

Received on  
12/13/05 Jm

Jim, it is a pleasure working with you on this complicated RAM application.

As discussed via our phone conversation, there are four(4) topics that need to be resolved.

1. Item 11 Waste Management Pharmacy-Generated Radioactive Wastes  
And  
Waste Management Returned Wastes from Customers.  
commitments were missing from checklist.

This has been corrected, please see the new checklist showing the commitment to the above mentioned items.

2. The non-related information at the bottom of the request form labeled "Nuclides-Form-Quantity-Uses" specifically referencing 10 CFR 32.11.

This information has been deleted. Please see the revised attached form labeled  
"Nuclides-Form-Quantity-Uses"

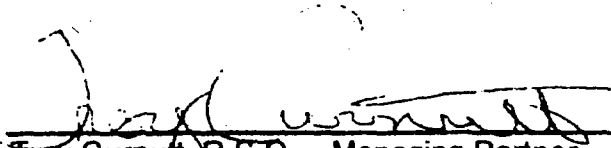
3. Please give a maximum amount of Yttrium<sup>90</sup> that will be onsite at any one time.

The therapeutic dose is 0.4mCi/kg body weight of yttrium<sup>90</sup> ibritumomab tiuxetan with a maximum dose of 32mCi regardless of weight.

We request maximum amount of 75 mCi of Yttrium<sup>90</sup> to have onsite at any one time.

4. A signature showing culpability of requested changes.

I authorize this and subsequent changes to Advanced Isotopes of Idaho's NRC RAM application

  
Troy Curnutt, R.S.O. - Managing Partner  
Advanced Isotopes of Idaho  
4968 Rainbow Lane  
Chubbuck Idaho 83202  
(208) 237-9730 office  
(208) 233-0186 fax

Information in this record was deleted  
in accordance with the Freedom of Information  
Act, exemptions 6  
FOIA 2007-0121

B/5

## NUCLIDES-FORM-QUANTITY-USES

	Element and/or chemical form	Maximum Quantity	Authorized Uses
<b>A. Molybdenum-99</b>	Any molybdenum-99-technetium-99m generator manufactured, labeled, packaged, and distributed in accordance with specific license issued pursuant to 32.72 of 10 CFR Part 32 or a specific license issued to a manufacturer by the NRC pursuant to equivalent regulations.	30 Curies	Production of technetium-99m pertechnetate. Redistribution to authorized recipients
<b>B. Xenon-133</b>	Unit dose containers of gas or gas in solution that is the subject of an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e. not withdrawn, terminated, or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA.	2 Curies	Distribution to authorized recipients
<b>C. Iodine-131</b>	Any form listed in 10 CFR 35.300	500 mCi	Dispensed and or distributed prepared radiopharmaceuticals to authorized recipients. Iodine-131 as iodine listed in 10 CFR 35.300 for compounding and dispensing as iodine-131 capsules and distributed to authorized recipients.
<b>D. Technetium-99m</b>	Any form listed in 10 CFR 35.200	30 Curies	Dispensing and or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium-99m pertechnetate for processing with reagent kits in preparation of radiopharmaceuticals.
<b>E. Any radioactive material, except Iodine-131 and Technetium-99m, listed in 10 CFR 35.100</b>	Any form listed in 10 CFR 35.100	As Needed	Dispensing and or distributing prepared radiopharmaceuticals to authorized recipients.
<b>F. Any radioactive material, except Iodine-131 and Technetium-99m, listed in 10 CFR 35.200</b>	Any form listed in 10 CFR 35.200	As Needed	Dispensing and or distributing prepared radiopharmaceuticals to authorized recipients.
<b>G. Uranium (depleted in the isotope Uranium 235)</b>	Plated or encapsulated metal	500 Kilograms	As shielding material in generators

