

The seal of the State of Arizona is faintly visible in the background. It is a circular emblem with the text 'GREAT SEAL OF THE STATE OF ARIZONA' around the perimeter. Inside the circle, there is a shield with a landscape scene, a banner at the top that reads 'DITAT DEUS', and the year '1912' at the bottom flanked by two stars.

**ARIZONA RADIATION REGULATORY AGENCY  
REGULATORY GUIDE**

**MEDICAL**

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**ARRA-M**  
July 2011

**ARIZONA RADIATION REGULATORY AGENCY  
APPLICATION FOR MATERIALS LICENSE  
MEDICAL**

**INSTRUCTIONS:** Complete all items in this application for a new license or the renewal of an existing license. Use supplemental sheets where necessary. Item 35 must be completed on all applications. **Mail original to: Arizona Radiation Regulatory Agency, 4814 South 40th Street, Phoenix, Arizona 85040.** Upon approval of this application, the applicant will receive an Arizona Radioactive Materials License issued in accordance with the requirements contained in the Arizona Administrative Code.

1. **NAME AND MAILING ADDRESS OF APPLICANT**  
(Institution, Firm, Clinic, Physician, etc.) **INCLUDE ZIP CODE**

2. **STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED** (if different from 1.A.)  
**INCLUDE ZIP CODE**

**TELEPHONE NUMBER:**

3. **PERSON TO CONTACT REGARDING THIS APPLICATION**

4. **THIS IS AN APPLICATION FOR:** (check appropriate item)

- NEW LICENSE (Fee required- Complete item 29)
- RENEWAL OF LICENSE NUMBER
- AMENDMENT TO LICENSE NUMBER

**TELEPHONE NUMBER:**

5. **INDIVIDUAL USERS** (Name individuals who will use or directly supervise use of radioactive material. **Complete the correct ARRA-2 Form, and submit with professional certification, if appropriate.** (Forms and Guide are available from the Agency)

6. **RADIATION SAFETY OFFICER** (Name of person designated as Radiation Safety Officer. Attach a completed ARRA-2 (RSO) Form

**7. RADIOACTIVE MATERIAL FOR MEDICAL USE**

RADIOACTIVE MATERIAL LISTED IN:	MAXIMUM POSSESSION LIMITS	RADIOACTIVE MATERIAL	MAXIMUM POSSESSION LIMITS
R12-1, ARTICLE 7, EXHIBIT A, GROUP 100			
R12-1, ARTICLE 7, EXHIBIT A, GROUP 200			
R12-1, ARTICLE 7, EXHIBIT A, GROUP 300			
R12-1, ARTICLE 7, EXHIBIT A, GROUP 400			
R12-1, ARTICLE 7, EXHIBIT A, GROUP 500			
R12-1, ARTICLE 7, EXHIBIT A, GROUP 600			
R12-1-306.F FOR IN-VITRO STUDIES			
OTHER			

8. **RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 7.** (Small sealed sources (up to 30 mCi) used for calibration and reference standards are authorized under R12-1-714. List all sealed sources greater than 30 millicuries on an attached sheet.

**INFORMATION REQUIRED FOR ITEMS 9 THROUGH 33**

For items 9 through 33, check the appropriate boxes and submit detailed description of all the requested information. Submit signed and dated "ready made" attachments or your equivalent procedures. Begin each item on a separate sheet.

9. **RADIATION SAFETY COMMITTEE**  
(Check one)

- Names and specialties attached
- Duties as in attachment A, and
- RDRC authority requested

10. **RADIATION SAFETY OFFICER**  
(Check one)

- Duties as in Attachment B, or
- Equivalent procedures attached

11. **TRAINING AND EXPERIENCE**  
(Check one)

- The correct ARRA-2 Forms are attached for each user and RSO
- Accepted certification attached \*

\* Certification alone is not normally adequate

12. **INSTRUMENTAL**  
(Check one)  
 Attachment C attached, or  
 Equivalent list attached
13. **CALIBRATION OF INSTRUMENTS**  
(Check one)  
 Attachment D procedure attached or  
 Equivalent procedures attached  
**Note:** a dose calibrator may not be needed, depending on the scope of your program
14. **FACILITIES AND EQUIPMENT**  
(Check one)  
 Description and diagram attached
15. **PERSONNEL TRAINING PROGRAM**  
(Check one)  
 Attachment E procedures attached, or  
 Equivalent procedures attached
16. **PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL**  
(Check one)  
 Attachment F procedures attached, or  
 Equivalent procedures attached
17. **PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL**  
(Check one)  
 Attachment G procedures attached, or  
 Equivalent procedures attached
18. **RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL**  
(Check one)  
 Attachment H-1 procedures attached, or  
 Equivalent procedures attached: and  
(Check one)  
 Attachment H-2 procedures attached, or  
 Equivalent procedures attached
19. **EMERGENCY PROCEDURES**  
(Check one)  
 Attachment I procedures attached, or  
 Equivalent procedures attached
20. **AREA SURVEY PROCEDURES**  
(Check one)  
 Attachment E procedures attached, or  
 Equivalent procedures attached
21. **WASTE DISPOSAL**  
(Check one)  
 Attachment K procedures attached, or  
 Equivalent procedures attached
22. **THERAPEUTIC USE OF RADIOPHARMACEUTICALS**  
(Check one)  
 Attachment L procedures attached,  
 Equivalent procedures attached  
 Palliative procedures are described on a separate sheet  
 No therapeutic use of radiopharmaceuticals
23. **THERAPEUTIC USE OF SEALED SOURCES**  
(Check one)  
 Detailed information attached; and  
(Check one)  
 Attachment M procedures attached  
 Equivalent procedures attached  
 No therapeutic use of sealed sources attached
24. **PULMONARY FUNCTION STUDIES**  
(Check one)  
 Attachment N attached, or  
 Equivalent supporting information and calculations attached or  
 Radioaerosol will be used  
(Procedures attached)
25. **PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS**  
(Check one)  
 Detailed information attached, or  
 No radioactive material used in animals
26. **PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 8**  
(Check one)  
 Detailed information attached, or  
 No material listed in item 8
27. **PERSONNEL DOSIMETRY AND BIOASSAY PROGRAMS**  
(Check one)  
 Attachment O procedures attached, or  
 Equivalent detailed information
28. **LEAK TEST PROGRAM**  
(Check one)  
 Attachment P procedures attached, or  
 Equivalent detailed information attached
29. **ALARA PROGRAM**  
(Radiation Levels As Low As Reasonably Achieved)  
(Check one)  
 Attachment Q program attached, or  
 Equivalent program attached
30.  Letter to local governing authority attached (Not necessary with renewal)
31. **LICENSE FEE REQUIRED**  
(See AAC Article 13 for fees)  
a. LICENSE FEE CATEGORY  
\_\_\_\_\_  
b. LICENSEE FEE ENCLOSED  
\_\_\_\_\_  
  
(Do not pay a fee with a license renewal application)
32. **LEGAL STRUCTURE**  
 Attached completed form (Attachment S)
33. **INVENTORY, if renewal**  
a.  Copy of RAM inventory attached  
b.  Mobile Nuclear Medicine (Use Attachment R)
34. **INCREASED CONTROLS**  
(See Attachment U)

### ITEM 35 – CERTIFICATION

(This item must be completed by applicant official)

THE APPLICANT, OR ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFIES THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH ARIZONA RADIATION REGULATORY AGENCY RULES FOR THE CONTROL OF IONIZING RADIATION, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF.

\_\_\_\_\_  
APPLICANT NAMED IN ITEM 1

DATE: \_\_\_\_\_

BY: \_\_\_\_\_  
SIGNATURE

\_\_\_\_\_  
TYPED OR PRINTED NAME OF CERTIFYING OFFICIAL

\_\_\_\_\_  
TITLE OF CERTIFYING OFFICIAL

**ARIZONA RADIATION REGULATORY AGENCY  
REGULATORY GUIDE**

**INSTRUCTIONS FOR THE PREPARATION OF APPLICATION  
FOR MEDICAL LICENSE PROGRAMS**

**I. PURPOSE OF GUIDE:**

This Guide is provided to describe the type and extent of information needed by the Agency to evaluate an application for a medical use license. Attachments A through T are provided to describe model radiation safety procedures. Each applicant should carefully read the applicable rules and model procedures and then decide if the model procedures are appropriate for the applicant's specific radiation safety needs. **ALL INDIVIDUALS LISTED ON A RADIOACTIVE MATERIALS LICENSE NEED TO GO THRU E-VERIFY. THIS REQUIRES A COPY OF THEIR SOCIAL SECURITY CARD AND DRIVERS LICENSE. WITHOUT THIS INFORMATION, YOUR LICENSE COULD BE DELAYED AN ADDITIONAL 4-6 WEEKS.**

**II. FILING AN APPLICATION:**

To apply for a license complete Form ARRA-M. Items 1 through 8, 35 and 36 are completed on the form itself. If additional room is required, an additional sheet may be added. For Items 9 through 34, submit the required information on supplementary sheets. Identify and key each separate sheet or document submitted to the item number on the application to which it refers. Applicants may certify that they will follow a model procedure or develop their own procedure and enclose it for review.

All items should be completed in enough detail to allow the Agency to determine that the equipment, facilities, training and experience, and radiation safety program are adequate to protect health and property.

All license applications are available for review by the general public. Do not submit proprietary information or personal information about individual employees unless it is necessary. **Please be aware of the new requirements for documenting qualifications for individual users. The requirements have again changed, potentially exposing personal information to public viewing. In addition to the possibility of home addresses and home telephone numbers, social security numbers and copies of driver licenses must be submitted for all users listed on the radioactive material license. If the applicant wants this information protected from public viewing, please indicate so in the application.**

Submit the completed application to the address shown below. The applicant shall retain a copy of the application and will be required to possess and use licensed material in accordance with the statements and representations made in the application and any supplements to it.

Radioactive Materials Program  
Arizona Radiation Regulatory Agency  
4814 South 40th Street  
Phoenix, Arizona 85040  
(602) 255-4845  
Fax (602) 437-0705  
[www.azrra.gov](http://www.azrra.gov)

### **III. CONTENTS OF AN APPLICATION:**

This portion of the Guide explains, item by item, the information requested on the application. The attachments serve several different purposes; i.e., to provide additional information on certain subject areas, to provide a model procedure the licensee may adopt in response to an item on the application or, to provide an outline the applicant may use to develop a procedure for review by the Agency staff.

If, after careful review of this Guide, an applicant has specific questions, they should contact the Radioactive Materials Program at (602) 255-4845.

#### **Item 1: Name and Mailing Address of Applicant.**

Enter the name, mailing address, and telephone number of the applicant. If the request is for a private license, enter the name of the physician or partnership. It is particularly important that the mailing address be sufficiently complete so that all correspondence to the licensee will reach persons responsible for the radiation safety program.

#### **Item 2: Street Address at Which Material Will Be Used.**

List the address(es) and location(s) where radioactive material will be used. If multiple addresses are used, explain the extent of use at each address and the facilities and equipment located at each place of use. The actual locations of use should be listed whether or not they are the same as the mailing address in Item 1; e.g., a P.O. Box may be most suitable for Item 1 in some cases, but a P.O. Box does not adequately describe the location of use. Item 2 must be an in-state address.

#### **Item 3: Person to Contact.**

Enter the name and telephone number (including area code) of the individual. This individual should be familiar with the proposed radioactive materials program and be able to answer questions about the application. This individual will serve as the point of contact during the review of the application and during the period of the license.

#### **Item 4: Type of Application.**

Indicate whether this is an application for a new license, an amendment, or a renewal. If this application is for a new license, also complete Item 31. The appropriate license fee must accompany the application in order for the review process to begin. The appropriate fee for each program is located in **R12-1-1306**. Remember, the Agency prorates the application fee on a quarterly basis.

#### **Item 5: Individual Users.**

List the names of all persons who will use, supervise or direct the use of radioactive material. This list should include the RSO, physicians, physicists, and nuclear pharmacists who direct other users in training and/or who supervise technologists or other paramedical personnel who use radioactive material for human or nonhuman use. These individuals must be qualified by training and experience, in accordance with Agency rule, to use the requested radioactive materials for the purposes requested in such a manner as to protect health and property. Non-physicians may be authorized to use radioactive material for nonhuman use; e.g., instrument calibration.

- A. Authorized users involved in medical use have the following special responsibilities. These responsibilities may be delegated to physicians who are in training under the direction<sup>1</sup> of an authorized user.
1. Examination of patients and medical records to determine if a radiation procedure is appropriate and to approve procedures involving the administration of radiopharmaceuticals or the application of radiation to patients from radioisotope sources.
  2. Prescription of the radiopharmaceutical or source of radiation and the amount or dose to be administered.
  3. Determination of the route of administration
  4. Actual use of, or supervision of technologists or other paramedical personnel in the use of, radioactive materials.
  5. **NOTE:** The interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered, may be performed by any Arizona licensed physician.
- B. Medical Radiologic Technologists Board of Examiners (MRTBE) registered nuclear medicine technologists are the only persons authorized to handle radioactive material under the supervision of an authorized user as of January 2004. A nuclear medicine technologist may operate a PET/CT unit in the CT mode, provided the CT cannot operate alone diagnostically.

Broad scope medical use applicants must submit the criteria they will use to evaluate the training and experience of authorized users. The applicant must reference the appropriate Sections in Arizona rule and commit to maintaining records of their reviews for Agency inspection. Other licensing requirements for broad scope programs are listed in **R12-1-310**.

The following rules contain standards for training that must be met by persons that are authorized to use radioactive material:

Training for authorized medical physicist in **R12-1-711**

Training for authorized nuclear pharmacist in **R12-1-712**

Training for uptake, dilution, and excretion studies in **R12-1-719**

Training for use of unsealed radioactive material requiring a written directive in **R12-1-723**

Training for the use of manual brachytherapy sources and Sr-90 eye applicators in **R12-1-727**

Training for use of sealed sources for diagnosis in **R12-1-728**

Training for the use of remote afterloader units, teletherapy machines, and gamma knives in **R12-1-744**.

Training for nuclear medicine technologists in **R12-2-501 and R12-2-502**

**Item 6: Radiation Safety Officer (RSO).**

State the name and title of the person designated by, and responsible to, the institution's management for the coordination of the institution's radiation safety program. The RSO should be either a full-time employee of the licensee, or be designated in writing by an applicant representative to oversee the radiation safety program with all the associated duties, responsibilities and powers as outlined in Attachment B. If the RSO is assisted by a consultant or part-time employee, state the consultant's name and describe his/her duties, responsibilities, and the amount of time to be devoted to the radiation safety program. Submit the name of the person responsible for the radiation safety program on a day-to-day basis. Specific RSO training requirements are in **R12-1-710**.

<sup>1</sup>DIRECTION means that the user:

- (1) Instructs the physician-in-training in the principles of radiation safety appropriate to that individual's use of radioactive material;
- (2) requires the physician-in-training to follow the instructions of the authorized user, the procedures established by the RSO, and comply with license conditions; and
- (3) periodically reviews the work and assures that proper medical records are made of each use. It does not mean that the user is necessarily present for each radiopharmaceutical administration. A licensee is responsible for the acts and omissions of the physician-in-training.

