RECORD #127

TITLE: Transfer and/or Disposal of Spent Generators

FICHE: 38351-075

SSINS No.: 6830
Accession No.:
8103300409
IN 81-32

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
WASHINGTON, D.C. 20555

October 23, 1981

IE INFORMATION NOTICE NO. 81-32: TRANSFER AND/OR DISPOSAL OF SPENT GENERATORS

Description of Circumstances:

Upon responding to a complaint recently from a private citizen, local police discovered boxes labeled as radioactive materials on the driveway of a private residence. Subsequent investigation by NRC revealed that the boxes contained eleven used molybdenum-99/technetium-99m (Mo-99/Tc-99m) generators manufactured by a major supplier of radiopharmaceuticals. Four of the generators had intact lead shielding, and seven generators had no lead shielding. The occupant of the residence was later identified as a subcontractor of the transporting company which has a contract with the major supplier to deliver new generators to, and pick up spent generators from, medical institutions. According to this individual, these spent generators had been given to him for temporary storage, and he had removed lead shielding from some of them for sale. Apparently, many drivers routinely store spent generators at their residences for indefinite periods, and return them to the contractors of the transporting companies only when they are ready to pick up new generators for delivery. NRC inspectors have encountered other situations where recovery of lead shielding from generators apparently had taken place.

Average exposure rates measured on these generators were approximately 25 mR/hr at contact and 2 mR/hr at 3 feet. Based on information included on the generator labels, the generators were estimated to contain, at the maximum, a total of 43 millicuries of Mo-99 on the day of the investigation. Assuming that 5 mCi of Mo-99 remains on a generator column and that 10 seconds are required to handle the column and to separate both internal and external layers of the lead shielding, a person could typically receive a dose of roughly 25 mrem to the hands from dismantling such a generator.

Caution to Licensees - Users of Generators:

You should note the following if you are involved in the receipt, possession, use, and transfer of these generators:

1. Your NRC license should contain specific procedures for disposing of spent generators (e.g., return to supplier, etc.). You are also reminded of the letter dated June 4, 1981 from the NRC Material Licensing Branch to all medical licensees. As stated in this letter, a condition authorizing decay-in-storage of certain radioactive materials, including

generators, would be automatically placed in new licenses issued, or added to existing licenses in response to renewal requests. You were also informed in this letter that you have the option of submitting an amendment request should you desire to add this condition to your license immediately. The proper way to store spent generators for decay and subsequent disposal is to segregate the generator columns and monitor them separately prior to disposal to ensure decay to background levels. Necessary precautions (e.g., use of disposable gloves) should be taken to avoid hand contamination.

If the columns are held for decay to background levels, there are no special requirements on disposal except for appropriate surveys to verify total decay, records of the surveys, and defacing or removal of labels on the devices. Any surveys should include the lead shielding. If no contamination is present on the shielding they may be disposed of as normal (non-radioactive) waste.

When storing spent generators for decay and disposal, you must comply with the requirements of 10 CFR 20.105 (Permissible levels of radiation in unrestricted areas) and 10 CFR 20.207 (Storage and control of licensed materials in unrestricted areas), and 10 CFR 20.203 (posting and labeling requirements).

2. Until verification surveys determine that no radioactivity remains, these spent generators must be treated as licensed material. None of the exemptions in Part 30 would apply. Any person possessing these items (for the purposes of lead recovery or waste disposal, for instance) would be required to have an NRC license. Any transfer to a person without a license is an unauthorized transfer. The only exception would be the delivery of a properly packaged and labeled item to a common or contract carrier for expeditious transport to an authorized recipient.

3. 10 CFR 30.41 (b)(5) requires that licensed material be transferred only to a person who is generally or specifically licensed by NRC or one of the Agreement States* to receive the material. You should ensure that when transferring spent generators back to the supplier, the common or contract carrier transporting the generators is fully aware that any operations with or use of the material, other than the actual transport or storage incident thereto, is not authorized. Upon delivery of the generators to the carrier for transport, you are urged to provide specific instructions on the shipping papers, indicating that the generators are to be delivered to the consignee without unnecessary delay, are not to be stored in unauthorized locations, and should not be dismantled or used by unauthorized persons. As an additional precaution, it would be judicious to establish a routine point-of-contact with the supplier to inform him of the carriers being used, and to ask for the supplier's cooperation in reporting to you any apparent instances of improper actions, such as unauthorized lead removal activities.

*Agreement States - Those States that have entered into an Agreement with the NRC to license and regulate nuclear materials and facilities.

4. The generator supplier may have provided instructions in the package inserts regarding proper, safe and legal packaging and transport of generators. If you do not already have these instructions or are unfamiliar with them, contact the supplier's representative immediately.

5. The instructions described in item 4 above may also apply to instances during which defective generators need to be shipped back to the manufacturer.

No written response to this information notice is required. If you need additional information with regard to this matter, contact the appropriate NRC regional office.