<b>Radioactive Nuclide</b>	<b>Chemical and/or physical form</b>	<b>Maximum Quantity</b>	<b>Authorized Uses</b>
<b>H. Any radionuclide with atomic numbers 3-83, inclusive</b>	Sealed source. Any sealed source listed in 10 CFR 35.65 that has been manufactured, labeled, packaged, and distributed in accordance with specific license issued pursuant to 32.72 of 10 CFR Part 32 or a specific license issued to a manufacturer by the NRC pursuant to equivalent regulations	250 millicuries; no single source to exceed 30 millicuries	Instrument calibration. Redistribution of sealed sources to specifically authorized recipients. Pursuant to 10 CFR 35.65(b), the licensee is authorized to redistribute sources to persons licensed pursuant to 10 CFR 32.11, or other persons specifically licensed to receive such source.
<b>I. Any radioactive material</b>	Analytical Samples	As Needed	For possession incident to the performance of wipe tests of sealed sources for the licensee and as a customer service
<b>J. Iodine-125</b>	Sealed source	500 millicuries	Receipt, storage and distribution upon prescription to authorized recipients.
<b>K. Gold-198</b>	Sealed source	500 Millicuries	Receipt, storage and distribution upon prescription to authorized recipients.
<b>L. Iridium-192</b>	Sealed source	500 millicuries	Receipt, storage and distribution upon prescription to authorized recipients.
<b>M. Cesium-137</b>	Sealed source	500 millicuries	Receipt, storage and distribution upon prescription to authorized recipients.
<b>N. Palladium-103</b>	Sealed source	2 Curies	Receipt, storage and distribution upon prescription to authorized recipients.
<b>O. Fluorine-18</b>	Any	As Needed	Receipt, storage and distribution upon prescription to authorized recipients
<b>P. Yttrium-90</b>	Liquid	As Needed	Receipt, storage and distribution upon prescription to authorized recipients.

Pursuant to 10 CFR 32.72, we request authorization to distribute the radioactive material described in Table C.2 of this application to authorized licensed recipients, for the Groups indicated below:

C. Through P. (Above)

Any form listed 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 and 10 CFR 35.400 may be distributed to persons licensed pursuant to those sections.

## Appendix C: Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313

Item No.	Title and Criteria	Yes	Description Attached
<b>5.</b>	<b>RADIOACTIVE MATERIAL</b>		
	<b>Sealed And/Or Unsealed Byproduct Material</b>		
	For unsealed materials:		
	<ul style="list-style-type: none"> <li>Identify each radionuclide (element name and mass number) that will be used, the form, and the maximum requested possession limit.</li> </ul>		<b>See attached</b> [X] <b>"Nuclides-Form-Quantity-Uses"</b>
	<b>AND</b>		
	For potentially volatile materials (e.g., iodine-131):		
	<ul style="list-style-type: none"> <li>Specify whether the material will be manipulated at the radiopharmacy</li> </ul>		[X] <b>See Attached</b> <b>"Procedures for Handling millicurie quantities of radio-iodine"</b>
	For sealed materials:		
	<ul style="list-style-type: none"> <li>Identify each radionuclide (element name and mass number) that will be used in each source;</li> </ul>		<b>See Attached</b> [X] <b>"Brachytherapy Seed Information"</b>
	<ul style="list-style-type: none"> <li>Provide the manufacturer's (distributor's) name and model number for each sealed source and device requested;</li> </ul>		<b>See Attached</b> [X] <b>"Brachytherapy Seed Information"</b>
	<ul style="list-style-type: none"> <li>We confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State;</li> </ul>		[X]
	<ul style="list-style-type: none"> <li>We confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State</li> </ul>		[X]
	For depleted uranium, specify the total amount (in kilograms).		<b>999 Kg</b> [X]
<b>5</b>	<b>RADIOACTIVE MATERIAL (Cont'd)</b>		
	<b>Financial Assurance and Record Keeping for Decommissioning</b>		
	If financial assurance is required, submit documentation required by 10 CFR 30.35.		<b>N/A</b> [ ]
<b>6.</b>	<b>PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED</b>		
	For radiopharmaceuticals:		
	<ul style="list-style-type: none"> <li>We confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to 10 CFR 32.72; and</li> </ul>		[X]
	<ul style="list-style-type: none"> <li>Describe all licensed material to be distributed or redistributed.</li> </ul>		<b>See attached</b> [X] <b>"Nuclides-Form-Quantity-Uses"</b>

For generators:

- We confirm that the generators will be obtained from a manufacturer licensed pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements; and [X]
- We confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging. [X]

**6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED (Cont'd)**

For redistribution of used generators:

- Describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport; See Attached Policy & Procedure Manual [X]
- We confirm that the manufacturer's packaging and labeling will not be altered; [X]
- We confirm that the generator will not be distributed beyond the expiration date shown on the generator label; [X]
- We confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator; and [X]
- We confirm that only generators used in accordance with the manufacturer's instructions will be redistributed. [X]

For Redistribution of Sealed Sources C for Brachytherapy or Diagnosis:

- We confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements; and [X]
- We confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources. [X]

**6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED (Cont'd)**

For Redistribution of Calibration and Reference Sealed Sources:

- We confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to 10 CFR 32.74 to initially distribute such sources; and [X]
- We confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources. [X]

For Redistribution of Prepackaged Units for *In Vitro* Tests:

- We confirm that the prepackaged units for *in vitro* [X]

tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for *in vitro* tests in accordance with a specific license issued pursuant to 10 CFR 32.71 or under an equivalent license of an Agreement State.