**New requirements, as of March 2008, include the following: First, the State of Arizona now requires, in accordance with A.R.S. §1-501, a licensed user demonstrate United States citizenship by submitting with the application, a copy of a social security card and a copy of the user's driver's license. Secondly, all potential users are now required to use the NRC standards to demonstrate qualifications for listing their names on a radioactive material license. The NRC standards that must be met are addressed in the ARRA-2 Form (Preceptor Series) and associated guide, available on the Agency website or, from the agency by mail. There are six form sets available to each of the six user subgroups.**

**Item 7: Radioactive Material For Medical Use.**

For routine human use, the applicant may check the group numbers for which the license is requested. The following is a listing of the Groups and associated authorized uses: **(For more information see Exhibit A at the end of Article 7).**

**Group 100** - Included is the use of any unsealed radioactive material for medical use, not requiring a written directive. Use includes uptake, dilution, or excretion studies.

**Group 200** - Included is the use of any unsealed radioactive material for medical use, not requiring a written directive. PET radiopharmaceuticals may be used if the applicant meets the requirements in **R12-1-716**. Use includes radiopharmaceuticals prepared for imaging and localization.

**Group 300** - Included is the use of any unsealed radioactive material for medical use (radiopharmaceutical) for which a written directive is required. **The applicant shall list each therapy activity and associated radiopharmaceutical in the application. Also, include the amount of each radionuclide.**

**Groups 400** - Included is the use of any brachytherapy source for therapeutic medical use approved in the Sealed Source and Device Registry. **The applicant shall list in the application each therapy activity and associated sealed source that contains radioactive material. Also, include the amount of each radionuclide. Provide a copy of the sealed source and devices registry description if possible.**

**Group 500** - Included is the use of any sealed source for diagnostic medical purposes approved in the Sealed Source and Device Registry. **The applicant shall list in the application each diagnostic activity and associated sealed source that contains radioactive material. Also, include the amount of each radionuclide. Provide a copy of the sealed source and devices registry description if possible.**

**Group 600** - Included is the use of any sealed source in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units approved for therapeutic medical uses in: **The applicant shall list in the application each therapy activity and associated sealed source that contains radioactive material. Also, include the amount of each radionuclide. Provide a copy of the sealed source and device registry description if possible.**

**Item 8: Radioactive Material Not Listed in Item 7.**

For routine human use not listed in Groups 100 through 600 and for nonhuman use, list each radionuclide to be used, the chemical and physical form, the maximum quantity desired (in millicuries or becquerels), and the purpose for which the material will be used. If the radioactive material is for human use has not been approved for routine human use by the Food and Drug Administration (FDA), submit evidence the procurement, preparation and use of the material will be in accordance with the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. If the study is conducted under a "Notice of Claimed Investigational Exemption for a New Drug" (IND) sponsored by the physician or institution, state the radionuclide, chemical form, possession limit and use, and submit a copy of the IND acceptance letter from the FDA. For human research for which an IND from the FDA has not been obtained the applicant must have a RDRC (Radioactive Drug Research Committee) **See R12-1-703 and R12-1-704.**

List the manufacturers name, model number and activity (in millicuries or becquerels) for all sealed sources greater than 30 millicuries. Calibration and reference standards are authorized under Arizona Administrative Code (AAC) **R12-1-714**. Proper maintenance of sealed sources, to include inventory and leak testing are required in **R12-1-417, R12-1-449, and R12-1-714.**

Describe the intended use and form for each radionuclide listed in Item 8. A specific authorization must be obtained from the Agency to perform studies involving the use of radioactive material in animals. The information required is specified in Item 25.

**Item 9: Radiation Safety Committee.**

In accordance with **R12-1-705**, a medical applicant will be required to have a Radiation Safety Committee (RSC) if the applicant is applying for more than one Group use or two units under Group 600. The committee shall evaluate all proposals for research, diagnosis, and therapeutic use of radioactive material.

- A. Membership of the committee must consist of at least three members and include:
  1. An authorized user of each type of use permitted by the license.
  2. The Radiation Safety Officer.
  3. A representative of the institutions management who is neither an authorized user nor the RSO.
  4. A representative of the nursing staff.
  5. Other members as deemed appropriate.
- B. The following information must be submitted with the application:
  1. The responsibility and duties of the committee.
  2. The meeting frequency of the committee.
  3. The name and specialty of each member of the committee.

Attachment A contains an example of a model charter including the charge, responsibilities and administrative information for a RSC. If Attachment A will be used, indicate by checking the appropriate box in Item 9. Sign, date and include the Attachment with the application. If Attachment A will not be used, check the appropriate box and submit equivalent information.

Remember, the RSC is only required to meet on an annual basis. However, the RSC is still responsible for performing a review of the radiation safety program on an annual basis in accordance with **R12-1-407**.

**Item 10: Radiation Safety Officer.**

Include with the application a description of the duties and responsibilities of the Radiation Safety Officer (RSO). Attachment B contains typical duties for a RSO. If these duties/responsibilities are adopted, indicate by checking the appropriate box in Item 10. Sign, date, and include the Attachment with the application. If Attachment B will not be used, check the appropriate box and submit an equivalent description.

**Item 11: Training and Experience.**

Item 5(B) above contains the training requirements for radioactive material users. Acceptable training and experience requirements for the RSO are found in **R12-1-710**.

- A. Authorized User. If an authorized user has been previously authorized to use the radioactive material requested in this application, it is necessary to submit:
1. **A social security number and a copy of the user's driver's license;**
  2. A copy of the license (if issued by another Agreement State or the NRC), **or**
  3. If not previously authorized **within the last seven years,, Submit the correct ARRA-2 Preceptor Form (found at the end of the application or obtain the correct form from the Agency website)**
  4. **If submitting a certification, it must be one of those accepted by the NRC. A current listing of accepted certificates is available from the Agency or can be accessed at the NRC/Agreement state website.**
- B. **RSO. The candidate's training must meet the NRC training requirements. If a certificate is submitted, it must be accepted by the NRC. A listing of accepted certificates is available from the Agency and is available at the NRC/Agreement State website. An ARRA-2 (RSO) Form should be completed in any case.**

**Item 12: Instrumentation.**

Instruments generally required in a typical nuclear medicine facility are:

- A. Survey Instruments:
1. A portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour.
  2. A portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.
- B. Dose calibrators and other instruments to assay radiopharmaceuticals:
1. Instruments used for diagnostic procedures in nuclear medicine; e.g., gamma camera, thyroid probe, well counter, scintillation counter for in-vitro studies.

**NOTE:** It is not required to have and use a dose calibrator. However, each dosage must be determined prior to administration, by the radiopharmaceutical manufacturer, nuclear pharmacy, or by the licensee using a dose calibrator. If the medical licensee chooses to not have a dose calibrator the dosage can be checked using a volume/decay determination. Records of dosage checks must be maintained for Agency inspection.

- C. Other pertinent instrumentation (e.g., well counter, liquid scintillation counter, area monitor) needed to meet the requirements contained in Article 4, include:
1. An instrument capable of measuring 2200 dpm/100 cm<sup>2</sup>; and
  2. An instrument capable of measuring a bioassay level of 0.1 of the Annual Limits of Intake (ALI) of iodine-131 in a person's thyroid.

It is highly recommended there be available for use a low/high energy scintillation probe or GM pancake probe for use with a survey meter for detection of contamination. A scintillation probe of choice would be appropriate for the gamma energy being detected.

Attachment C may be used to list and describe the instruments to be used. If Attachment C is adopted, indicate by checking the appropriate box in Item 12. Sign, date, and include the Attachment with the application. If Attachment C is not used, check the appropriate box and submit equivalent information.

### **Item 13: Calibration of Instruments.**

- A. Survey Instruments:

An adequate calibration of survey instruments cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Daily constancy checks of survey instruments shall be made before and after each use and should be supplemented at intervals not to exceed 12 months with a battery check and two-point calibration (at about 1/3 and 2/3 of full scale on each scale of the instrument to be used for radiation protection surveys<sup>2</sup>). Survey instruments should also be calibrated after repair or maintenance that may affect the calibration of the instrument.

A survey instrument may be considered properly calibrated if the requirements in **R12-1-450** are met.

If you propose to calibrate your own radiation survey and monitoring instruments, submit a detailed description of your planned calibration procedures. Include in the description:

1. The manufacturer's name and model number of the source(s) to be used (must be National Institute and Technology [NIST] traceable). The source should be of sufficient strength to give at least a 2/3 scale reading on the highest scale to be calibrated when the source is 20 cm from the effective center of the detector.
 

<sup>2</sup>Scales up to 1 R/hr should be calibrated but, in order to keep personnel exposures ALARA, high-range scales above 1 R/hr need not be calibrated when they will not be needed in a particular institution. Scales above 1 R/hr that are not calibrated should be checked for operation when possible. The results should be noted on the instrument. The user should be alerted to scales not calibrated or checked.
2. The nuclide and either (a) activity (in millicuries or equivalent SI units) of radioactive material contained in the source, or (b) exposure rates at fixed distances from the source as certified by measurements involving direct comparisons with sources or dosimeters calibrated at the National Bureau of Standards.
3. The accuracy<sup>3</sup> of the source(s).
4. The step-by-step procedures including associated radiation safety procedures. For each instrument, these procedures should include a two-point calibration on each scale used for radiation protection surveys.

Each meter shall be checked for constancy of operation prior to each use. A small reference source of appropriate energy and half-life is needed for this test.

If a consultant or outside firm will perform the calibration of the radiation survey and monitoring instruments, specify the name, address and license number of the firm. Contact the firm or consultant that will provide the calibration to determine whether information concerning calibration services and procedures has been filed with the Agency. If this information has not been filed, submit it with your application including details the outside firm will supply you about the results of the calibration. **The consultant may need a radioactive material license if he or she uses your radioactive material unsupervised.**

Section 1 of Attachment D contains an acceptable procedure for calibrating survey instruments and a form that may be used to supply the information required in Item 13. If the procedures described in Attachment D will be followed, indicate by checking the appropriate box in Item 13. Sign, date, and include the Attachment with the application. If the procedures in Attachment D are not used, check the appropriate box and submit equivalent procedures.

As a final requirement for this section, provide an example calibration report, so the Agency can determine if all of the necessary information is present. This is true for outside consultants, especially those consultants the Agency is not familiar with.

B. Dose Calibrator.

All patient dosages must be assayed for activity to an accuracy of +/- 10 percent of the true value prior to being administered to patients. The usual method for performing assays is with a dose calibrator. Upon installation and periodically thereafter, dose calibrators should be tested for accuracy of response for the energies commonly used, for geometrical variation, for linearity of response over the entire range of activities to be used, and for day-to-day constancy of operation.

1. Submit a description of your calibration procedures. These should include as a minimum:
  - a. The manufacturer's name and model number of any sealed sources to be used.
  - b. The nuclide and activity (in millicuries or becquerels) of radioactive materials in the standards.
  - c. The accuracy of the standard and NBS or foreign equivalent traceability.
  - d. The step-by-step procedures used for calibration.

<sup>3</sup>The maximum deviation of the nominal value of the source from the true value. This information is normally provided by the manufacturer.
2. If an instrument other than a dose calibrator is used to assay patient doses, submit a complete description of:
  - a. The assay method.
  - b. The method of calibration.
  - c. The frequency of calibration.
  - d. The standards to be used for calibration (radionuclide, activity, accuracy).

Section 2 of Attachment D contains a description of an acceptable procedure for calibrating dose calibrators and a form that may be used to supply the information required in Item 13. If the procedures described in Attachment D will be followed, indicate by checking the appropriate box in Item 13. Sign, date, and include the Attachment with the application. If the procedures in Attachment D are not used, check the appropriate box and submit equivalent procedures.

C. Sealed Source Calibration.

Each radioactive sealed source dose output shall be determined by calibration before the source is used to treat a patient. The following rules explain very clearly the calibration requirements for dosimetry equipment. **R12-1-733** requires that except for low dose-rate remote afterloader sources, where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available. The calibration shall be in accordance with this rule. The applicant must commit to following this rule and provide as attachments example records for documenting the requirements.

D. Instruments Used for Diagnostic Purposes.

Calibration, quality control and maintenance of instrumentation used for diagnostic procedures should be performed routinely in accordance with the manufacturer's recommendations. **A description of the calibration and quality control program, including tests and checks performed, and the frequency that they are performed, and associated records, is no longer requested with this application.**

**Remember, it is important to get all nuclear pharmacist involved in radiopharmaceutical preparation procedures at your facility on the radioactive material license.**

**Item 14: Facilities and Equipment.**<sup>4</sup>

Describe the available facilities and equipment; e.g., remote handling equipment, storage containers, shielding, fume hoods, etc., at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage (including waste), preparation and measurement of radioactive material.

Submit a detailed diagram of the facility, indicating the type, dimensions, position and thickness of shielding that will be used for:

- A. Use and storage of Tc-99m generators and positron emitter generators, like Rb-82.
- B. Storage of radiopharmaceuticals (refrigerated and non-refrigerated).
- C. Storage of radioactive waste, including decay-in-storage prior to disposal as non-radioactive waste. (This area should be large enough to handle an accumulation of used Tc-99m generators as well as other solid waste. If this area is located outside the users department, describe how the material will be secured. Confirm that this area will be surveyed at least weekly.)
- D. Preparation and dispensing of radiopharmaceutical kits (e.g., lead glass L-block).

**PET Programs**

- E. Use and storage of F-18.
- F. Storage of PET calibration and reference sources.
- G. Shielding considerations around, above, and below all PET use areas in the facility. Of special concern are the patient staging areas. In most cases, 6 millimeters of lead in the walls will provide sufficient protection from the high energy photons emitted by F-18. Also, buildup should be considered when applying added shielding to floors that already contain concrete. (see the AAPM guide listed in the reference list at the end of this part of the application) Lastly, be sure to designate all restricted and unrestricted areas, as it may be difficult to install sufficient shielding to maintain some areas as being uncontrolled, because of radiation exposure to non-radiation workers located near PET patient holding areas.

Identify adjacent areas from use and storage locations, and show that adequate steps have been taken to ensure that radiation levels in immediate unrestricted and restricted areas do not exceed the limits in **R12-1-416** and **R12-1-408**. (See Attachment T for PET facility considerations.)

<sup>4</sup>See U.S. NRC NUREG-1556 for checklists of suggestions for facilities and equipment consider when designing hospitals for medical uses of radioactive material. Adequate distances should be allowed between technologists and patients being scanned or imaged. If the size of a work area is limited, portable shields can be used to diminish the exposure from patients undergoing a PET scan.

If Xe-133 gas is to be used, submit a version of your facility diagram that specifies the location and associated measured airflow rate for each air exhaust duct and each air supply duct in areas where the Xenon-133 will be used or stored. This information is necessary in order to determine that the vents are properly located and that use and storage areas are under negative pressure. An annual air flow measurement and a semi-annual air flow check will be required of the licensee to verify that the air flow is maintained at a negative pressure in the room with respect to surrounding areas. Provide a copy of the most recent air flow measurement with the application.

For other facilities in which radioactive material may become airborne, include schematic descriptions of the ventilation system in the diagrams with pertinent airflow rates, pressures, filtration equipment and monitoring instruments. The airflow rates and pressures shall be tested annually to verify they remain as originally designed. Draw diagrams to a specified scale or indicate dimensions.

**Item 15: Personnel Training Program ( other than authorized users listed on the license)**

All individuals who work with, or in the vicinity of, radioactive materials must receive training appropriate to their duties. It may not be assumed that safety instructions have been adequately covered by prior occupational training, board certification, etc. Site-specific training should be provided to all workers. Outline and submit the program for providing the necessary instructions.

Ancillary personnel (e.g., clerical, nursing, housekeeping and security personnel) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions.

Describe the training that will be provided to all personnel who work with, or in the vicinity of, radioactive materials. Include the form of training (e.g., formal course work, lecture, etc.), frequency of training, duration of training and subject matter. Of special concern are patients that may receive in excess of the public limit of 100Mrem from PET patients. Anyone that may receive greater than 100Mrem and less than 500Mrem must receive training even if they have not been issued personnel dosimetry.

