

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

December 15, 1989

NRC INFORMATION NOTICE NO. 89-85: EPA'S INTERIM FINAL RULE ON MEDICAL WASTE TRACKING AND MANAGEMENT

Addressees:

All medical, academic, industrial, waste broker, and waste disposal site licensees.

Purpose:

This information notice is provided to inform licensees that the Environmental Protection Agency (EPA) has promulgated an interim final rule (40 CFR 259) on medical waste tracking and management under a mandate from the Medical Waste Tracking Act of 1988. As of June 6, 1989, EPA has determined that the regulation applies to the medical wastes generated in five States (known as "Covered States"). These "Covered States" are: Connecticut, New Jersey, New York, the Commonwealth of Puerto Rico, and Rhode Island. This notice also identifies and clarifies areas of overlap between Nuclear Regulatory Commission (NRC) and EPA requirements. Licensees may wish to review this information for applicability to their programs and consider actions, as appropriate, as may be required by rule. However, suggestions contained in this information notice do not constitute NRC requirements; therefore, no specification or written response is required by NRC. In addition no specific written response is required by EPA.

Description of Circumstances:

On March 24, 1989, an interim final rule on medical waste tracking and management under the authority of the Medical Waste Tracking Act of 1988 was published in the Federal Register, Vol. 54, No. 56, pp. 12326 - 12395. On June 6, 1989, a supplementary Federal Register Notice, Vol. 54, No. 107, pp. 24310 - 24311, identified the participating States, identified the effective dates of the new rule, and extended the public comment period. On August 24, 1989, a Federal Register Notice, Vol. 54, No. 153, pp. 35189 - 35191, removed Louisiana and the District of Columbia from the demonstration program leaving the States of New York, New Jersey, Connecticut, and Rhode Island, and the Commonwealth of Puerto Rico as participants in the program. NRC Part 35 licensees constitute one category of medical institutions covered by the new EPA rule. Since radioactive materials are sometimes associated with medical wastes, NRC licensees may be affected by that rule.

Discussion:

The Medical Waste Tracking Act of 1988 requires the EPA to promulgate regulations on the management of medical wastes by establishing a two-year demonstration

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program to track medical waste. On March 24, 1989, EPA published "Standards for the Tracking and Management of Medical Waste; Interim Final Rule and Request for Comments" in the Federal Register (54 FR 12326). In general, this EPA rule established criteria and procedures for State participation in the demonstration program, EPA's definition of "medical wastes" for use under the Act, and the regulations and standards to be used in the demonstration program.

The EPA regulation defines the regulated medical wastes applicable to the demonstration program, it establishes a waste tracking system, and sets out segregation, packaging, storage, labeling, and marking requirements.

The EPA regulation defines "medical wastes" as "any solid waste which is generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The term does not include any hazardous waste as defined in §261.4(b)(1) of this chapter." The regulation also defines the "regulated medical waste" subject to the new waste tracking requirements. These "regulated medical wastes" include cultures and stocks, pathological wastes, human blood and blood products, animal wastes, isolation wastes, and used and unused sharps (syringes, needles, scalpel blades, etc.). Regulated medical waste that has been both treated, so as to substantially reduce or eliminate its potential for causing disease, and destroyed, is not regulated once the treatment and destruction processes have been completed. However, generators who both treat and destroy regulated medical waste on-site are subject to specified recordkeeping requirements. Note that hazardous wastes as defined under the Resource Conservation and Recovery Act (RCRA) in 40 CFR Part 261 are not covered by the new EPA rule. Therefore, "mixed waste" (waste with both a RCRA hazardous component and a radioactive component) are not included in these new requirements. However, mixtures of RCRA hazardous waste and regulated medical waste may be subject to the tracking requirements in some circumstances.