For Redistribution to General Licensees:

- We confirm that the manufacturer's packaging and labeling of the prepackaged units for *in vitro* tests will not be altered in any way; and ☒
- We confirm that each redistributed prepackaged unit for *in vitro* tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees. ☒

**6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED (Cont'd)**

For radiopharmaceutical preparation, we will perform:

- compounding of iodine-131 capsules; ☒
- radioiodination; ☒
- technetium-99m kit preparation; and ☒
- other, specify. ☐ ☐

Supply specific information concerning the use of sealed sources for reference and calibration, and depleted uranium.

**Please see original application, including policy & procedure manual.** ☒

We will provide customer the following radiation protection services involving licensed material:

- leak testing; ☐ ☒

**See Attached**

**Policy & Procedure Manual**

- instrument calibration; and ☐ ☒
- other, specify. ☐ ☒

**See Attached**

**Policy & Procedure Manual**

**Page 50  
(6.4)(A)(B)(C)(D)**

**7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE**

For applicant's management structure, provide:

- An organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the RSO. **See Attached Organizational Chart** ☒

**7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Cont'd)**

For the Radiation Safety Officer (RSO), provide:

- Name of the proposed RSO; [X]

See Attached

Vincent T. Curnutt

AND

- A copy of the license (NRC or Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, an ANP, or an AU; See Original attached information on [X]

Vincent T. Curnutt

OR

- Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to commercial nuclear pharmacies. See Original attached information on [X]

Vincent T. Curnutt

**Note:** See Appendix G for convenient formats to use for documenting hours of training in basic radioisotope handling techniques and hours of experience using radioisotopes. Figures G-1 and G-2 are specific to RSO training and experience.

**7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Cont'd)**

For each proposed Authorized Nuclear Pharmacist (ANP), provide the following:

- Name of the pharmacist; See Original attached Training and Experience and Preceptor Statement Catherine A. Heyneman [X]

AND

- A copy of the State pharmacy licensure or registration of the pharmacist; [ ]

AND

- A copy of the license (NRC or Agreement State) on which the individual was specifically named as an ANP; [ ]

OR

- A copy of the permit maintained by a licensee of broad scope that identifies the individual as ANP; [ ]

OR

- A copy of previous NRC license issued to a commercial radiopharmacy prior to December 2, 1994, on which the pharmacist was specifically named as an authorized user; [ ]

OR

- A copy of the pharmacist's certification(s) from the radiopharmacy board(s) approved by NRC; [ ]

**7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Cont'd)**

OR



- Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience; and written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy; See Attached Training and Experience and Preceptor Statement [X]  
  
Catherine A. Heyneman

**AND**

- Description of the recentness of training, if necessary. [ ]
- 7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Cont'd)**  
For each proposed Authorized User (AU), provide the following:

- Name of each proposed AU; N/A [ ]

**AND**

- Identify types, quantities, and proposed uses of licensed material; [ ]

**AND**

- A copy of license (NRC or Agreement State) on which the individual was specifically named as an AU for the types, quantities, and proposed uses of licensed materials; [ ]

**OR**

- A copy of the permit maintained by a licensee of broad scope that identifies the individual as an AU for the types, quantities, and proposed uses of licensed materials; [ ]

**OR**

- Description of the training and experience demonstrating that the proposed AU is qualified by training and experience to use the requested licensed materials. The applicant may find it convenient to describe this training and experience using a format similar to Figures G-1 and G-2 in Appendix G. [ ]

**8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (INSTRUCTIONS TO OCCUPATIONALLY EXPOSED WORKERS AND ANCILLARY PERSONNEL)**

**Occupationally Exposed Workers and Ancillary Personnel**

We have developed and will implement and maintain written procedures for a training program for each group of workers, including: topics covered; qualifications of the instructors; method of training; method for assessing the success of the training; and the frequency of training and refresher training. [X]

**Personnel Involved in Hazardous Materials Package Preparation and Transport**

We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702, and 49 CFR 172.704, as applicable. [X]

**Instruction for Supervised Individuals Preparing Radiopharmaceuticals**

**Need Not Be Submitted with Application**

**9. FACILITIES AND EQUIPMENT**

Provide a copy of the registration or license from a State Board of Pharmacy as a pharmacy; or provide evidence that the facility is operating as a nuclear pharmacy within a Federal medical institution;

[X] [ ]

**Idaho will not  
issue a Pharmacy  
License until the  
NRC issues a RAM  
License**

**AND**

Describe the facilities and equipment to be made available at each location where radioactive material will be used. A diagram should be submitted showing the applicant's entire facility and identify activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to a specified scale, or dimensions should be indicated.