Attachment E provides a minimum training program. If this program is adopted, check the appropriate box in Item 15. Sign, date, and include the Attachment with the application. If Attachment E is not used, check the appropriate box and submit an equivalent training program. In either case, attach a separate sheet indicating the groups of workers who will receive training, who will give the training, and the method of training (e.g., lecture, demonstration, etc.).

**Item 16: Procedures for Ordering and Receiving Radioactive Material.**

Describe procedures for ordering radioactive material (RAM), receiving RAM during off-duty hours, and for notifying responsible persons upon receipt of RAM. These procedures should be adequate to ensure that possession limits are not exceeded, RAM ordered for human use are adequately verified upon receipt and checked before use, RAM are secured at all times against unauthorized removal and radiation levels in unrestricted areas do not exceed the limits specified in Title 12, Article 4.

Security personnel, nursing personnel or anyone else who receives packages during off-duty hours should be issued written instructions as to procedures to be followed for (a.) receiving, examining and securing packages; and (b.) notifying specific personnel (including names and telephone numbers of persons to be contacted) if the package is found or suspected to be leaking and the immediate steps to be taken to prevent the spread of contamination.

Attachment F contains sample procedures and instructions for ordering and receiving packages containing RAM. If the procedures in Attachment F are to be followed, check the appropriate box in Item 16. Sign, date, and include the Attachment with the application. If Attachment F is not used, check the appropriate box and attach equivalent procedures that will be used.

**Item 17: Procedures for Safely Opening Packages Containing Radioactive Materials.**

Although **R12-1-433** exempts certain packages from immediate monitoring with a survey instrument, **R12-1-433** does require that each licensee establish procedures for safely opening all packages containing licensed material.

Describe your procedures for examining incoming packages for leakage, contamination, or damage. Monitoring should be performed as soon as practicable after receipt of the package of radioactive material. The procedures may vary depending on the quantity of radioactive material received but should, at a minimum, include instructions for:

1. Surveying a RAM package;
2. Wearing gloves while opening a RAM package;
3. Checking packing material for contamination after opening; and
4. Verifying the contents of a RAM package.

Attachment G contains a flow diagram that demonstrates the proper survey (exposure and/or contamination survey) procedures for RAM package receipt.

Attachment G contains a description of an acceptable procedure for safely opening packages. If these procedures will be followed, indicate by checking the appropriate box in Item 17. Sign, date, and include the Attachment with the application. If Attachment G is not used, check the appropriate box and submit equivalent procedures.

**Item 18: General Rules for the Safe Use of Radioactive Material.**

Describe the general instructions to be followed by physicians, **physicists**, radiopharmacists and technologists while working with radioactive materials. The instructions should:

- A. Outline control procedures for obtaining permission to use radioactive material at the institution.
- B. Explain what laboratory apparel to wear and what equipment to use (e.g., wear laboratory coats and disposable gloves and use trays).
- C. Prescribe limitations and conditions for handling liquid or loose radioactive materials and the laboratory equipment to be used in working with them. For example, specify which materials and operations should be confined to radiochemical fume hoods or glove boxes.

- D. Specify the shielding or remote handling equipment to be used when using beta- and/or gamma-emitting materials, and special considerations made for the high energy photons associated with PET radiopharmaceuticals. Preparation of radiopharmaceuticals from reagent kits should always be done behind shielding and within appropriate hoods or enclosures. Syringe shields should be used for the routine preparation and administration of patient doses, except on the rare occasions where difficulties in properly administering the dose to the patient would warrant expedited use of lighter syringes. Even in these cases, syringes with the best possible finger protection or remote delivery of the dose (e.g., through use of a butterfly valve) should be used.
- E. Give instructions for preparation and assay of patient doses, including instructions to check each therapy dose against the ordering physician's written request.
- F. Give instructions concerning movement of material between rooms, in halls, or in corridors if applicable.
- G. Explain requirements for storage of RAM, labeling of containers and identification of areas where radioactive materials are used. Describe the shielding used for areas where large amounts of RAM are stored.
- H. Specify personnel monitoring devices to be used, where to obtain them, procedures for properly turning in personnel monitoring devices for processing at appropriate intervals, and instructions for recording exposure results. **Describe where personnel monitoring devices and control dosimeters will be stored to ensure accuracy in monitoring,** employee occupational exposures, and to avoid inadvertent exposure of the devices when they are not being worn.
- I. Describe waste disposal procedures to be followed for each type of waste (e.g., liquids, gases, solids, long-lived, short-lived). Properly shielded waste receptacles should be employed for used syringes and other radioactive wastes. Special consideration should be given to high energy RAM like F-18 which is used in PET.
- J. Describe contamination control procedures, including:
1. Prohibitions against smoking, eating, drinking or applying cosmetics in restricted areas;
  2. Prohibition against storing food, beverages, and personal effects with radioactive materials; and
  3. Instructions for individuals who prepare and administer doses of radiopharmaceuticals to monitor their hands after each procedure and at the end of the day.

For smaller programs, Attachment H contains an acceptable set of laboratory rules for the safe use of radioactive materials. If these procedures are adopted, indicate by checking the appropriate box in Item 18. Sign, date, and include the Attachment with the application. If Attachment H is not used, check the appropriate box and submit equivalent procedures.

**Item 19: Emergency Procedures.**

Describe the emergency instructions to be posted in all laboratory areas where radioactive materials are used. These instructions should include:

1. A describe immediate action to be taken in order to prevent contamination of personnel and work areas (e.g., turning off the ventilation, evacuation of the area, containment of the spill);
2. The names and telephone numbers of the responsible persons to be notified in case of an emergency; and
3. Instruction on appropriate methods for re-entering, decontaminating and recovering facilities that may have been accidentally contaminated.

An acceptable set of emergency procedures is contained in Attachment I. If these procedures are adopted, indicate by checking the appropriate box in Item 19. Sign, date, and include the Attachment with the application. If Attachment I is not used, check the appropriate box and submit equivalent procedures.

**Item 20: Area Survey Procedures.**

Describe the routine survey program, including the areas to be surveyed, the levels of contamination considered to be acceptable and provisions for maintaining records of surveys. Current minimal standards are:

1. Area surveys 5.0 mR/hr for restricted areas and 0.1 mR/hr for unrestricted areas; and
2. Removable contamination survey 22,000dpm/100cm<sup>2</sup> for restricted areas and 5,000 dpm/100cm<sup>2</sup> for unrestricted areas.

**The licensee may prefer to replace the initial wipe survey with a contamination survey using a suitable survey probe like a pan cake or appropriate scintillation probe. This technique would be followed by a removable contamination surveys when, and if, a spill is suspected. Describe the procedure in the application.**

If the application is to cover multiple users and areas of use, the individual user should perform surveys of the work areas in addition to those performed by the radiation safety staff. Acceptable procedures and frequencies for routine surveys are described in Attachment J. If these procedures are adopted, indicate by checking the appropriate box in Item 20. Sign, date, and include the Attachment with the application. If Attachment J is not used, check the appropriate box and submit equivalent procedures.

**Item 21: Waste Disposal.**

Describe specific methods used for disposal of radioactive material waste. A licensee may dispose of waste by:

- A. Careful segregation of non-radioactive waste from radioactive waste, decay of radioactive waste in storage, monitoring and release to normal trash. Wastes may be held for decay until radiation levels, as measured in a low background area with a low level radiation detection survey meter and with all shielding removed, have reached background levels with consideration given to proper meter error. **After radiation labels have been removed or obliterated**, the waste may be disposed of in normal trash.
- B. Release into a sanitary sewer in conformance with **R12-1-436**. Describe the methods and provide calculations showing that disposal of radioactive material in the sewer is within the limits specified.

- C. Release into the air in conformance with Article 4, Appendix B, Table II, Column 1.
- D. Other methods specifically approved by the Agency in accordance with **R12-1-435** or for H-3, C-14, or I-125 as described in **R12-1-438**.
- E. Transfer to a person or firm properly licensed to receive such waste; e.g., commercial waste disposal firm (see **R12-1-434**). Submit the name and the NRC or Agreement State license number of the commercial firm selected.

The Agency is encouraging its licensees to reduce the volume of waste sent to these facilities. Important steps in volume reduction are to segregate radioactive from non-radioactive waste, to hold short-lived radioactive waste for decay in storage and to release certain materials into the sanitary sewer (see paragraphs A and B above).

Attachment K contains model procedures for the disposal of radioactive waste. If these procedures are adopted, indicate by checking the appropriate box in Item 21. Sign, date, and include the Attachment with the application. If Attachment K is not used, check the appropriate box and submit equivalent procedures.

**Item 22: Therapeutic Use of Radiopharmaceuticals.**

Describe special precautions for patients treated with radioactive material listed in Group 300. Although some procedures are often performed on an outpatient basis, appropriate procedures need to be developed because hospitalization is sometimes required. Regulatory requirements concerning use of radiopharmaceutical therapy purposes can be found in **R12-1-703, R12-1-706, R12-1-707, R12-1-708, R12-1-713, and R12-1-722**.

Those applicants considering the use of a mobile nuclear medicine service must also meet the additional requirements in **R12-1-718**.

The Agency is no longer concerned with misadministrations associated with the use of radioactive material. However, as is required by the NRC, a licensee is required to report to the Agency certain “medical events” as required by **R12-1-745**.

- A. Describe radiation safety procedures associated with the care of therapy patients, including:
  1. Procedures for held in hospital rooms. Private rooms should be designated for I-131 therapy patients or any other patients that may constitute an internal or external exposure hazard for roommates. Also procedures should be developed patients treated on an outpatient basis, especially those receiving a dosage in excess of 33 millicuries. For example procedures see the Society of Nuclear Medicine reference listed at then end of this section of the application.
  2. Procedures for contamination control in the patient's room; e.g., protective covering for areas of likely contact, use of disposable dishes and utensils, and procedures for posting and controlling radiation areas or potentially contaminated areas.

3. Procedures for surveys of:
    - a. Areas, equipment and personnel involved in administration of radiopharmaceuticals.
    - b. The patient's room at the beginning of the procedure and at the time of patient release before it is reassigned to another patient.
    - c. Unrestricted areas (i.e., areas adjacent to the patient's room).
    - d. Linens and other items removed from the patient's room.
  4. Records of surveys.
  5. Instructions to nursing staff (see Attachment L).
  6. Personnel monitoring procedures for medical and nursing staff.
  7. Procedures for disposal of wastes, including:
  8. Procedures to be followed in case of emergency surgery or death (see NCRP Report No 37, see reference list).
  9. Procedures for release of patients, including:
    - a. Criteria for release of patients. (**R12-1-717** and Reg Guide 8.9, See reference list)
    - b. Instructions to patients and families (NCRP Report No 37, see reference list).
- B. Describe radiation safety procedures involved with all other aspects of therapy procedures, including:
1. Criteria for determining when it is appropriate to use protective facilities, equipment, or supplies (e.g., hoods, shielding blocks, tongs, disposable gloves) and procedures for their use. Personnel should always wear gloves and work within fume hoods or special enclosures whenever opening vials containing therapeutic quantities of volatile radiopharmaceuticals such as I-131. These hoods should have adequate airflow and operating procedures should be designed to prevent contamination of personnel and surrounding areas.
  2. Criteria and procedures for bioassay of personnel. Significant thyroid uptakes have been detected in individuals who open and prepare oral solutions of I-131 for therapeutic doses. Bioassays should also be considered for personnel (e.g., radiation safety, nursing) who are involved in other aspects of therapy procedures. Remember, that bioassay should be performed at 6 to 72 hours following the exposure to radioiodine, however, the bioassay may be performed up to two weeks following the exposure if conditions exist that prevent a more timely assay.
  3. Describe in detail procedures and precautions for each radiopharmaceutical that will be used for therapeutic purposes. In many cases the procedures and precautions will be similar because the radiation hazards are similar.

Submit detailed responses to Items 22.A and B. In lieu of submitting a detailed response to Item 22.A, the procedures in Attachment L may be adopted. If these procedures are adopted, check the appropriate box in Item 22. Sign, date, and include the Attachment with the application. If Attachment L is not used, check the appropriate box and submit equivalent procedures.

**Remember, it is important to get all physicists involved in therapy procedures on the radioactive material license.**

**Item 23: Therapeutic Use of Sealed Sources.**

Describe special procedures for patients treated with sealed radioactive sources. These procedures<sup>6</sup> should include descriptions of:

- A. The areas where the sealed sources will be stored, including:
  - 1. Placement and thickness of shielding.
  - 2. Proximity of the storage area to unrestricted areas.
  - 3. Any calculations or measurement data used to check the adequacy of the shielding and protection specifications.

Regulatory requirements concerning use of radioactive material for sealed source therapy purposes can be found in **R12-1-703, R12-1-706, R12-1-707, R12-1-708, R12-1-719, R12-1-715, R12-1-717, R12-1-724, R12-1-725, R12-1-726, R12-1-729 through R12-1-739 and R12-1-741 through R12-1-744**. Those applicants considering the use of a mobile remote afterloader must also meet the additional requirements in **R12-1-740**.

The Agency is no longer concerned with misadministrations associated with the use of radioactive material. However, as is required by the NRC, a licensee is required to report to the Agency certain “medical events” as required by **R12-1-745**.

Radiation levels in unrestricted areas must be less than 2 millirems in any 1 hour and less than 100 millirems in a year (See **R12-1-416**).

- B. Special precautions to be used while handling sealed sources.
- C. The method for determining the radiation doses to the extremities of personnel handling sealed sources.
- D. The equipment and shielding available for transporting sources from storage to the place of use.
- E. The method for maintaining source accountability at all times. This should include a description of sign-in and sign-out procedures, periodic inventory and for determining that all sources are accounted for and returned immediately following treatment.
- F. Surveys to be performed during the course of and at the conclusion of treatment. The patient and room should be surveyed with a radiation survey instrument immediately following the conclusion of treatment and before the patient is discharged. This survey should include a source count and should be adequate to determine that all temporary implant sources have been removed from the patient and all areas the patient occupied.
- G. Special instructions for nurses caring for patients who are treated with sealed sources. (Attachment M contains a description of procedures which may be followed for patients treated with sealed sources.)

Submit detailed responses to Items 23.A through 23.E. In response to Items 23.F and 23.G, the procedures in Attachment M may be adopted and indicated by checking the appropriate box in Item 23. Sign, date, and include the Attachment with the application. If the procedures described in Attachment M are not used, check the appropriate box and submit equivalent procedures.

**Item 24: Procedures and Precautions For Use of Radioactive Gases (e.g., Xenon-133) and Aerosols.**

The use of radioactive gases (e.g., Xenon-133 gas or gas in saline) and aerosols requires attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive gas or aerosol in restricted and unrestricted areas. The Agency requires that each applicant make such determinations for his own unique situation and submit sufficient evidence to the Agency in support of the request.

Attachment N contains instructions for submitting an application to use Xenon-133 or aerosol. If the model procedures in Attachment N will be followed, indicate by checking the appropriate box in Item 24. Sign, date, and include the Attachment with the application. If Attachment N is not used, check the appropriate box and submit equivalent procedures. Attach copies of all calculations performed to support the application.

Allowable concentration of Xe-133 gas in restricted and unrestricted areas is listed in Schedule B of Article 4. It is important to install exhaust systems in nuclear medicine departments where radioactive gas is used. Return systems should be avoided to prevent recirculation of contaminated air. The Agency requires that the air handling system be evaluated for flow rate on an annual basis with a directional check of air flow on a six month basis. Records of these tests shall be maintained for Agency inspection.