The NRC regulation 10 CFR §20.311 requires that wastes shipped to a commercial low-level radioactive waste disposal site meet the waste classification and waste form requirements in 10 CFR Part 61. The low-level radioactive waste regulations, 10 CFR Part 61, require that hazardous, biological, pathogenic, or infectious material be treated to reduce to the maximum extent practical the potential hazard from the non-radiological materials. Hazardous wastes are covered under the EPA requirements in 40 CFR 260-270. However, radioactive medical wastes having a biological, pathogenic, or infectious component need to be treated prior to shipment for disposal. Since treated wastes must also be destroyed in order to be exempted from the new EPA regulation, we expect some impact on low-level radioactive waste disposal facility licensees for tracking biological, pathogenic, and infectious wastes. Licensees in the Covered States

who treat and destroy radioactive medical wastes would need to track these wastes up to the point of treatment and destruction. Because some medical wastes regulated under the new EPA regulation are only treated, but not destroyed, and some medical wastes (e.g., unused radioactive material in syringes) may not require treatment under 10 CFR Part 61, some radioactive medical wastes would need to be tracked to the disposal site.

The EPA tracking system will provide assurance that regulated medical waste is properly handled and managed. The regulations require each person in the chain-of-custody of medical waste management to take responsibility for assuring that the waste reaches the proper treatment or disposal facility. A tracking form, described in the new regulation, is required to be used.

The EPA regulation requires generators of regulated medical wastes in the Covered States to segregate sharps and fluids from other regulated medical waste and general refuse, to the extent practicable, prior to transport off-site. The regulation also prescribes packaging in rigid, leak-resistant containers. Storage of medical wastes must be (a) performed in a manner and location that maintains the integrity of the packaging and affords protection from water, rain, and wind, and (b) maintained in a nonputrescent state. Specific labeling and marking requirements are also set out.

It should be noted that the low-level radioactive waste disposal regulation, 10 CFR Part 61, prohibits the use of cardboard and fiberboard containers. These requirements were adopted due to several instances where low-level waste disposal operators injured themselves on needles that penetrated cardboard and fiberboard package containing medical wastes. Since radioactive medical wastes are generally shipped for disposal in DOT 17H steel drums, no impact to licensees is expected.

The EPA regulations include a new tracking form for covered medical materials. In the Federal Register notice it is stated that the EPA tracking forms would be sufficient for meeting the NRC manifest requirements under 10 CFR §20.311 for radioactive wastes provided that the additional 10 CFR §20.311 information is included in Box 14 of the form. This statement needs clarification. Commercial low-level radioactive waste disposal sites have very different manifest information requirements that could not be placed on the available space on the EPA form. In addition, Agreement States regulating commercial low-level radioactive waste disposal sites require approval of new manifest formats. Consequently, licensees in Covered States who ship regulated medical waste offsite for treatment or disposal would need to attach the low-level radioactive waste disposal site manifest forms to the EPA medical waste tracking forms.

In some cases, generators of regulated medical waste in Covered States may use waste brokers or processors in non-Covered States. Also, the three commercial low-level radioactive waste disposal sites are located in non-Covered States (Nevada, South Carolina, and Washington). The new EPA regulations apply throughout the country, but only to wastes generated in Covered States.

Therefore, waste brokers, processors, and disposal site operators in non-Covered States will need to comply with the new EPA medical waste tracking requirements when they handle, process, or dispose of wastes generated in Covered States.

This information notice is issued for information only and should not be construed as a legal interpretation of the EPA regulation. No specification or written response is required by this information notice. If you have any questions about this information notice, please contact Timothy C. Johnson at 301-492-0558 of this office. If you have any questions on the new EPA regulations, please contact the toll-free RCRA/Superfund Hotline at 800-424-9346 or 202-382-3000 in Washington, DC or Mary Greene, 202-475-8551, Office of Solid Waste, U.S. Environmental Protection Agency, OS-332, 401 M Street, S.W., Room S-242, Washington, D.C. 20460. Copies of the new EPA regulations are available by calling the RCRA/Superfund Hotline.