**See Original [X]  
attached  
information  
Description of  
facility, with  
photos**

Include the following information:

- Descriptions of the area(s) assigned for the receipt, storage, preparation, and measurement of radioactive materials and the location(s) for radioactive waste storage;
- Sufficient detail in the diagram to indicate locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety;
- Descriptions of the ventilation systems, including gloveboxes or fume hoods, with pertinent airflow rates, area differential pressures, filtration equipment, and monitoring systems for the use or storage of radioactive materials with the probability of becoming airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions; and
- Verification that ventilation systems ensure that effluents are within 10 CFR 20.1301 and are ALARA constraints for air emissions established under 10 CFR 20.1101(d)

**Please see new [X]  
attached map.**

**Please see new [X]  
attached map.**

**Please see [X]  
attached  
Procedures for  
Handling  
millicuries  
quantity of  
Radioiodine**

**Please see [ ]  
attached  
Procedures for  
Handling  
millicuries  
quantity of  
Radioiodine**

**10. RADIATION SAFETY PROGRAM**

**Need Not be  
Submitted with  
Application**

**Audit Program**

The applicant's program for reviewing the content and implementation of its radiation protection program will be examined during inspections, but it should not be submitted in the license application.

**See attached Policy  
and Procedure  
manual  
Page 33**

**Instruments**

We will use equipment that meets the radiation monitoring instrument specifications and implement the model survey meter calibration program published in Appendix J to NUREG - 1556, Vol. 13, "Program-Specific Guidance About Radiopharmacy Licenses," dated September 1999;

[ ]

**OR**

We will use equipment that meets the radiation monitoring instrument specifications published in Appendix J to NUREG-1556, Vol. 13, "Program-Specific Guidance About

[X]

Radiopharmacy Licenses," dated September 1999, and instruments will be calibrated by other persons authorized by the NRC, an Agreement State, or a licensing State to perform that service;

**OR**

A description of alternative minimum equipment to be used for radiation monitoring and/or alternative procedures for the calibration of radiation monitoring equipment. [ ]

**10. RADIATION SAFETY PROGRAM (Cont'd)**

**Material Receipt and Accountability**

We have developed, and will implement and maintain written procedures for safely opening packages that meet the requirements in 10 CFR 20.1906;

[X]

**AND**

We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months;

[X]

**AND**

We have developed, and will implement and maintain written procedures for licensed material accountability and control to ensure that:

[X]

- license possession limits are not exceeded;
- licensed material in storage is secured from unauthorized access or removal;
- licensed material not in storage is maintained under constant surveillance and control; and
- records of receipt, transfer, and disposal of licensed material are maintained.

**Occupational Dosimetry**

We have developed and will implement and maintain written procedures for monitoring occupational dose that meet the requirements in 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, and 10 CFR 20.2106, as applicable.

[X]

**10. RADIATION SAFETY PROGRAM (Cont'd)**

**Need Not Be  
Submitted with  
Application**

**Public Dose**

The applicant's program to control doses received by individual members of the public will be examined during inspection, but it should not be submitted in a license application.

**Safe Use of Radionuclides and Emergency Procedures**

We have developed and will implement and maintain written procedures for the safe use of radioactive materials that address:

[X]

- facility and personnel radioactive contamination minimization, detection, and control;
- performing molybdenum-99 breakthrough measurements on all generator elutions used to prepare radioactive drugs for human medical use; and
- use of protective clothing and equipment by personnel

**See attached  
Policy and  
Procedure manual**

**See attached  
Policy and  
Procedure manual**

**See attached**

**Policy and  
Procedure manual**

that meet the requirements in 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.34(g), and 10 CFR 19.11(a)(3), as applicable;

**10. RADIATION SAFETY PROGRAM (Cont'd)**

**AND**

We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including:

**[X]**

- lost, stolen, or missing licensed material;
- exposures to personnel and the public in excess of NRC regulatory limits;
- releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits;
- excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas;
- radioactive spills and contamination;
- fires, explosions, and other disasters with the potential for the loss of containment of licensed material; and
- routine contacts with local fire departments

that meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201-2203, and 10 CFR 30.50, as applicable.