**Item 25: Procedures and Precautions for Use of Radioactive Material in Animals.**

Describe procedures to be followed if radioisotopes will be used in animals. Include:

- A. A description of the animal housing facilities.
- B. A copy of instructions provided to animal caretakers for the handling of animals, animal waste, and carcasses.
- C. Instructions for cleaning and decontaminating animal cages.
- D. Procedures for ensuring the animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material.

Instructions to animal caretakers should reflect the types of studies done at the institution.

**Item 26: Procedures and Precautions for Use of Radioactive Materials Specified in Item 8.**

Clearly state any additional radiation safety procedures to be followed while individuals are using the materials listed in Item 8; e.g., air sampling, other special surveys, bioassays, leak testing sealed sources, and inventory. Include with your procedure description any additional radiation safety precautions.

Bioassays may be required when individuals work with millicurie quantities of H-3, I-125, or I-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassays may also be required for other radionuclides if the chemical or physical form or procedures and equipment used make it likely that the radioactive material will be ingested, inhaled, or absorbed into the body. Show in the application that the need for bioassays has been thoroughly considered and that the proposed bioassay program is appropriate for the intended use of radioactive material. General guidance on bioassay programs for I-125 and I-131 is provided in ARRA Regulatory Guide 8.20. Guidance for bioassay programs for Tritium and other radionuclides which is available from the Agency's Radioactive Materials Program.

Remember, the action levels have changed. The current levels are listed in Article 4, Schedule B. The Agency has developed a license condition incorporating these level that will be inserted in a radioactive material license if bioassays are a necessary part of the applicants' safety program.

**Item 27: Personnel Dosimetry and Bioassay Programs.****A. Personnel Monitoring Devices.**

Provide the name of the organization furnishing the personnel monitoring device. The monitoring device (film badge or TLD) shall be from a NVLAP approved service. Specify the frequency with which the badge or TLD will be changed and evaluated, and give a description of the type (whole-body, wrist, or finger dosimetry). Where wrist dosimetry is worn to monitor extremity exposures and exposures to fingertips are likely to be greater than the wrist exposures, describe how fingertip exposures will be estimated from the wrist badge data in lieu of using finger monitors, and provide any backup data used to perform or verify these estimates. Wrist or ring dosimetry should be worn toward the palm side of the hand for measuring hand exposures. Where feasible, ring dosimeter should be worn on the index finger facing toward the palm side of the hand. When pocket ionization chambers (pocket dosimeters) are to be used for personnel monitoring, give the manufacturer's name, model number, range of scale readings, calibration and check procedures, frequency of calibration, frequency of reading, and commit to recording personnel exposures. Use Attachment O to provide personnel monitoring information.

**B. Prior Occupational Dose.**

The licensee shall attempt to determine a radiation workers prior exposure history in accordance with **R12-1-412**. Records of prior exposure shall be maintained on Form Y or equivalent. (Form Y available in Attachment O.)

**C. Bioassay Program.**

If I-125 or I-131 is handled or processed, include bioassay program information. As stated above, ARRA Reg Guide 8.20 provides criteria for the development and implementation of a bioassay program. The program as described in ARRA Regulatory Guide 8.20 may be used to satisfy the bioassay program requirement. If this Agency program is not compatible, submit a description of an equivalent program. (Use Attachment O for bioassay program.)

**D. Records.**

Personnel monitoring records maintained by the licensee shall contain the committed effective dose equivalent as required in **R12-1-419**. Form Z or equivalent shall be used to record the doses. (See attachment O for Form Z.)

**Item 28: Sealed Source Leak Test Program.**

Each radioactive sealed source possessed under the provisions of a specific license, other than Tritium, with an activity greater than 100 microcuries for beta and gamma emitters and greater than 10 microcuries for alpha emitters, must be tested for leakage and/or contamination prior to initial use and at intervals specified by the license and in accordance with **R12-1-417**. Attachment P provides sealed source leak test program information. If Attachment P is adopted, indicate by checking the appropriate box in Item 28. Sign, date, and include the Attachment with the application. If Attachment P is not used, check the appropriate box and submit an equivalent program.

**Item 29: ALARA Program.**

In addition to complying with the specific requirements as set forth in **R12-1-407**, each licensee shall make every reasonable effort to maintain radiation exposures and releases of radioactive materials in effluent to unrestricted areas as low as reasonably achievable. The term "as low as reasonable achievable" means as low as is readily achievable taking into account the state of technology and the economics of improvements in relation to benefits to the public health and safety, and in relation to the utilization of nuclear energy, ionizing radiation and radioactive materials in the public interest.

Applications for new licenses, renewal requests and requests for significant license amendments (i.e., to broaden programs, to increase possession limits) should be accompanied by a description of the applicant's/licensee's ALARA program. The success of an ALARA program depends on the cooperation of each person who works at the licensee's facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources. Applicants/licensees may adopt the model program described in Attachment Q or may develop and submit for Agency review an equivalent program. If the model program in Attachment Q is adopted, check the appropriate box in Item 29. An individual authorized to make commitments for the applicant/licensee should sign and date Attachment Q and include it with the application. If Attachment Q is not used, check the appropriate box and submit equivalent procedures.

**Item 30: Letter to Local Governing Authority.**

Attach a copy of the letter to the Mayor's Office of the city or town in which the radioactive material will be used or, if not within an incorporated community, to the County Board of Supervisors, providing the following information:

1. The nature of the proposed activity involving radioactive materials; and
2. The facility including use and storage areas. (Required by **R12-1-309**)

**Item 31: License Fee Required.**

If this is an application for a new license, the appropriate fee must accompany the application before review can begin. **A description of activities by License Type and a Table of Fees and are located in R12-1-1302 and R12-1-1306 respectively.**

**Item 32: Legal Structure Form**

If you agree to complete the legal structure form as attached to this application sign, date, and complete the form. If the form is not used submitted an equivalent document containing the necessary information about the legal structure of the applicant's business with the application.

**Item 33: Inventory**

With the application provide a listing of the sealed sources you plan to possess, or if this a renewal, provide a listing of the sources you currently possess and the disposition record for each source that has been disposed of or transferred since the last Agency inspection.

**Item 34: Increased Controls**

Some forms of radioactive material present a terrorist concern. Most medical licensees will not possess the radiation sources of concern. For a listing of the sources and material of interest that must be addressed with this application, see Attachment U.

**Item 35: Certification.**

Provide the signature and date of signature of an individual authorized by management to represent an applicant institution or the signature and date of signature of an individual physician (in the case of private practice or a non-institutional clinic).

#### IV. AMENDMENTS TO LICENSES:

**Licensees are required to conduct their programs in accordance with statements, representations and procedures contained in the license application and supporting documents. The license must therefore be amended if the licensee plans to make changes in the facilities, equipment (including types of monitoring and survey instruments), procedures, authorized users, Radiation Safety Officer or radioactive material to be used.**

Applications for license amendments may be filed either on the application form or in letter form. The application or letter should identify the license by license number and name. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page and paragraph.

Amendment applications should be signed and dated by a representative of the licensee's administrative management (e.g., the hospital administrator). An original and one copy of the application for amendment should be prepared, and the original should be submitted, as in the case for new or renewal applications.

**REFERENCE LIST**

1. NUREG-1556 Vol.9, Rev.1, *Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Use Licenses*, published in May 2005 by the NRC.
2. *Guide for Diagnostic Nuclear Medicine*, published in 2001 by the Society of Nuclear Medicine.
3. AAPM Task Group on PET and PET/CT Shielding Requirements published in 2005 by the American Association of Physicists in Medicine.
4. *Applying Nuclear Regulatory Commission Guidelines to the Release of Patients Treated with Sodium Iodine-131*, published in the Journal of Nuclear Medicine, Vol. 28, No.4, Dec. 2000.
5. Regulatory Guide 8.39 *Release of Patients Administered Radioactive Material*, published by the NRC in April 1997.
6. NCRP Report No. 37, *Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides*, printed in 1978.
7. NCRP Report No. 147, *Structural Shielding Design for Medical X-ray Imaging Facilities*, printed in 2004
8. ARRA Regulatory Guide 8.20. *Guidance for Bioassay Programs for Tritium and Other Radionuclides*, available from the Agency.
9. Preceptor forms for authorized users on a medical radioactive materials license: In Arizona they are the ARRA-2 forms (RSO, AMP, ANP, AUD, AUT, AUS), and associated guide for completing the forms. These forms can be obtained from the Agency or equivalent NRC forms (313A Series) are located under “Forms” in the Medical Uses Licensee Toolbox at the NRC/Agreement State website.
10. List of Specialty Board(s) Certification Recognized by NRC under 10 CFR Part 35, available from the Agency or it can be located under “Other Guidance” in the Medical Uses Licensee Toolbox at the NRC/Agreement State website.

**Retain one copy of the application with all attachments. The license will require, as a condition, that the institution follow the statements and representations set forth in the application and any supplement to it. Mail the original to:**

Radioactive Materials Program  
Arizona Radiation Regulatory Agency  
4814 South 40th Street  
Phoenix, Arizona 85040  
(602) 255-4845  
Fax (602) 437-0705  
[www.azrra.gov](http://www.azrra.gov)

## APPENDIX A

### INSTRUCTIONS FOR THE PREPARATION OF A LICENSE APPLICATION MEDICAL PROGRAM

#### TRAINING AND EXPERIENCE REQUIREMENTS (See Title 12, Article 7)

#### I. GENERAL CRITERIA:

(Training must be within the last seven years if not active within the profession)

Any human use of radioactive material must be carried out by, or under the supervision of a person who is:

- A. Licensed in Arizona to practice medicine; and
- B. A citizen of the United States (A.R.S. §1-501).**

An “**authorized user**” candidate can meet these requirements by providing the Agency a copy of State medical license, driver’s license and social security number.

**Note 1:** A physician does not have to be on a radioactive material license to read nuclear medicine scans.

**Note 2:** The Agency continues to require that the training standards for authorized users meet the requirements in 10 CFR 35, which means there is now a separate preceptor statement (ARRA-2 Form Series) for each type of authorized user candidate. Included in this group of forms are a form for: radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, an authorized user of Groups 100, 200, and 500, an authorized user of Group 300, and an authorized user of Groups 400 and 600. **There is also a new guide, developed by the NRC, to assist in completing these ARRA-2 forms. The guide is available on the Agency website.**

The Agency will approve a medical license application to use radioactive material if it determines, among other things, that the radiation safety officer (RSO), physicist(s), nuclear pharmacist(s), and physician(s), all designated as authorized user(s), are adequately trained and experienced.

The requirements listed below for authorized users have been established by the Nuclear Regulatory Commission (NRC) in 10 CFR 35, and adopted by the Agency.

**Use the correct ARRA-2 Form (Preceptor Statement) to document authorized user training and experience. The available forms are as follows:**

- ARRA-2 (RSO) - Radiation Safety Officer
- ARRA-2 (AMP) - Authorized Medical Physicist
- ARRA-2 (ANP) - Authorized Nuclear Pharmacist
- ARRA-2 (AUD) - Authorized Physician (diagnostic)
- ARRA-2 (AUT) - Authorized Physician (unsealed therapy)
- ARRA-2 (AUS) - Authorized Physician (sealed therapy)

#### **Licensing Guidance for using ARRA-2 Series Forms (January 2008)**

**Note 3:** Board certification has been looked at very closely by the NRC. A Board certification will not be recognized in Arizona unless it is recognized by the NRC. In any case a preceptor statement will have to be submitted by each candidate unless the candidate has been listed on a radioactive material license within the last seven years.

**Note 4:** The **Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35** are available from the Agency or can be viewed on the NRC Medical License Toolbox web-page.

**Note 5:** The federal training standards can be found by using Google. Type in Code of Federal Regulations followed by clicking on Available CFR Titles on GPO Access.

**II. RADIATION SAFETY OFFICER:**

The Agency will consider a candidate for RSO if the candidate is qualified through training and experience to meet the requirements in **R12-1-710**, which references the federal standards in 10 CFR 35.57.

**II. TRAINING FOR AUTHORIZED MEDICAL PHYSICISTS:**

The Agency will consider a candidate to be an authorized medical physicist and perform the many supportive duties to an authorized user treating patients with the radiation from sealed sources, if the candidate meets the requirements in **R12-1-711**, which references the federal standards in 10 CFR 35.51.

**III. TRAINING FOR AUTHORIZED NUCLEAR PHARMACISTS:**

The Agency will consider a candidate to be an authorized nuclear pharmacist and perform the many radiopharmacy duties, if the candidate meets the requirements in **R12-1-712**, which references the federal standards in 10 CFR 35.55.

**IV. TRAINING FOR GROUPS 100, 200, AND 500, AUTHORIZING UPTAKE, DILUTION AND EXCRETION STUDIES), AND IMAGING AND LOCALIZATION STUDIES NOT REQUIRING A WRITTEN DIRECTIVE:**

The Agency will consider a candidate for listing as an authorized user on a radioactive material license authorizing unsealed radioactive material in uptake, dilution, and excretion studies, if the candidate is qualified through training and experience to meet the requirements in **R12-1-719**, which incorporates by reference the federal standards in 10 CFR 190.

The Agency will consider a candidate for listing as an authorized user on a radioactive material license authorizing unsealed radioactive material in imaging and localization studies, not requiring a written directive, if the candidate is qualified through training and experience to meet the requirements in **R12-1-721(A)**, which incorporates by reference the federal standards in 10 CFR 290. A candidate wishing to use PET radiopharmaceuticals to diagnose disease shall also meet the requirements in **R12-1-721(A)**. A candidate wishing to use radioactive material limited to the diagnosis of heart disease and cannot meet the training requirements in **R12-1-721(A)**, shall meet the requirements in **R12-1-721(B)**, which incorporates by reference the federal standards in 10 CFR 290(c).

The Agency will consider a candidate for listing as an authorized user on a radioactive material license authorizing sealed sources of radioactive material in imaging and localization studies, not requiring a written directive, if the candidate is qualified through training and experience to meet the requirements in **R12-1-728**, which incorporates by reference the federal standards in 10 CFR 590.

**V. TRAINING FOR GROUP 300, AUTHORIZING THE USE OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE, INCLUDING TREATMENT OF HYPERTHYROIDISM, AND TREATMENT OF THYROID CARCINOMA:**

The Agency will consider a candidate for listing as an authorized user on a radioactive material license authorizing the treatment of human disease and requiring a written directive, if the candidate is qualified through training and experience to meet the requirements in **R12-1-723**. Depending on the requested authorization, the candidate will have to meet the federal standards incorporated by reference in 10 CFR 35.390, 392, and 394.

**VI. TRAINING FOR GROUP 400 AND 600 AUTHORIZING THE USE OF MANUAL BRACHYTHERAPY SOURCES, THE USE OF STRONTIUM-90 SOURCES FOR TREATMENT OF OPHTHALMIC DISEASE, AND THE USE OF REMOTE AFTERLOADER UNITS, TELE THERAPY UNITS, AND GAMMA STEREO TACTIC RADIOSURGERY UNITS IN THE TREATMENT OF HUMAN DISEASE:**

The Agency will consider a candidate for listing as an authorized user on a radioactive material license authorizing the treatment of human disease with brachytherapy sources, if the candidate is qualified through training and experience to meet the requirements in **R12-1-727(A)**, which incorporates by reference the federal standards in 10 CFR 35 490. If a candidate will be limited to the authorized use of a Sr-90 eye applicator for the treatment of ophthalmic disease, the candidate shall meet only the requirements in **R12-1-727(B)**, which incorporates by reference the federal standards in 10 CFR 35 491.