Attachment:
Recently issued IE Information Notices

RECENTLY ISSUED
IE INFORMATION NOTICES

Information Notice No.	Subject	Date of Issue	Issued to
81-31	Failure of Safety Injection Valves to Operate Against Differential Pressure	10/8/81	All power reactor facilities with an OL or CP
81-30	Velan Swing Check Valves	9/28/81	All power reactor facilities with an OL or CP
81-29	Equipment Qualification Testing Experience	9/23/81	All power reactor facilities with an OL or CP
81-28	Failure of Rockwell-Edward Main Steam Isolation Valves	9/3/81	All power reactor facilities with an OL or CP
81-27	Flammable Gas Mixtures in the Waste Gas Decay Tanks in PWR Plants	9/3/81	All power reactor facilities with an OL or CP
81-26	Compilation of Health Physics Related Information Items	9/3/81	All power reactor facilities with an OL or CP
81-25	Open Equalizing Valve of Differential Pressure Transmitter Causes Reactor Scram and Loss of Redundant Safety Signals	8/21/81	All power reactor facilities with an OL or CP
81-24	Auxiliary Feed Pump Turbine Bearing Failures	8/5/81	All power reactor facilities with an OL or CP
81-23	Fuel Assembly Damaged due to Improper Positioning of Handling Equipment	8/4/81	All power reactor facilities with an OL or CP

OL = Operating License
CP = Construction Permit

Attachment # 5, 6

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUN 04 1981

TO ALL MEDICAL LICENSEES:

On June 23, 1980 all medical and academic licensees were sent a letter describing steps that they could take to substantially reduce or eliminate radioactive waste sent to commercial low-level waste disposal facilities. One of these steps was to hold radioactive waste in storage for decay to background levels before disposal in ordinary trash. For those licensees who do not have decay-in-storage as a method for disposal of radioactive waste in their NRC license, this requires a license amendment.

In order to ease the burden of applying for an amendment to your license for decay-in-storage of radioactive waste, we have decided that we will place a condition on all medical and academic licenses which states:

"The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

a. Effected radioactive waste shall be held for decay a minimum of ten (10) half-lives.

b. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.

c. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal."

There are two ways that the above condition can be incorporated into your license:

1. Without your prior request, we will automatically place this condition on all medical byproduct material licenses as they are issued in response to new or renewal applications and amendment requests; or

2. If you desire to have this condition placed on your present license right away, you should submit a request for amendment referencing this document. This type of amendment request will be fee exempt.

A 4 XA

XA Copy Has Been Sent to PDR

You are reminded of the requirements contained in 10 CFR 20.105 and 10 CFR 20.207, which address established limits for radiation levels in unrestricted areas and storing or securing radioative material respectively.

Sandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety, NMSS

SEP 14 1982

Mr. William H. Miller, Consultant
Nuclear Medicine Associates, Inc.
9726 Park Heights
Cleveland, Ohio 44125

Dear Mr. Miller:

In your letter dated August 10, 1982, you request the Office of the Executive Legal Director's views on the relationship between residual I-125 in radioimmunoassay vials and "licensed material" as used in 10 CFR 20.301 of our regulations. Section 20.301 prescribes the general requirements for the way licensees must dispose of licensed material. As you are aware, it lists transfer, disposal approved pursuant to §20.302, and disposal as provided for in §20.106 (effluents), §20.303 (sewers), and §20.306, (H-3 and C-14 biomedical waste alternatives).

Your specific question is: "How much I-125 can remain in a Radioimmunoassay vial before it is no longer licensed material for disposal purposes?"

In response to your question, no quantitative limits on residual I-125 activity exist in the regulations or in staff guidance for complying with §20.301. The staff has not established for I-125 any exemption for a trivial level, nor has it established a level of "no regulatory concern" for the purpose of disposal under §20.301. In other words, licensed material remains licensed material until it is disposed of.

Licensees have considerable flexibility in the way they manage I-125 wastes from radioimmunoassays. Soluble or dispersable activity in liquid wastes poured from the vials or resulting from decontamination treatment to remove residual activity may be disposed of to the sanitary sewers in accordance with §20.303. No specific approval for disposals under §20.303 is required. If residual activity on the vials is not distinguishable from background, using a survey or assay instrument suitable to detect the low energy gammas from I-125, the vials may be reused or discarded in ordinary trash. Such management of glassware would likely be covered by general laboratory procedures already approved in a licensee's use of the vials.

Methods requiring specific approval under §20.302 are also available. The most common method licensees choose is to hold the vials or the contents, or both, for decay of the 60 day half life I-125. Holding for decay, survey, and disposal in ordinary trash is based on the principle previously described, namely that there is no residual activity distinguishable from background. As noted, though, specific approval for this kind of method is required to assure that licensees have adequate procedures, equipment, and facilities for proper storage, controls, and surveys.

L-4-1PT20

DESIGNATED ORIGINAL

Certified By _____

I hope these views are helpful. For your information, I have enclosed copies of letters dated June 25, 1980 and June 4, 1981 sent to all medical licensees on alternatives for managing wastes. The letters specifically address "hold for decay" methods.