**Surveys**

We have developed and will implement and maintain written procedures for a survey program that specifies the performance of radiation and contamination level surveys in restricted and unrestricted areas, personnel contamination monitoring, action levels, and the frequencies and records maintenance of those surveys and monitoring that meet the requirements in 10 CFR 30.53, 10 CFR 20.1501, and 10 CFR 20.2103 as applicable.

**[X]**

**10. RADIATION SAFETY PROGRAM (Cont'd)**

**Dosage Measurement Systems**

Describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, and photon-emitting radioactive drugs;

**See attached description of "Capintec CRC-15E" Dose Calibrator** **[X]**

**AND**

For each dose measurement system used to measure the amount of radioactivity in alpha-, beta-, or photon-emitting radioactive drugs, state: "We have developed, and will implement and maintain a written procedure for the performance of dosage measurement system checks and tests that meets the requirements in 10 CFR 32.72(c)";

**[X]**

**See Original attached Policy and Procedure manual**

**AND**

If applicable, include a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers;

**Dose calibrator does not require correction factors to accurately read Beta emitters** **[ ]**

**OR**

If applicable, include a means for ensuring the accuracy of

**Dose calibrator** **[ ]**

beta-correction factors supplied by the instrument manufacturer or other entity.

**does not require  
correction factors  
to accurately read  
Beta emitters**

#### **Transportation**

**Need Not Be  
Submitted with  
Application**

The applicant's program for transportation will be examined during inspection, but should not be submitted in a license application.

#### **10. RADIATION SAFETY PROGRAM (Cont'd)**

**Need Not Be  
Submitted with  
Application**

##### **Minimization of Contamination**

The applicant *does not need to provide a response to this item* under the following condition: NRC will consider that the criteria have been met if the applicant's responses meet the criteria for the following sections: "Facilities and Equipment; Radiation Safety Program - Safe Use of Radionuclides and Emergency Procedures; Radiation Safety Program - Surveys; Radiation Safety Program - Leak Testing; and Waste Management" of NUREG - 1556, Vol. 13, dated September 1999.

##### **Radioactive Drug Labeling for Distribution**

Describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g., on the "transport radiation shield" or the container used to hold the radioactive drug); and agree to affix the required labels to all "transport radiation shields" and each container used to hold the radioactive drugs.

##### **Radioactive Drug Shielding for Distribution**

For each radioactive drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package), provide:

[X]

- The radionuclide and the maximum activity for each type of container (e.g., vial, syringe);
- Describe the type and thickness of the "transport radiation shield" provided for each type of container; and
- Indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.

**Please see  
originally  
attached Policy &  
Procedure Manual**

**Please see  
Attached  
Unit Dose Syringe  
Pigs**

**Please see  
originally  
attached Policy &  
Procedure Manual**

#### **10. RADIATION SAFETY PROGRAM (Cont'd)**

##### **Leak Tests**

We have developed and will implement and maintain written procedures for leak testing that meet the requirements in 10 CFR 30.53, 10 CFR 20.1501, and 10 CFR 20.2103

[X]

11. Waste Management  
Pharmacy-Generated  
Radioactive Wastes

We have developed, and will implement and maintain, written procedures for waste management that meet the requirements in 10 CFR 20.2001(a), 10 CFR 20.2003, and 10 CFR 20.2006, 10 CFR 20.2108, 10 CFR 30.51, as

[X]

[ ]

**Please see  
originally  
attached Policy &  
Procedure Manual**

11 Waste Management  
Returned Wastes from  
Customers

applicable.

We have developed and will  
implement and maintain written  
procedures for customer return of  
pharmacy supplied syringes and  
vials and their contents, to specify  
that:

☒ [X]

☐ [ ]

**Please see  
originally  
attached Policy &  
Procedure Manual**

- only pharmacy supplied  
syringes and vials and their  
contents may be returned  
to the pharmacy;
- instructions will be provided  
to radiopharmacy  
customers for the proper  
preparation and packaging  
of the radioactive waste for  
return to the  
radiopharmacy; and
- instructions will be provided  
to pharmacy staff for the  
pick-up, receipt and  
disposal of the returned  
radioactive waste

that meet the requirements in  
10 CFR 20.2001(a), 10 CFR 30.33,  
and 10 CFR 71.5, as applicable.

470722

**COVER SHEET FOR CORRESPONDENCE**  
**USE THIS COVER SHEET TO PROTECT ORIGINALS OF**  
**MULTI-PAGE CORRESPONDENCE**