The Agency will consider a candidate for listing as an authorized user on a radioactive material license authorizing the use of remote afterloader units, teletherapy units, and gamma STEREO TACTIC radiosurgery units for treatment of human disease, if the candidate is qualified through training and experience to meet the requirements in **R12-1-744**, which incorporates by reference the federal standards in 10 CFR 35 690.

**VII. RECENTNESS OF TRAINING, AND ADEQUATE SUPERVISED EXPERIENCE:**

The training and experience specified in this Appendix must have been obtained within the **seven years** preceding the date of license application or amendment requesting a candidate be authorized to use radioactive material, or the individual must have had related continuing education and experience since the candidate was last authorized to use radioactive material. The recentness of training is specified throughout the rules in Article 7 and the federal regulation 10 CFR 35.59.

Candidates being considered for authorization on a radioactive material must participate in a minimum of **three cases** for each requested authorization if the authorization requested requires the authorized user to function under a written director.

**VIII. NUCLEAR MEDICINE TECHNOLOGISTS:**

As of January 2004 all persons functioning in the capacity of a nuclear medicine technologist shall be registered with the Medical Radiologic Technologist Board of Examiners (MRTBE). The Inspectors will be checking all personnel that handle radioactive material in the practice of nuclear medicine for a current MRTBE registration card. Registration of nuclear medicine technologists is required in **R12-2-501** and **R12-2-502**.

## APPENDIX B

### RECORD RETENTION

The following information is not part of the model duties, but is provided as guidelines for the RSO in the retention of records generated in the use of radioactive material under an Arizona Radioactive Material License.

1. Records kept for 10 years: Medical event reports (ARRA Form 16) and unintended deviations from a physician's directive.
2. Records kept for 3 years after creation: (The following records shall be maintained 3 years past the date of license termination)
  - A. Sealed source inventory (R12-1-450).
  - B. Sealed source leak test results (R12-1-417).
  - C. Area surveys (R12-1-418) and various Sections in Article 7.
  - D. Disposal records of decay-in-storage radioactive material (R12-1-438).
  - E. Molybdenum-99 and Aluminum Breakthrough assay records (R12-1-720).
  - F. Dose calibrator constancy, linearity, and accuracy (R12-1-713).
  - G. Area survey procedures (R12-1-418) and various Sections in Article 7.
  - H. Radiation accident investigation results (R12-1-443, R12-1-444, R12-1-445 and R12-1-446).
  - I. Radiation Safety Committee minutes (R12-1-705(D)).
  - K. Radiation Protection Program (R12-1-407).
  - M. Radiation safety training records (R12-1-1003 and various Sections in Article 7).
  - N. Increased Control (License Condition)**
4. Records kept for life of license and 3 years past date of termination:
  - A. Personnel monitoring records (Form Z or equivalent, R12-1-419).
  - B. Bioassay records.

**NOTE:** In many cases record retention is required in Article 4; Exposure histories will be needed for Planned Special Exposures (R12-1-413).

## ATTACHMENT A

### ITEM 9

#### RADIATION SAFETY COMMITTEE AND RADIOACTIVE DRUG RESEARCH COMMITTEE

##### RADIATION SAFETY COMMITTEE (RSC):

In accordance with **R12-1-705**, the following licensees are required to have a radiation safety committee:

1. Licensees that are authorized for two or more different types of uses of radioactive material listed in Groups 300, 400 and 600;
2. Two or more different types of units under Group 600;

##### THE RSC SHALL:

1. Ensure that all individuals who work with or in the vicinity of radioactive material or sources of radiation have sufficient training and experience to enable them to perform their duties safely and in accordance with law, rules, conditions of the license, and **commitments of the application for license**.
2. Ensure that radioactive material and radiation is used in a safe manner and in compliance with law, rules and the conditions of the license. This includes reviewing, as necessary, training programs, equipment, facilities, supplies and procedures, **and national citizenship in accordance with '1-501**.
3. Ensure that the use of radioactive material is consistent with **R12-1-407**.
4. Establish a table of investigational levels for individual occupational radiation exposures.
5. Identify program problems and solutions.

##### THE RSC RESPONSIBILITIES:

1. Be familiar with all pertinent **Arizona laws and rules, and incorporated NRC regulations**, the terms of the license, and information submitted in support of the request for the license and its amendments.
2. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radiation or radioactive material (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by Article 10 of the rules for use of ionizing radiation.
3. Review the training and experience of all individuals who use or handle radioactive materials (including physicians, technologists, physicists, and pharmacists) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with the laws, rules, conditions of the license, **and commitments in application for license**.
4. Review on the basis of safety and approve or deny, consistent with the limitations of the rules, the license, and the ALARA philosophy, all requests for authorization to use radiation or radioactive material within the institution.
5. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations, and special monitoring procedures. In addition, work very closely with the Radioactive Drug Research Committee (RDRC) to ensure that radiation safety standards are met.
6. Review at least annually the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive.

7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with **Arizona laws, rules, conditions of the license, and commitments of the application for license**, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of ARRA inspections, written safety procedures, and the adequacy of the management control system.
8. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
9. Maintain written minutes of all committee meetings including members in attendance and members absent, discussions, actions, recommendations and decisions.
10. Ensure that the radioactive material license is amended, when necessary, prior to any changes in facilities, equipment, policies, and personnel as specified in the license.

#### **ADMINISTRATIVE RESPONSIBILITIES:**

1. The Committee shall meet as often as necessary to conduct its business but not less than once in each calendar year.
2. At a minimum, the Committee shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer.
3. To establish a quorum, one-half of the Committee's membership, (not including adjunct members) including the RSO and the management representative, must be present.
4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as quality assurance oversight and research project review and approval.

#### **RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC):**

The RDRC program began under the FDA in 1975. All radioactive drugs were either classified as an investigational new drug ( IND), described under 21 CFR 312, or administered under conditions specified as a RDRC approved drug in 21 CFR 361.1. The RDRC will permit a licensee to conduct basic research using radioactive drugs\* in humans without an IND when the drug is administered under the following conditions:

1. The research is considered basic science research and is done for the purpose of advancing scientific knowledge. ( See 21 CFR 361.1(a))
2. The research study is approved by an FDA-approved RDRC based on the following requirements (see 21 CFR 361.1(b)(1)(iv)):
  - A. Qualified study investigators;
  - B. Properly licensed medical facility to possess and handle radioactive materials;
  - C. Appropriate selection and consent of research subjects;
  - D. Appropriate quality assurance of radioactive drug administered;
  - E. Sound Research protocol design;
  - F. Reporting of Adverse events by the investigator to the RDRC; and
  - G. Approval by an appropriate Institutional Review Board (IRB).

- 3. The pharmacologic dose of the radioactive drug to be administered is not known to cause any clinically detectible pharmacological effect in humans. (See 21 CFR 361.1(b)(2).
- 4. The radiation dose to be administered is justified by the quality of the study being undertaken and the importance of the information it seeks to obtain. (See 21 CFR 361.1(b)(1)(iii)) and is within the limits specified in 21 CFR 361.1(b)(3))

\* The term Aradioactive drug@ is defined in 21 CFR 310.3(n) and includes a Aradioactive biological product@ as defined in 21 CFR 600.3.

**RSC MEMBERSHIP**

<b><u>NAME</u></b>	<b><u>SPECIALTY</u></b>
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

**RDRC MEMBERSHIP**

<b><u>NAME</u></b>	<b><u>SPECIALTY</u></b>
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
<b>SIGNATURE</b>	<b>DATE</b>

**ATTACHMENT B**

**ITEM 10  
DUTIES OF THE RADIATION SAFETY OFFICER (RSO)**

**THE RSO SHALL:**

1. Be familiar with all applicable **laws, rules, license, and application and associated guides**, and ensure that license applications are properly filled out and submitted in a timely fashion. Ensure that the institutional radiation use and safety programs comply with the license application, conditions and **R12-1-407**.
2. Establish and maintain record systems of all radiation area surveys, wipe tests, leak tests, calibration of instruments. Perform a review each calendar quarter of records of surveys and personnel dosimetry to determine that they are ALARA for the period.
3. Review personnel dosimetry reports monthly and advise individual radiation workers of any high film badge report. Additionally, the RSO should determine the cause of all overexposures so as to preclude recurrence. At the conclusion of each calendar quarter, perform a quarterly review of occupational exposure to users and workers to determine that the exposures are within the limits established for the ALARA program. At the conclusion of each calendar year, apprise each employee of their accrued dose.
4. Ensure that individuals working with radiation have appropriate protective devices, including shielding, ventilation, clothing, gloves, remote handling equipment (where necessary), instrumentation, and facilities which aid in keeping exposures ALARA. If responsible for a PET program, ensure that radiation exposure in adjoining areas to the PET facility do not exceed the limit, determined at the time of application, due to a change in occupancy or increase in workload. If applicable, a report of the finding should be provided to the RSC for review on an annual basis.
5. Act as liaison agent with regulatory authorities to include being available for assistance in inspections and audits, and notifying the Agency:
  - A. In writing before making any change which would render the Application for Radioactive Materials License, Radioactive Materials License, Application for Registration of Radiation Producing Machines, or Notice of Registration no longer accurate.
  - B. Immediately in the event of any radiation accident or incident, including high film badge readings that meets the Agency notification requirements in Article 4.
  - C. Within five (5) days of any positive leak test result of a sealed source.
  - D. Within 30 days in a report stating remedial action taken after an accident or incident.
  - E. Using ARRA Form 16, report all medical events in accordance with the requirements listed in **R12-1-745**. The following is the basic information that must be maintained for all medical events:

**Medical Events:**

- I. Event Date: \_\_\_\_\_ Information Source: \_\_\_\_\_
- II. Notifications:  
Referring Physician \_\_\_\_\_ Patient: \_\_\_\_\_
- III. In writing/by telephone: \_\_\_\_\_
- IV. If notification did not occur, why not?
- V. Written report to the Agency within 15 days

6. Perform, or cause to be performed, during every six months, an inventory of all sealed sources received or possessed. Ensure all surveys, calibrations, and leak tests are performed on time.
7. Post conspicuously Form ARRA-6, "Notice to Employees", items required under Article 4 and Article 10, and notices of items of noncompliance resulting from Agency inspections.
8. Supply employers of terminated occupationally exposed personnel with radiation exposure records as required.
9. Establish and cause to be maintained inventory control of radioisotopes at the institution. Ensure the inventory never exceeds amounts licensed. Keep, or cause to be kept, records of receipts of incoming isotopes and surveys of incoming and outgoing shipments. Ensure that all incoming and outgoing radioactive material shipments are properly packaged and labeled according to DOT requirements, and that shipments are accompanied by proper shipping papers. Ensure that radioactive materials are disposed of properly and that records are maintained of all radioactive wastes disposed.
10. Perform a review, at intervals not to exceed 12 months, of the radiation safety program for adherence to ALARA concepts. Ensure that the safety program is followed by all workers dealing with radioactive materials. Investigate any deviation from the program and take any remedial action necessary.
11. Schedule briefings and educational sessions to inform workers of radiation safety rules and procedures:
  - A. For all new personnel;
  - B. With each change in license condition or safety program (that will affect the employee); and
  - C. At intervals not to exceed 12 months, in the refresher course for all personnel. This includes instruction in the ALARA program and philosophy.
12. Take charge in all emergency situations, in the event of major or minor spills, or release of radioactive material, to ensure correct emergency decontamination and protection procedures are carried out. Also, evaluate the situation that led to the emergency, to reduce the chance of reoccurrence.
13. Maintain, or cause to be maintained, written records of all radiation safety committee meetings, actions, recommendations, and decisions, and RDRC records if appropriate.

---

**SIGNATURE**

---

**DATE**

**ATTACHMENT C**

**ITEM 12  
INSTRUMENTATION**

**1. SURVEY METERS:**

At a minimum, a low-range survey meter with a GM side window or end window probe is required to assess shipping packages.

For contamination surveys a scintillation or pancake GM probe is desirable.

- A. Manufacturer's name: \_\_\_\_\_  
Model Number: \_\_\_\_\_  
Number of Instruments Available: \_\_\_\_\_  
Window Thickness: \_\_\_\_\_ mg/cm<sup>2</sup>  
Wall Thickness: \_\_\_\_\_ mg/cm<sup>2</sup>  
Minimum Range: \_\_\_\_\_ mR/hr to \_\_\_\_\_ mR/hr  
Maximum Range: \_\_\_\_\_ mR/hr to \_\_\_\_\_ mR/hr
  
- B. Manufacturer's name: \_\_\_\_\_  
Model Number: \_\_\_\_\_  
Number of Instruments Available: \_\_\_\_\_  
Window Thickness: \_\_\_\_\_ mg/cm<sup>2</sup>  
Wall Thickness: \_\_\_\_\_ mg/cm<sup>2</sup>  
Minimum Range: \_\_\_\_\_ mR/hr to \_\_\_\_\_ mR/hr  
Maximum Range: \_\_\_\_\_ mR/hr to \_\_\_\_\_ mR/hr
  
- C. Manufacturer's name: \_\_\_\_\_  
Model Number: \_\_\_\_\_  
Number of Instruments Available: \_\_\_\_\_  
Window Thickness: \_\_\_\_\_ mg/cm<sup>2</sup>  
Wall Thickness: \_\_\_\_\_ mg/cm<sup>2</sup>  
Minimum Range: \_\_\_\_\_ mR/hr to \_\_\_\_\_ mR/hr  
Maximum Range: \_\_\_\_\_ mR/hr to \_\_\_\_\_ mR/hr

**2. DOSE CALIBRATOR:**

A. Manufacturer's name: \_\_\_\_\_

Model Number: \_\_\_\_\_

Number of Instruments Available: \_\_\_\_\_

B. Manufacturer's name: \_\_\_\_\_

Model Number: \_\_\_\_\_

Number of Instruments Available: \_\_\_\_\_

**3. OTHER INSTRUMENTS:** (e.g., well counter, liquid scintillation counter, area monitor, velometer)  
(List type of instrument, manufacturer's name and model number in spaces provided below)

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

\_\_\_\_\_  
**SIGNATURE**

\_\_\_\_\_  
**DATE**

## ATTACHMENT D

### ITEM 13 CALIBRATION OF INSTRUMENTS

#### SECTION 1 METHODS FOR CALIBRATION OF SURVEY METERS

##### PROCEDURE:

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable.

- A. The source shall approximate a point source.
- B. The source activity or exposure rate at given distances shall be traceable by documented measurements to a standard certified within five percent accuracy by the U.S. National Bureau of Standards (NBS), or its foreign equivalent.
- C. The frequency shall be at intervals not to exceed 12 months and after servicing. Battery changes are not considered "servicing".
- D. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.
- E. A single point on a survey meter may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.
- F. The source used must be of sufficient strength to give an exposure rate of 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 mCi of Cs-137 and 21 mCi of Co-60.
- G. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.
- H. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.
- I. The following three kinds of scales are frequently used on survey meters:
  - 1. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.
  - 2. Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.
  - 3. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.
- J. A record must be made of each survey meter calibration.
- K. At the time of calibration, the apparent radiation reading from a built-in or owner-supplied check source shall be determined and recorded.

- L. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:
1. The owner or user of the instrument;
  2. A description of the instrument that includes manufacturer, model number, serial number, and type of detector;
  3. A description of the calibration source, including exposure rate at a specified distance on a specified date;
  4. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
  5. The reading indicated with the instrument in the "battery check" mode (if available on the instrument).
  6. The angle between the radiation flux field and the detector (for external cylindrical GM or ionization- type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument);
  7. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;
  8. The apparent radiation reading from the check source; and
  9. The name of the person who performed the calibration and the date on which the calibration was performed.
- M. The following information will be attached to the instrument as a calibration sticker or tag:
1. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
  2. For each scale or decade, one of the following as appropriate:
    - a. The average correction factor;
    - b. A graph or graphs from which the correction factor for each scale or decade may be deduced;
    - c. An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;
  3. The date the calibration was done and when it will be due for re-calibration; and
  4. The apparent radiation reading from the check source.
- N. See Figure D-1 (at the end of Section 2) for a form which may be used.