Sincerely,

Thomas F. Dorian, Attorney
Regulations Division
Office of the Executive Legal Director

Enclosures:
1. Ltr dtd 9/25/80
2. Ltr dtd 6/4/81

DISTRIBUTION:
NMSS R/F
WMLL R F
WM S/F
KDragonette
WWalker, FCML
VMiller, FCML
RAScarano
REBrowning
JBMartin
TFDorian, OELD
WJOlmstead, OELD
OELD S/F
OELD R/F
Regs R/F
Central Files

C	:OELD	:OELD	:	:	:	:	:
ME	:TDorian:rb	:WJOlmstead	:	:	:	:	:
TE	:9/14/82	:9/\1/82	:	:	:	:	:

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

June 25, 1980

TO ALL MEDICAL AND ACADEMIC LICENSEES

There are a number of steps licensees engaged in nuclear medicine practice and biomedical research can take under NRC rules to substantially reduce, and in some cases eliminate, the need to send radioactive waste to commercial low-level waste disposal facilities. By taking advantage of these alternatives and following good waste management practices, licensees can often reduce the risk of having their programs impacted through further curtailment of commercial waste disposal facilities. Some of the more important steps that can be taken are to:

1. Segregate radioactive waste from non-radioactive waste to reduce unnecessary volume. This simply requires a little time and discipline in the laboratory.

2. Hold waste with short-lived radionuclides in storage for decay to background levels, then dispose of it in the ordinary trash. This procedure requires a license amendment. (See Enclosure 1 for information to be submitted with the amendment request).

3. Release certain materials into the sanitary sewage system in accordance with 10 CFR Part 20.303. No license amendment is required but 10 CFR Part 20.303 should be carefully reviewed to stay within limits.

Judicious use of these three steps can substantially reduce the volume of waste shipped to burial grounds. Some nuclear medicine laboratories using only short-lived radionuclides can eliminate waste shipments.

Waste from biomedical research is generally somewhat more difficult to manage. Two of the most common problems are disposal of liquid scintillation counting waste (LSCW) and animal carcasses. The most frequently used radioisotopes in both are tritium and carbon-14. LSCW presents a particularly troublesome problem due to the flammability and toxicity of the solvents. Disposal of LSCW has been given special consideration by NRC. The staff has investigated alternatives to managing these wastes and the results have been published in NUREG-0656.

Enclosure 1

Information to be Submitted When Requesting Amendment to Dispose of Radioactive Waste by Decay-In-Storage Method

This is in reference to your request for information concerning authorization to dispose of radioactive waste via decay-in-storage. In order to approve such an amendment request, we need the following information:

1. Please submit a diagram of the area where the waste will be decayed-in-storage. Show the type, location, and thickness of shielding that you will have available in this area on your diagram. Your storage area should be large enough to handle an accumulation of used Tc-99m generators as well as other solid waste.

   Identify adjacent unrestricted areas located across the walls from the storage area and show that adequate steps have been taken to assure that radiation levels do not exceed the limits specified in 10 CFR 20.105 (enclosed).

2. Describe your security measures for the decay-in-storage area.

3. Confirm that radiation levels in this area will be surveyed and recorded at least weekly.

4. Describe your procedures for monitoring the waste to assure that it has decayed to background levels prior to disposal. As a minimum, your description should include these points:

   a. Monitor the waste in a low background area.

   b. Monitor with a low level GM type survey meter as appropriate for contamination surveys. Use the most sensitive scale.

   c. Remove all shielding prior to monitoring.

   d. Maintain records of these surveys as required under 10 CFR 20.

5. Note that decay-in-storage may not be a practical method of disposal for Tc-99m generators. These generators may contain long-lived radioisotopic contaminants. If you intend to dispose of generators by this method, you should include procedures for segregating the generator columns so that they may be monitored separately.

Be certain to submit your amendment request in duplicate. Unless your institution is fee exempt, your request should be accompanied by the appropriate amendment fee. Refer to 10 CFR 170.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUN 04 1981

TO ALL MEDICAL LICENSEES:

On June 23, 1980 all medical and academic licensees were sent a letter describing steps that they could take to substantially reduce or eliminate radioactive waste sent to commercial low-level waste disposal facilities. One of these steps was to hold radioactive waste in storage for decay to background levels before disposal in ordinary trash. For those licensees who do not have decay-in-storage as a method for disposal of radioactive waste in their NRC license, this requires a license amendment.

In order to ease the burden of applying for an amendment to your license for decay-in-storage of radioactive waste, we have decided that we will place a condition on all medical and academic licenses which states:

"The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

a. Effected radioactive waste shall be held for decay a minimum of ten (10) half-lives.

b. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.

c. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal."

There are two ways that the above condition can be incorporated into your license:

1. Without your prior request, we will automatically place this condition on all medical byproduct material licenses as they are issued in response to new or renewal applications and amendment requests; or

2. If you desire to have this condition placed on your present license right away, you should submit a request for amendment referencing this document. This type of amendment request will be fee exempt.