Richard L. Bangart
Richard L. Bangart, Director
Division of Low-Level Waste Management
and Decommissioning
Office of Nuclear Material Safety
and Safeguards

Technical Contact: Timothy C. Johnson, NMSS
301-492-0557

Attachments:

1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
89-82	Recent Safety-Related Incidents at Large Irradiators	12/07/89	All U.S. NRC licensees authorized to possess and use sealed sources at large irradiators.
89-78	Failure of Packing Nuts on One-Inch Uranium Hexafluoride Cylinder Valves	11/22/89	All U.S. NRC licensees authorized to possess and use source material and/or special nuclear material for the heating, emptying, filling, or shipping of uranium hexafluoride in 30- and 48-inch diameter cylinders.
89-60	Maintenance of Teletherapy Units	08/18/89	All U.S. NRC Medical Teletherapy Licensees.
89-47	Potential Problems with Worn or Distorted Hose Clamps on Self-Contained Breathing Apparatus	05/18/89	All holders of operating licenses or construction permits for nuclear power reactors and fuel facilities.
89-46	Confidentiality of Exercise Scenarios	05/11/89	All holders of licenses for fuel cycle facilities and byproduct material licensees having an approved emergency response plan.
89-37	Proposed Amendments to 40 CFR Part 61, Air Emission Standards for Radionuclides	04/04/89	All U.S. NRC licensees.
89-35	Loss and Theft of Unsecured Licensed Material	03/30/89	All U.S. NRC byproduct, source and special nuclear material licensees.
89-34	Disposal of Americium Well-Logging Sources	03/30/89	All holders of U.S. NRC specific licenses authorizing well-logging activities.

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
89-84	Failure of Ingersoll Rand Air Start Motors as a Result of Pinion Gear Assembly Fitting Problems	12/12/89	All holders of OLs or CPs for nuclear power reactors.
89-83	Sustained Degraded Voltage on the Offsite Electrical Grid and Loss of Other Generating Stations as a Result of a Plant Trip	12/11/89	All holders of OLs or CPs for nuclear power reactors.
89-82	Recent Safety-Related Incidents at Large Irradiators	12/7/89	All NRC licensees authorized to possess and use sealed sources at large irradiators.
89-59, Supp. 1	Suppliers of Potentially Misrepresented Fasteners	12/6/89	All holders of OLs or CPs for nuclear power reactors.
89-81	Inadequate Control of Temporary Modifications to Safety-Related Systems	12/6/89	All holders of OLs or CPs for nuclear power reactors.
89-80	Potential for Water Hammer, Thermal Stratification, and Steam Binding in High-Pressure Coolant Injection Piping	12/1/89	All holders of OLs or CPs for nuclear power reactors.
89-79	Degraded Coatings and Corrosion of Steel Containment Vessels	12/1/89	All holders of OLs or CPs for LWRs.
89-56, Supp. 1	Questionable Certification of Material Supplied to the Defense Department by Nuclear Suppliers	11/22/89	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit

Therefore, waste brokers, processors, and disposal site operators in non-Covered States will need to comply with the new EPA medical waste tracking requirements when they handle, process, or dispose of wastes generated in Covered States.

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JGlenn	BCuthbertson/EPA	MGreen/EPA		
PDR YES	NO	Category: Proprietary ___ or CF Only ___		
ACNW YES	NO			
SUBJECT ABSTRACT:	INFO NOTICE ON EPA INTERIM FINAL RULE ON MEDICAL WASTE TRACKING MANAGEMENT *SEE PREVIOUS CONCURRENCE			

OFC :LLRB* :LLRB* :IMAB* :IMAB* :LLWY :

 NAME:TJohnson/es:MBell :SJones :JGlenn :RBangart :

 DATE:12/04/89 :12/04/89:12/06/89 :12/06/89 :12/07/89 :

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 JGlenn BCuthbertson/EPA MGreen/EPA
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 ACNW YES NO
 SUBJECT ABSTRACT: INFO NOTICE ON EPA INTERIM FINAL RULE ON MEDICAL WASTE TRACKING MANAGEMENT

OFC :LLRB :LLRB :IMAB :IMAB :LLWM :
 NAME: Johnson/es:MBell :SJones :JGlenn :RBangart :
 DATE: 12/11/89 : 12/14/89 : 12/16/89 : 12/16/89 : 12/17/89 :