**NOTE:** All meters shall be checked for constancy with a small reference source prior to each use.

**CALIBRATION OF SURVEY INSTRUMENTS**

**INITIAL THE APPROPRIATE ITEM:**

\_\_\_\_\_ A. Survey instruments will be calibrated by the licensee at an interval not to exceed 12 months and following repair in accordance with the Model Procedures contained in Attachment D.

Calibration Source: \_\_\_\_\_

Manufacturer's Name: \_\_\_\_\_

Model No.: \_\_\_\_\_

Activity in millicuries: \_\_\_\_\_

or

Exposure rate and distance: \_\_\_\_\_

Accuracy: \_\_\_\_\_

Traceability: \_\_\_\_\_

\_\_\_\_\_ B. Survey instruments will be calibrated by the licensee at an interval not to exceed 12 months and following repair in accordance with the equivalent procedures attached.

Calibration Source: \_\_\_\_\_

Manufacturer's Name: \_\_\_\_\_

Model No.: \_\_\_\_\_

Activity in millicuries: \_\_\_\_\_

or

Exposure rate and distance: \_\_\_\_\_

Accuracy: \_\_\_\_\_

Traceability: \_\_\_\_\_

\_\_\_\_\_ C. By a consultant or outside firm:

Name: \_\_\_\_\_

Location: \_\_\_\_\_

License Number: \_\_\_\_\_

\_\_\_\_\_  
**SIGNATURE**

\_\_\_\_\_  
**DATE**

## SECTION 2 METHODS FOR CALIBRATION OF DOSE CALIBRATOR

Radiopharmaceuticals must be assayed for activity to an accuracy of +/- 10 percent prior to administration. The most common instrument for accomplishing this is a dose calibrator. The instrument must be checked for accuracy of operation at specified times in order to verify it is operating correctly.

### PROCEDURE:

- A. Test for the following at the indicated frequency. Consider repair, replacement or arithmetic correction if the dose calibrator falls outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the rules to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.)
  1. Constancy at least once each day prior to assay of patient dosages (+/- 5 percent).
  2. Linearity at installation and at least each calendar quarter thereafter (+/- 5 percent).
  3. Geometry dependence at installation (+/- 5 percent).
  4. Accuracy at installation and at intervals not to exceed 12 months thereafter (+/- 5 percent).
- B. After repair or adjustment, repeat the above tests as appropriate.
- C. Constancy

Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Ba-133, or Co-57 using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

  1. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
  2. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
  3. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
  4. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
  5. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. Repair or replacement is required if the error exceeds 10 percent of the correct value.
- D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

## E. Linearity

Linearity means that the calibrator is able to indicate the correct activity over the range of use of the calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

### 1. Decay Method

- a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at, for example, 8 a.m.
- b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 10 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.
- c. Convert the time and date information you recorded to hours elapsed since the first assay.
- d. On a sheet of semi-log graph paper label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date, model number, and serial number of the dose calibrator. Then plot the data.
- e. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line  $(\text{Activity observed} - \text{Activity on line}) / (\text{Activity on line}) = \text{deviation}$ .
- f. If the worst deviation is more than  $\pm 0.05$ , the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity".
- g. Put a sticker on the dose calibrator that says when the next linearity test is due.

### 2. Lineator or Calicheck Method

If the Calicheck or Lineator Method will be used to test for linearity, refer to the manufacturer's instruction manual.

## F. Geometry Independence

Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

1. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. You may also use tap water.
2. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated on the Dose Calibrator Geometry and Accuracy Form (see Figure D-2).

3. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
4. Repeat the process until you have assayed a 2.0-cc volume.
5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume".
6. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity". If this is necessary, be sure to label the table or graph "syringe geometry dependence", and note the date of the test and the model number and serial number of the calibrator.
7. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
8. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
9. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.
10. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume".
11. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity". If this is necessary, be sure to label the table or graph "vial geometry dependence", and note the date of the test and the model number and serial number of the calibrator.

G. Accuracy

Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS), or its foreign equivalent, or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. The activity of at least one reference source should be within the range of activities normally assayed. At least three sources with different principal photon energies (such as Co-57, Ba-133, and Cs-137) should be used. The rules require that, if a Ra-226 source is used, it must be at least 10 microcuries; if any other source is used, it must be at least 50 microcuries.

1. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement on the Dose Calibrator Geometry and Accuracy Form (see Figure D-2). Repeat for a total of three determinations.
2. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.

3. Repeat the procedure for other calibrated reference sources.
  4. If the average value does not agree, within 5 percent, with the certified value of the reference source, the calibrator will be repaired or adjusted.
  5. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.
  6. Put a sticker on the dose calibrator that says when the next accuracy test is due.
- H. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

**QUALITY ASSURANCE CHECKS OF DOSE CALIBRATOR**

**INITIAL THE APPROPRIATE ITEM WHERE APPLICABLE:**

1. Constancy

Constancy check will be performed each patient day in accordance with model procedures in Attachment D.

2. Linearity

Linearity test will be performed at installation and during each calendar quarter. Test will be performed in accordance with procedures listed in Model Procedures in Attachment D utilizing:

The Decay Method only

The Calicheck Method

The Lineator Method

3. Geometric Dependence

Geometric dependence will be performed at installation in accordance with procedures listed in model procedures in Attachment D.

4. Accuracy

Accuracy test will be performed at installation and at intervals not to exceed 12 months thereafter in accordance with procedures listed in Attachment D.

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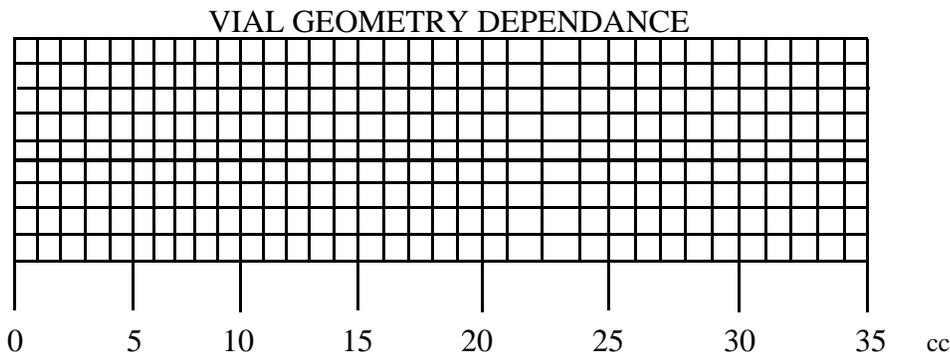
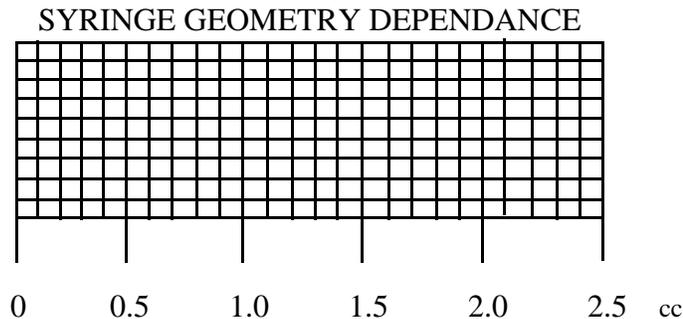
**SIGNATURE**

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**DATE**

**DOSE CALIBRATOR GEOMETRY AND ACCURACY**

Manufacturer: \_\_\_\_\_ Model: \_\_\_\_\_ S/N: \_\_\_\_\_



**NAME:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

**ACCURACY SOURCES**      19 \_\_\_\_\_      19 \_\_\_\_\_

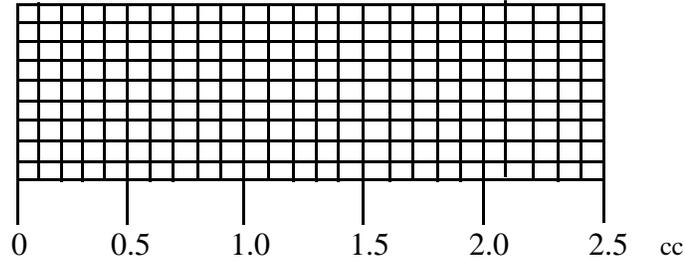
_____ mCi OF _____ Model: _____ S/N: _____ Calibration Date: _____	FIRST ASSAY: _____ mCi SECOND ASSAY: _____ mCi THIRD ASSAY: _____ mCi AVERAGE: _____ mCi	FIRST ASSAY: _____ mCi SECOND ASSAY: _____ mCi THIRD ASSAY: _____ mCi AVERAGE: _____ mCi
_____ mCi OF _____ Model: _____ S/N: _____ Calibration Date: _____	FIRST ASSAY: _____ mCi SECOND ASSAY: _____ mCi THIRD ASSAY: _____ mCi AVERAGE: _____ mCi	FIRST ASSAY: _____ mCi SECOND ASSAY: _____ mCi THIRD ASSAY: _____ mCi AVERAGE: _____ mCi
_____ mCi OF _____ Model: _____ S/N: _____ Calibration Date: _____	FIRST ASSAY: _____ mCi SECOND ASSAY: _____ mCi THIRD ASSAY: _____ mCi AVERAGE: _____ mCi	FIRST ASSAY: _____ mCi SECOND ASSAY: _____ mCi THIRD ASSAY: _____ mCi AVERAGE: _____ mCi

**NAME:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

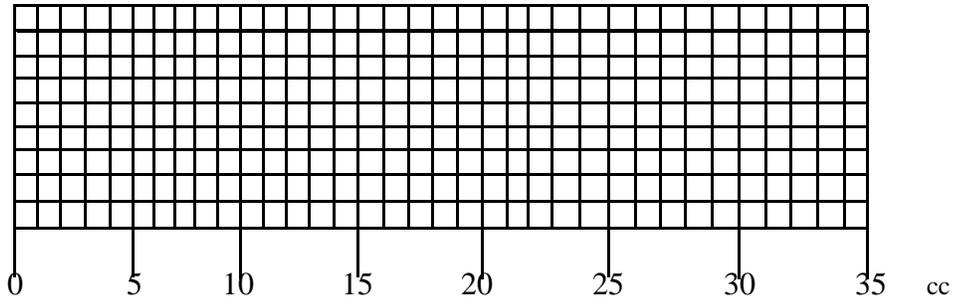
**DOSE CALIBRATOR GEOMETRY AND ACCURACY**

Manufacturer: \_\_\_\_\_ Model: \_\_\_\_\_ S/N: \_\_\_\_\_

**SYRINGE GEOMETRY DEPENDANCE**



**VIAL GEOMETRY DEPENDANCE**



**NAME:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

**ACCURACY SOURCES**                      19 \_\_\_\_\_                      19 \_\_\_\_\_

_____ mCi OF _____ Model: _____ S/N: _____ Calibration Date: _____	FIRST ASSAY: _____ mCi SECOND ASSAY: _____ mCi THIRD ASSAY: _____ mCi  AVERAGE: _____ mCi	FIRST ASSAY: _____ mCi SECOND ASSAY: _____ mCi THIRD ASSAY: _____ mCi  AVERAGE: _____ mCi
_____ mCi OF _____ Model: _____ S/N: _____ Calibration Date: _____	FIRST ASSAY: _____ mCi SECOND ASSAY: _____ mCi THIRD ASSAY: _____ mCi  AVERAGE: _____ mCi	FIRST ASSAY: _____ mCi SECOND ASSAY: _____ mCi THIRD ASSAY: _____ mCi  AVERAGE: _____ mCi
_____ mCi OF _____ Model: _____ S/N: _____ Calibration Date: _____	FIRST ASSAY: _____ mCi SECOND ASSAY: _____ mCi THIRD ASSAY: _____ mCi  AVERAGE: _____ mCi	FIRST ASSAY: _____ mCi SECOND ASSAY: _____ mCi THIRD ASSAY: _____ mCi  AVERAGE: _____ mCi

**NAME:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

**ATTACHMENT E**

**ITEM 15  
PERSONNEL TRAINING PROGRAM**

**PROGRAM:**

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, rules, or the terms of the license.

Instruction for individuals in attendance will include the following subjects:

1. Applicable rules and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. Licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
7. Appropriate response to emergencies or unsafe conditions.
8. Worker's right to be informed of occupational radiation exposure and bioassay results.
9. Locations where the licensee has posted or made available notices, copies of pertinent rules, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required in **Articles 4 and 10**.

\_\_\_\_\_  
**SIGNATURE**

\_\_\_\_\_  
**DATE**

**ATTACHMENT F**

**ITEM 16  
PROCEDURES FOR ORDERING  
AND  
RECEIVING RADIOACTIVE MATERIAL**

1. The RSO or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
  - A. For routinely used materials:
    - 1) Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made. In many cases, the pharmacy prescription form may be adequate.
    - 2) The above records will be checked to confirm that material received was ordered through accepted methodologies.
  - B. For occasionally used materials (e.g., therapeutic dosages):
    - 1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.
    - 2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.
3. For deliveries during normal working hours, carriers will deliver radioactive packages directly to a specified area.
4. For deliveries during off-duty hours, security personnel or other designated persons will accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum (attach a copy of the actual memorandum issued by the hospital).

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**SIGNATURE**

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**DATE**

**SAMPLE MEMORANDUM**

**TO:** Chief of Security

**FROM:** Radiation Safety Officer

**SUBJECT:** Receipt of Packages Containing Radioactive Material

The security guard on duty shall sign for any packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room \_\_\_\_\_. Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged or is wet/leaking, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, \_\_\_\_\_, at extension \_\_\_\_\_.

**NAME**

**TELEPHONE**

Radiation Safety Officer: \_\_\_\_\_

\_\_\_\_\_

Chief of Nuclear Medicine: \_\_\_\_\_

\_\_\_\_\_

Chief Nuclear Medicine Technologist: \_\_\_\_\_

\_\_\_\_\_

Nuclear Medicine Technologist on call  
(call page operator at extension \_\_\_\_\_)

Nuclear Medicine Physician on call  
(call page operator at extension \_\_\_\_\_)

## ATTACHMENT G

### ITEM 17 PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

#### PROCEDURE:

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in **R12-1-433** (more than 20 Curies for Molybdenum-99 and Technetium-99m). Packages will be monitored for surface contamination and external radiation levels, if appropriate, within three hours after receipt if received during normal working hours or within three hours from start of the next working day if received after normal working hours. All shipments of liquids greater than exempt quantities will be tested for leakage. The Agency will be notified in accordance with **R12-1-433** if removable contamination exceeds 22 dpm/cm<sup>2</sup> for beta-gamma emitting radionuclides or 2.2 dpm/cm<sup>2</sup> for alpha emitting radionuclides, wiping a minimum surface area of 300 square centimeters (46 square inches) or the entire package surface if less than 300 square centimeters (46 square inches) or if the external radiation exceeds 2 millisieverts (200 mR) per hour at the package surface.
2. To meet the requirements above, the following procedure for opening each package will be followed:
  - A. Put on gloves to prevent hand contamination.
  - B. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
  - C. Monitoring: (See Figure G-2)
    - 1) Monitor the external surfaces of a package, labeled with a Radioactive White I, Yellow II, or Yellow III for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in **R12-1-102** of these rules; and
    - 2) Monitor the external surfaces of a package, labeled with a Radioactive White I, Yellow II, or Yellow III reference in Paragraph one above, for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as listed in 49 CFR 173.435; and
    - 3) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
  - D. Open the package with the following precautionary steps:
    - 1) Remove the packing slip.
    - 2) Open the outer package following the supplier's instructions, if provided.
    - 3) Open the inner package and verify that the contents agree with the packing slip.
    - 4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packaging material.
    - 5) If anything is other than expected, stop and notify the RSO.

