded when not in use. Irradiations occur in air.

Irradiators are currently licensed under the general requirements of the regulations of the NRC or Agreement States (which are States that have assumed authority, through agreement with the NRC, over the licensing of radioactive materials within the State) and license conditions. The rule formalizes and codifies the specific conditions. Requirements include:

- Irradiator operator training;
- Written operating and emergency procedures;
- Insolubility and nondispersibility of radioactive material used in sealed sources;
- Double encapsulation of sealed sources installed after the effective date of the rule;
- Access controls to prevent inadvertent personnel entry into a radiation room at a panoramic irradiator while the radioactive sources are exposed;
- Limits on radiation dose rates in normally accessible areas;
- Radiation monitors and surveys; and
- Safety requirements for design and construction.

Proposed amendments on this subject were published in the Federal Register for public comment on December 4, 1990. NRC also held a public meeting on February 12 and 13, 1991, to discuss the proposed rule. Changes made as a result of the comments received are described in a Federal Register notice published on February 9, 1993.

The new requirements, which are primarily contained in a new Part 36 of the Commission's regulations, will be effective on July 1, 1993.