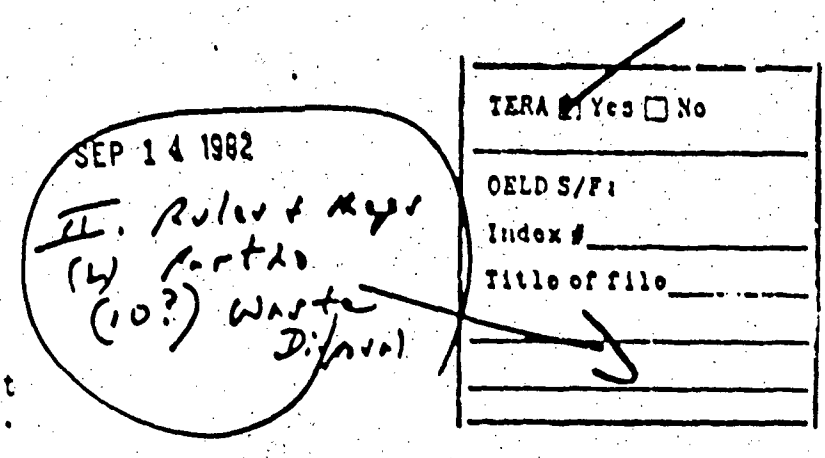
RECORD #45

TITLE: Decay In-Storage and Disposal of Radioactive Waste As Ordinary Trash

FICHE: 66380-248

0474/82



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.

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

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

SEP 10 1982

0474/82

FILE
Waste Disposal

Also Copy to Interpretati

MEMORANDUM FOR: Thomas F. Dorian
Attorney Regulations Division, OELD

FROM: Kitty S. Dragonettte
Low-Level Waste Licensing Branch
Division of Waste Management, NMSS

SUBJECT: NUCLEAR MEDICINE ASSOCIATES REQUEST REGARDING RESIDUAL I-125

You asked the Low-Level Waste Licensing Branch to help you prepare a response to Mr. William Miller of Nuclear Medicine Associates concerning disposal of residual I-125 in radioimmunoassay vials. A draft response is enclosed. This response has been coordinated with the Material Licensing Branch who conducts the day-to-day licensing of the use of these materials.

Kitty S. Dragonette

Kitty S. Dragonette
Low-Level Waste Licensing Branch
Division of Waste Management

Enclosure: As stated

cc: [redacted]
A. Gibson, RO II
J.R. Miller, RO III
G.D. Brown, RO IV
H. Book, RO V

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

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 requested 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 lists the general requirements for how licensees shall dispose of licensed material. As you are aware, it lists transfer, and disposal approved pursuant to §20.302, and disposal as provided in §20.106 (effluents), §20.303 (sewers), and §20.306, (H-3 and C-14 biomedical waste alternatives).

Your specific question was, "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 numerical or quantitative limits on residual I-125 activity exist in the regulations or in staff guidance for complying with §20.301. No exempt quantity, de minimis level, or level of no regulatory concern has been established for I-125 for purposes of disposal under §20.301.

Licensees have considerable flexibility in how they manage the 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 the ordinary trash. Such management of glassware would likely be covered by general laboratory procedures already approved in licensing use of the vials.

Methods requiring specific approval under §20.302 are also viable. The most common method licensees choose is to hold the vials and/or contents for decay of the 60 day half life I-125. Hold for decay, survey, and disposal in ordinary trash is based on the same administrative principle

of no residual activity distinguishable from background. However, specific approval is required to assure adequate procedures, equipment, and facilities for proper storage, controls, and surveys. 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 6/25/80
2. Ltr dtd 6/4/81

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.

Consideration should be given to disposal by incineration for LSCW and laboratory animals containing small amounts of tritium and carbon-14. This method requires a license amendment; 10 CFR Part 20.305 contains the provisions for incineration. Enclosure 2 identifies the information to be submitted with an amendment request for incineration.

There are other provisions in the regulations that cover waste disposal. We have mentioned only the few that are most easily and commonly used. Other regulatory provisions include:

1. Disposal by burial in soil in accordance with 10 CFR 20.304 (A proposed rule change is under consideration to delete this provision. It will likely be replaced by a provision which requires specific approval by license amendment for burial).

2. Release as effluents to unrestricted areas pursuant to 10 CFR Part 20.106. In keeping with the ALARA concept, this method should normally be used only for releases incident to the procedures involved.

We suggest that you review and consider alternatives to commerical land burial for the management of your low-level radioactive waste. Implementation of some of these alternatives may require an amendment to your license. Amendment requests should be submitted to the Material Licensing Branch through the use of normal channels. Specific licensing questions concerning NUREG-0656 should be directed to the Material Licensing Branch (301) 427-4232. Copies of the NUREG-0656 may be obtained from the Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Sincerely,

Vandy L. Miller

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

Enclosures:

1. Information to be submitted When Requesting Amendment to Dispose of Radioactive Waste by Decay-In-Storage.

2. Information Required for Commission Approval of Treatment or Disposal by Incineration.

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.

INFORMATION REQUIRED FOR COMMISSION APPROVAL OF TREATMENT OR DISPOSAL BY INCINERATION

Revised October 3, 1979

1. State specifically the isotopes you wish to incinerate. For each isotope listed, you should submit calculations demonstrating that air concentrations of the effluents at the stack are in accordance with the requirements of Section 20.106 of 10 CFR Part 20.

2. Submit the characteristics of the incinerator such as height of the stack, height of and distance to buildings in the surrounding areas, rated airflow of the incinerator in cubic feet per hour or similar units and its proximity to any air intake ducts.

3. The gaseous effluent from the incinerator stack should not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20, when averaged over a twenty-four (24) hour period.

4. In order to be in compliance with the ALARA philosophy stated in Section 20.1(c) of 10 CFR Part 20, the gaseous effluent from the incinerator stack should be a fraction (approximately 10%) of the limits specified for air in Appendix B, Table II, 10 CFR Part 20, when averaged over a one year period.

5. Describe the method of measurement or estimation of the concentration of radioactive material appearing in ash residue.

6. Describe the procedures for handling and disposing of ash from the incinerator.

7. Describe procedures to be followed to prevent overexposure of personnel during all phases of the operation, including instruction given to personnel handling the combustibles and the ash.

8. Submit evidence that all State and local regulations concerning incineration of radioactive material have been met by your institution.

9. State the maximum number of burns to be performed in any one week and the maximum number of burns per year.

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.

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