- E. Listed below is the instrument, for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter should be used for the surface contamination assay required in Paragraph one above, and the calculations demonstrating its ability to measure the action level. (Note that a dose calibrator is not sufficiently sensitive for this measurement and Figure G-2 contains a package survey flow diagram demonstrating survey requirements.)

Instrument: \_\_\_\_\_

Calculation: See attached page

- F. Check the user request to ensure that the material received is the material that was ordered.
- G. Monitor the packing material and the empty packages for contamination with a survey instrument capable of detecting radiation contamination at levels suitable for discarding in normal trash.
- 1) If contaminated, treat this material as radioactive waste.
  - 2) If not contaminated, remove or obliterate the radiation labels before discarding in-house trash.
- H. Make a record of the receipt. (See Figure G-1 for an example form which may be used. Attach a copy of the actual hospital form which will be used.)
3. For packages received under the general license in **R12- 1-306(F)**, the following procedure for opening each package will be followed:
- A. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
  - B. Check to ensure that the material received is the material that was ordered.

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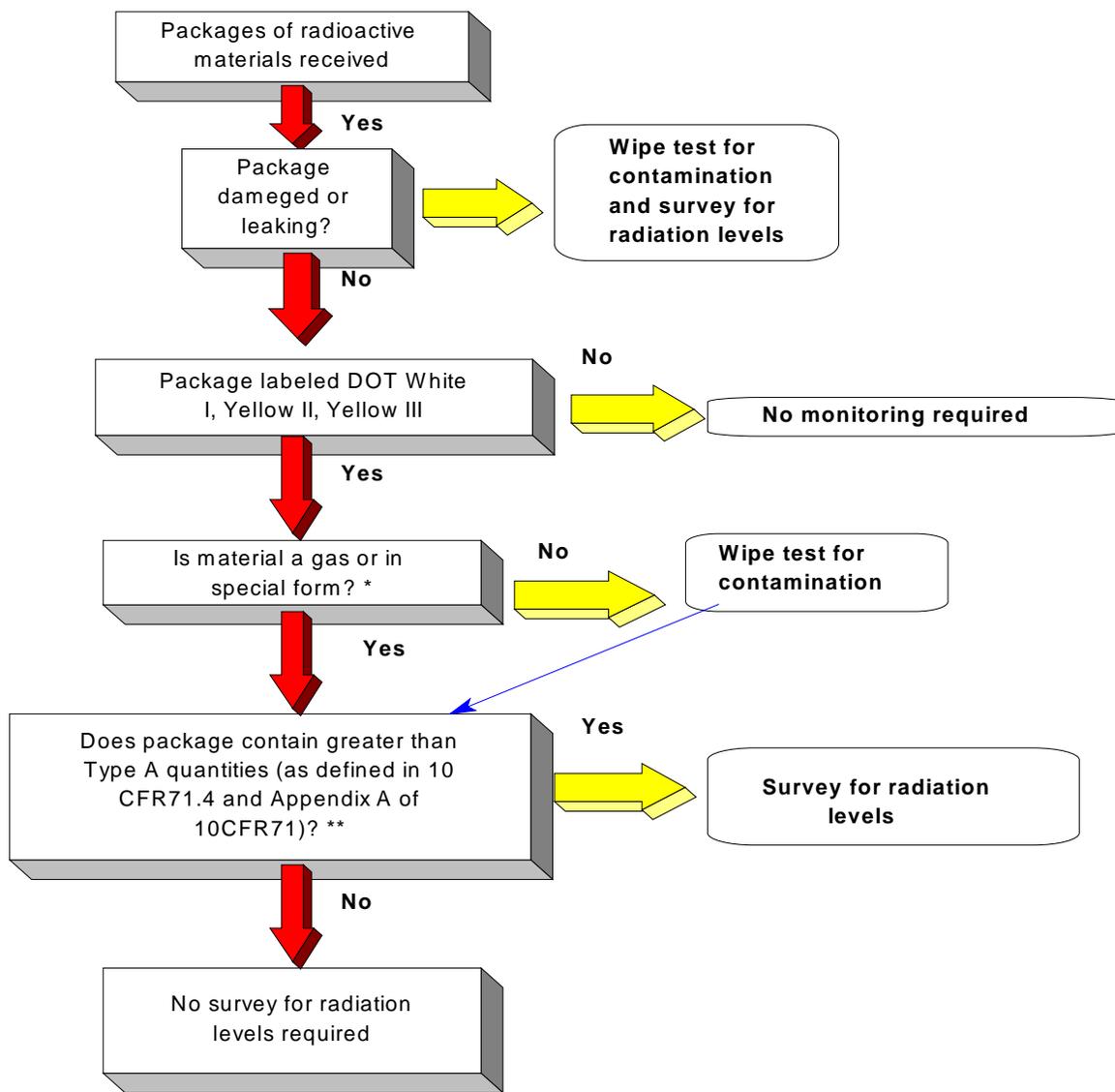
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**DATE**



# PACKAGE RADIATION MONITORING



\* Special form material refers to sealed sources unlikely to be dispersed if involved in an accident. A more complete definition of special form material is contained in 10CFR71. Very few materials received by medical facilities are of special form.

\*\* The type A quantities (in curies) are higher than most medical facilities normally receive. Below is a table of some common medical radionuclide Type A quantities.

<u>Radionuclide</u>	<u>Quantity in Curies Special Form (A1)</u>	<u>Quantity in Curies Normal Form (A2)</u>	<u>(49CFR 10/1/00 Edition) 49CFR 173.435</u>
C-14	1080	54.1	
Co-57	216	216	
Cs-137	54.1	13.5	
F-18	27	13.5	
H-3	1080	1080	
I-131	81.1	13.5	
In-111	54.1	54.1	
Mo-99	16.2	13.5	
P-32	8.11	8.11	
Sm-153	108	13.5	
Sr-89	16.2	13.5	
Tc-99m	216	216	
Tl-201	270	270	
Xe-133	541	541	

Figure G-2 9/99

## ATTACHMENT H-1

### ITEM 18 GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low-background area with a radiation detection instrument.
4. Use syringe shields for routine preparation of patient dosages and administration to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal effects with radioactive material.
7. Assay each patient dose in the dose calibrator prior to each administration. Do not use any doses that differ from the prescribed dose by more than 10 percent, except for prescribed doses of less than 10 microcuries. Also, check the patient's name and identification number, the radionuclide, the chemical form, and the activity vs. the order written by the physician. Make a record of the information. (See Figure H-1 for an example form which may be used.)
8. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
9. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.
10. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
11. Never pipette by mouth.
12. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.
13. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

- 14. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. (See Figure H-2 for an example form which may be used.) Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or patient's name and identification number.
- 15. Always keep flood sources, syringes, waste and other radioactive material in shielded containers.
- 16. Use a cart or wheelchair to move flood sources, syringes, waste, and other radioactive material, as even sources with small amounts of radioactivity exhibit a high dose rate on contact.

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**SIGNATURE**

---

**DATE**

## ATTACHMENT H-2

### ITEM 18 RECORDS OF RADIOACTIVE MATERIAL USE

#### GENERAL:

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the rules. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does not have to be recorded in the order given in these procedures. Also, you do not have to replicate entries. For example, if you prepare a multidose vial for use one day, you do not have to record the date each time you draw a dosage from it; if you take 30 Ir-192 seeds that are each 0.5 millicuries, you do not have to list each seed individually.

#### PROCEDURE FOR RECORDS OF UNIT DOSAGE USE:

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Supplier;
5. Lot number or control number, if assigned;
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
7. Date of administration or disposal;
8. If administered,
  - a. Prescribed dosage (unless already recorded in clinical procedure manual),
  - b. Measured activity in millicuries or microcuries and date and time of measurement,
  - c. Patient name and identification number if one has been assigned;
9. If discarded, the date, method of disposal (i.e., return to pharmacy) and any survey results; and
10. Initials of the individual who made the record.

**PROCEDURE FOR RECORDS OF MULTIDOSE USE**

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt or preparation;
4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);
5. Supplier or kit manufacturer;
6. If administered,
  - a. Prescribed dosage (unless already recorded in clinical procedure manual),
  - b. Date and time dosage was drawn and measured,
  - c. Calculated volume that is needed for the prescribed dosage,
  - d. Measured activity in millicuries or microcuries,
  - e. Patient name and identification number if one has been assigned;
7. If discarded, the method of disposal and date; and
8. Initials of the individual who made the record.

**PROCEDURE FOR MEASURING AND RECORDING MOLYBDENUM CONCENTRATION AND ALUMINUM BREAKTHROUGH:**

**R12-1-720** requires that each licensee test each technetium generator for its molybdenum concentration. (This does not have to be done when using radiopharmaceuticals obtained from a distributor.) This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m at the time of administration.

The model procedure for measuring molybdenum concentration is based on the use of a "molybdenum breakthrough pig." Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert from measured Mo-99 to total Mo-99.

Each time a generator is eluted, make a record of the:

1. Date the generator was received;
2. Date and time of elution;
3. Measured Mo-99 activity in microcuries;
4. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;
5. Measured Tc-99m activity in millicuries;

6. Ratio of the total Mo-99 microcuries per millicurie of Tc- 99m and checkmark that the ratio is less than 0.07 microcurie of Mo-99 per millicurie of Tc-99m. (If it is not, stop and notify the RSO. The licensee must notify the Arizona Radiation Regulatory Agency if a leaking generator is detected.) The 0.07 action level allows for the quicker decay of the Tc through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Mo-99 to Tc-99m would have doubled;
7. Initials of the person who made the record.

In addition to the above, on the first elution of each generator, the licensee shall check the elution for aluminum breakthrough.

#### **MODEL PROCEDURE FOR KEEPING AN INVENTORY OF IMPLANT SOURCES:**

1. Use a locking, installed cabinet or safe to store all implant sources.
2. Make a list of names of those individuals you will allow to handle implant sources and have them initial beside their names.
3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.
4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.
5. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use or patient's name, and the time and date they were removed from storage; initial the record.
6. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Then make a record of the number and activity of sources returned, the room number of use or patient's name, and the time and date they were returned to storage; initial the record.
7. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.
8. All implant sources shall be physically inventoried on a six month basis to account for all sources and devices received and possessed.

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**SIGNATURE**

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**DATE**

**ATTACHMENT I**

**ITEM 19  
EMERGENCY PROCEDURES**

**PROCEDURES:**

**1. MINOR SPILLS (INCLUDE LICENSEE DEFINITION HERE)**

- A. **NOTIFY:** Notify persons in the area that a spill has occurred.
- B. **PREVENT THE SPREAD:** Cover the spill with absorbent paper.
- C. **CLEAN UP:** Use disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a labeled plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
- D. **SURVEY:** With a low-range radiation detection survey meter. Check the area around the spill. Also check your hands, clothing and shoes for contamination.
- E. **REPORT:** Report the incident to the Radiation Safety Officer.
- F. **DOCUMENT:** Complete the Radioactive Spill Report and the Radioactive Contamination Survey forms (See Figure I-1 and Figure I-2).

**2. MAJOR SPILLS (INCLUDE LICENSEE DEFINITION HERE)**

- A. **CLEAR THE AREA:** Notify all persons not involved in the spill to vacate the room.
- B. **PREVENT THE SPREAD:** Cover the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
- C. **SHIELD THE SOURCE:** If possible, shield the spill. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
- D. **CLOSE THE ROOM:** Lock or otherwise secure the area to prevent entry.
- E. **CALL FOR HELP:** Notify the RSO immediately.
- F. **PERSONNEL DECONTAMINATION:** Remove contaminated clothing and flush contaminated skin with lukewarm water and then wash with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
- G. **CLEANUP:** The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey report forms (See Figure I-1 and Figure I-2).

RADIATION SAFETY OFFICER \_\_\_\_\_

OFFICE PHONE: \_\_\_\_\_

CELL PHONE \_\_\_\_\_

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RSO:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
**SIGNATURE**

\_\_\_\_\_  
**DATE**

The following is not part of the model spill procedures but is provided for your information.

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides the best spill procedure may be restricted access pending complete decay. Table I-1 may be used as general guidance to determine whether a major spill procedure or a minor spill procedure should be implemented.

**TABLE I-1**

**RELATIVE HAZARDS OF COMMON RADIONUCLIDES**

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor.

<u>Radionuclides</u>	<u>Millicuries</u>	<u>Radionuclide</u>	<u>Millicuries</u>
Fluorine-18	10	Strontium-85	10
Phosphorus-32	10	Technetium-99m	100
Chromium-51	100	Indium-111	10
Cobalt-57	10	Iodine 123	10
Cobalt-58	100	Iodine-125	1
Iron-59	10	Iodine-131	1
Cobalt-60	1	Ytterbium-169	10
Gallium-67	100	Gold-198	10
Selenium-75	10	Thallium-201	100
Yttrium-90	100	Samarium-153	100
Strontium-89	100	Carbon-14	10

**SPILL KIT:**

- 6 pairs disposable gloves, 1 pair housekeeping gloves
- 2 disposable lab coats
- 2 paper hats
- 2 pairs shoe covers
- 1 roll absorbent paper with plastic backing
- 6 plastic trash bags with twist ties
- "Radioactive Material" labeling tape
- 1 china pencil or marking pen
- 3 prestrung "Radioactive Material" labeling tags
- Supplies for 10 contamination wipe samples
- Instructions for "Emergency Procedures"
- Clipboard with copies of Radioactive Spill Report Form and Pencil

**ATTACHMENT J**  
**ITEM 20**  
**AREA SURVEY PROCEDURES**

**PREFACE:**

The NRC is now allowing a daily contamination survey in lieu of the typical daily radiation (ambient) exposure level survey and weekly contamination checks. This new contamination survey must be performed with a survey system that will detect action levels acceptable to the Agency. Currently, the Agency is accepting twice background for this type of survey. The instrument of choice should be a GM system with a pancake or scintillation probe. The choice will depend on the type of radiation in use in the area being surveyed.

Should the survey find contamination in excess of the action levels, the licensee will be responsible for cleaning the contaminated area and repeating the survey. If the levels have not dropped to an acceptable level, the licensee will be required to perform a wipe survey to determine if what remains is removable or fixed. If removable the licensee should repeat the cleaning and resurvey, or if the contamination is fixed, the licensee should determine the hazard potential. Based on the determination mark/label the area and shield the contaminated area to prevent personnel exposure, and the radionuclide to decay.

The new survey procedure is not appropriate for programs involving therapeutic activities, including both sealed and unsealed therapy radiation sources. The example procedure listed below has been accepted in the past and will be accepted until further notice. **It does not incorporate the new NRC procedures.**

**PROCEDURES:**

**A. Ambient Exposure Rate Surveys**

1. Survey Areas
  - a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter.
  - b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.
  - c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.
  - d. In sealed source and brachytherapy storage areas, survey monthly with a radiation measurement survey meter.
2. The survey conducted with a radiation detection or measurement survey instrument shall be able to detect or measure dose rates as low as 0.1 millirem per hour.
3. Notify the RSO immediately if the predetermined action level dose rate is exceeded. The action level is listed on each survey record.

**B. Removable Contamination Surveys**

1. Survey Areas:
  - a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination.
  - b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.
  - c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 200 dpm/100 cm<sup>2</sup> of removable contamination. You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute) to dpm.
3. Notify the RSO immediately, if the predetermined action level for removable contamination is exceeded. The action level is dependant on whether the area being surveyed is restricted or unrestricted, and whether the radionuclide in question is a gamma, high energy beta or alpha emitter. The action levels are listed on each survey record.

**C. Records**

1. Keep a record of exposure rate and contamination survey results (Figure J-1 has a sample record form which can be used). It must include the following information:
  - a. The date, area surveyed, and equipment used.
  - b. The name or initials of the person who made the survey.
  - c. A drawing of the areas surveyed and contamination and exposure rate action levels as established by the RSO. (Table J-1 is provided for guidance in establishing action levels.)
  - d. Measured exposure rates in mR/hr or contamination levels in dpm/100 cm<sup>2</sup>, as appropriate.
  - e. Actions taken in the case of excessive exposure rates or contamination and follow up survey information.
2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

---

**SIGNATURE**

---

**DATE**

**TABLE J-1**

**Recommended Action Levels in dpm/100 cm<sup>2</sup> for Surface Contamination by Radiopharmaceuticals**

Area	P-32	Co-58	Fe-59		
	Co-60	Se-75	Sr-85	Cr-51	Co-57
	In-111	I-123	I-125	Ga-67	Tc-99m
	I-131	Yb-169	Au-198	Hg-197	Tl-201
1. Unrestricted areas, personal clothing	200			2,000	
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000			20,000	

**NOTE:** **Higher levels may be acceptable** in unrestricted areas for lower hazard radionuclides, in accordance with NRC guidance for release of equipment and facilities to unrestricted use and termination of licensed programs. The NRC levels are also attached to this application and can be incorporated into your procedures if applicable for the radionuclides in use.

## ATTACHMENT K

### ITEM 21 WASTE DISPOSAL

#### I. OVERVIEW:

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of patient excreta and generally licensed in-vitro kit exemptions, nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material.

#### II. GENERAL GUIDANCE:

- A. All radioactivity labels must be defaced or removed from containers and packages prior to disposal. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
- B. Establish procedures to ensure that non-radioactive waste such as leftover reagents, boxes, and packaging material are not mixed with radioactive waste.
- C. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- D. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.
- E. In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, licensees are encouraged to reduce the volume of waste sent to these facilities. Important steps in volume reduction are to segregate radioactive from non-radioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials into the sanitary sewer in accordance with AAC R12-1-436.
- F. In all cases, the applicant should check for any local restrictions dealing with the disposal of radioactive and/or hazardous wastes.

#### III. DISPOSAL PROCEDURES:

- A. Disposal of Liquids and Gases

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere in accordance with levels authorized in Article 4, Schedule B. This does not relieve the licensee from complying with other regulations regarding toxic or hazardous properties of these materials.

- 1. Rules for disposal in the sanitary sewer appear in AAC R12-1-436. Material must be readily soluble or dispersible in the water. **(Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations.)** Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet used to dispose of the radioactive waste.

2. Limits on permissible concentrations in effluents to unrestricted areas are listed in Schedule B of Article 4 located in Title 12. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and site at which the material was released.
3. Liquid scintillation-counting media containing 0.05 microcurie per gram of H-3, C-14, or I-125 may be disposed of without regard to its radioactivity. Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram and how the material was disposed of. The licensee must keep in mind that this method does not relieve the licensee from complying with other rules regarding toxic or hazardous materials.

B. Disposal by Decay-in-Storage (DIS)

Short-lived material (physical half-life less than 120 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles in one container, other injection paraphernalia (syringes, swabs, and gauze) in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.
2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.
3. Decay the material for at least 10 half-lives and/or follow the steps in D, below.
4. Prior to disposal monitor each container as follows:
  - a. Check your radiation detection survey meter for proper operation;
  - b. Monitor in a low-level (less than 0.05 mR/hr) area;
  - c. Remove any shielding from around the container;
  - d. Monitor all surfaces of each individual container;
  - e. Discard in waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.
  - f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transfer for burial.
5. If possible, Mo-99/Tc-99m generators should be held for 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

C. Transfer for Burial

Only waste determined to not be radioactive may be buried. Radioactive waste may be transferred to a waste site authorized for its disposal. For your record of burial disposals, keep the consignment sheet that the transfer agent gave you. The commercial waste disposal service used will be:

<b>Name</b>	<b>City</b>	<b>State</b>

**Radioactive Materials License No.:** \_\_\_\_\_

D. Release to In-house Waste

Waste from in vitro kits that are generally licensed pursuant to AAC R12-1-306(F) are exempt from waste disposal rules. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurements.

E. Returning of Used Generators to the Manufacturer

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with Article 15 of Title 12, Chapter 1 of the Arizona Administrative Code (AAC) or Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT specification 7A container (see 49 CFR 173.415(a)).
2. Assemble the package in accordance with manufacturer's instructions.
3. Perform the dose rate and removable contamination measurements required by 49 CFR 173.475(i).
4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

\_\_\_\_\_  
**SIGNATURE**

\_\_\_\_\_  
**DATE**

## ATTACHMENT L

### ITEM 22 THERAPEUTIC USE OF RADIOPHARMACEUTICALS

#### PROCEDURE:

- A. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.
- B. Prepare the room for the procedure as follows:
  - 1. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) and small items (telephone, door knobs, bed remote control, television control, and nurse call cord) that are likely to be contaminated.
  - 2. Prepare separate boxes for linen, disposable waste, and non-disposable contaminated items. Place a single large re-closable plastic bag in each box, or supply several small plastic bags.
  - 3. Determine whether urine will be discarded by release to the sanitary sewer or collected. Prepare collection containers if urine will be collected.
    - a. Containers should be unbreakable and closable.
    - b. If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.
    - c. To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.
    - d. Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately 3 mm of lead.)
    - e. Supply a wide-mouth anti-splash funnel.
  - 4. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.
- C. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.
- D. Supply the nurses with film badges, TLDs, or pocket ionization chambers.
- E. Brief the nurses as indicated in the attached nursing instructions sheets. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patients' chart or at the nurses' station.
- F. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.
- G. Only those persons needed for medical, safety, or training purposes should be present during the administration.

- H. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.
- I. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line", and in the surrounding hallways and rooms (the last rates must conform to requirements in AAC R12-1-416). Record this and any other necessary information on the nursing instructions form or the nurses' dosimeter sign-out form. Post the room with a "Radioactive Materials" sign.
- J. For patients treated with liquid or gelatin-capsuled I-131, 1 day after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Also consider a thyroid burden assay for patient care personnel 2 days after the administration. Make a record of the worker's name, amount of I-131 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden, and the date.
- K. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.
- L. Do not release any patient until either the residual activity remaining in the patient is less than 30 millicuries or the measured exposure rate from the patient is less than 5 mR/hr at 1 meter. If using the exposure rate as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.
- M. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.
1. Remove all absorbent paper, and place in the appropriate container.
  2. Transfer all containers to a decay-in-storage or decontamination area.
  3. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm<sup>2</sup>.
  4. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

---

**SIGNATURE**

---

**DATE**

**NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH  
A GROUP 300 RADIOPHARMACEUTICAL**

1. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these restrictions before administering to the patient. Call the Nuclear Medicine Department or the Radiation Safety Officer with any questions about the care of these patients. Nursing personnel who attend the patient will wear personnel monitoring devices.
2. Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.
3. Patients must remain in bed while visitors are in the room and visitors should remain behind the "safe line" on the floor.
4. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.
5. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether or not they are pregnant.
6. Attending personnel will wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins, or other containers having any material obtained from the body of the patient. Wash hands after removing gloves.
7. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container.
8. All clothes and bed linens used by the patient should be placed in the bags provided and should be left in the patients' room to be checked by the RSO or his designee.
9. Surgical dressings should be changed only as directed by the physician. Gold-198 leaking from a puncture wound may stain the dressing dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the RSO or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.
10. If a patient should need emergency surgery or should expire, notify the RSO or Nuclear Medicine Department immediately.

**NOTE:** To assist in preparing adequate procedures review NRC Reg. Guide 8.39 and the regulatory requirements in **R12-1-717 and R12-1-722.**

**NURSES INSTRUCTIONS FOR PATIENTS TREATED WITH  
A GROUP 300 RADIOPHARMACEUTICAL**

**PROCEDURE HISTORY:**

PATIENT NAME: \_\_\_\_\_ PATIENT NUMBER: \_\_\_\_\_  
 ATTENDING: \_\_\_\_\_ PHONE: \_\_\_\_\_ PAGER: \_\_\_\_\_  
 PATIENT ROOM: \_\_\_\_\_  
 DOSE: \_\_\_\_\_ mCi OF \_\_\_\_\_ AS \_\_\_\_\_ ADMINISTERED AT \_\_\_\_\_ pm  
 SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_

**RADIATION SURVEYS:**

UNRESTRICTED AREAS: DOOR: \_\_\_\_\_ mR/hr; RM: \_\_\_\_\_ mR/hr; RM: \_\_\_\_\_ mR/hr  
 PATIENT SUPINE IN BED OR \_\_\_\_\_

DATE	BEDSIDE	METER FROM BED	SAFE LINE	
_____	_____ mR/hr	_____ mR/hr	_____ mR/hr	_____ mR/hr
_____	_____ mR/h	_____ mR/hr	_____ mR/hr	_____ mR/hr
_____	_____ mR/hr	_____ mR/hr	_____ mR/hr	_____ mR/hr

**NURSING INSTRUCTIONS:**

- \_\_\_\_\_ Visiting time permitted: \_\_\_\_\_
- \_\_\_\_\_ Visitors must remain behind "safe line" on floor.
- \_\_\_\_\_ Patient may not leave room.
- \_\_\_\_\_ Visitors under 18 are not permitted.
- \_\_\_\_\_ Pregnant visitors are not permitted.
- \_\_\_\_\_ Pocket dosimeter must be worn when caring for patient.
- \_\_\_\_\_ Disposable gloves must be worn while attending patient.
- \_\_\_\_\_ All items must remain in room until approved for removal by the Radiation Safety Officer or his designee.
- \_\_\_\_\_ Housekeeping personnel not permitted in room.
- \_\_\_\_\_ Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.
- \_\_\_\_\_ Other \_\_\_\_\_

**IN CASE OF EMERGENCY CONTACT:**

RSO: \_\_\_\_\_ PHONE: \_\_\_\_\_  
 OR: \_\_\_\_\_ PHONE: \_\_\_\_\_

**RADIATION SAFETY CHECKLIST FOR  
RADIOPHARMACEUTICALS ADMINISTERED IN A HOSPITAL SETTING**

**PATIENT:** \_\_\_\_\_ **ROOM:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

**PREPARATION:**

- Schedule a private room with private sanitary facility, without carpet, and in a low traffic area.
- Cover large room surfaces with absorbent paper and small surfaces with absorbent paper or plastic.
- Prepare labeled boxes for used linen, disposable waste, and non-disposable contaminated items.
- Prepare urine collection containers if urine will be collected.
- Stock room with disposable gloves, absorbent paper and "Radioactive Waste" labels.
- Mark a visitor's "safe line" on the floor.
- Order disposable table service.
- Notify Housekeeping to not clean the room until further notice.
- Brief the nursing staff on radiation safety measures.
- Supply the nursing staff with personnel radiation dosimeters.

**ADMINISTRATION:**

- Clear the room of unneeded personnel.
- Brief the patient on the clinical procedure.
- Administer the dosage.
- Measure dose rates at bedside, 1 meter from bedside, "safe line", and surrounding hallways and rooms.
- Post the room with a "Radioactive Materials" sign.

**FOLLOW-UP:**

- If the patient has been treated with I-131, measure the thyroid burden of all personnel who were present for the administration.
- Pick up waste for decay-in-storage or decontamination.
- Release the patient.
- Decontaminate and survey the room. Remove the "Radioactive Materials" sign.
- Call the Housekeeping office to clean the room.

**RADIATION SAFETY CHECKLIST FOR  
TEMPORARY IMPLANT THERAPY**

**PATIENT:** \_\_\_\_\_ **ROOM:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

**PREPARATION:**

- Schedule a private room in a low traffic area.
- Mark a visitor's "safe line" on the floor.
- Brief the nursing staff on radiation safety measures.
- Supply the nursing staff with personnel radiation dosimeters.

**ADMINISTRATION:**

- Clear the room of unneeded personnel.
- Brief the patient on the clinical procedure.
- Insert the implant.
- Measure dose rates at bedside, 1 meter from bedside, "safe line", and surrounding hallways and rooms.
- Post the room with a "Radioactive Materials" sign.

**FOLLOW-UP:**

- Make a radiation survey of the patient to assure that all sources have been removed.
- Count the number of sources removed from the patient to assure that all sources have been removed.
- Remove the "Radioactive Materials" sign.

**ATTACHMENT M**

**ITEM 23  
THERAPEUTIC USE OF SEALED SOURCES  
TEMPORARY IMPLANTS**

**INTRODUCTION:**

To ensure that patients are not released at levels that do not meet the rules, the licensee should review NRC Reg Guide 8.39 and **R12-1-717**. To further ensure adequate safety, the licensee should review **R12-1-724 and R12-1-725** for additional requirements that must be met when performing brachytherapy..

**PROCEDURES:**

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room.
2. Supply the nurses with film badges, TLDs, or pocket ionization chambers, and a record to record their exposures if appropriate for the device being used.
3. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Temporary Implant Sources". Allow time for questions and answers during the briefing.
4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable consistent with good medical care.
5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.
6. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.
7. Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitor's "safe line", and in the surrounding hallways and rooms (the last rates must conform to requirements in AAC R12-1-416). Record this and any other necessary information on the nursing instruction form or the nurses' dosimeter sign-out form.
8. The patient's room will be properly posted or attended in accordance with AAC R12-1-429 and R12-1-430.
9. Do not release any patient who has received a temporary implant from the hospital until both a radiation survey of the patient and a count of implant sources confirm that all sources have been removed from the patient and are accounted for. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey on the implant source running inventory form. (See Figures M-1 and M-2 for examples of forms which may be used.) For low-activity seeds (less than 1 millicurie), use an individual seed to check the survey meter to be sure it will easily detect a seed that has not been removed or has been lost.

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**SIGNATURE**

---

**DATE**

**NURSING INSTRUCTIONS FOR PATIENTS TREATED  
WITH TEMPORARY IMPLANT SOURCES**

1. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these instructions before administering to the patient. The Radiation Safety Officer (RSO) should be contacted to answer any questions about the care of the patient in regard to radiation safety precautions.
2. Nurses should spend only the minimum time necessary near a patient for routine nursing care. Obtain and wear a film or TLD badge or a pocket ionization chamber as instructed by the RSO.
3. Never touch needles, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the far corner of the room or in the shielded container provided. Contact Radiation Therapy, the RSO, or the Nuclear Medicine Department at once.
4. Bed baths given by the nurse should be omitted while the sources are in place.
5. Perineal care is not given during gynecologic treatment. The perineal pad may be changed when necessary unless orders to the contrary have been written.
6. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or technologist and **MAY NOT BE DISCARDED** until directed by the RSO or his designee. Dressings should be kept in a basin until checked by the RSO or his designee.
7. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered, but these items should be saved for a check with a radiation survey meter to ensure that no sources have been inadvertently displaced into them.
8. All bed linens must be checked with a radiation survey meter before being removed from the patients' room to ensure that no dislodged sources are inadvertently removed.
9. The patient must stay in bed unless orders to the contrary are written. In any event, the patient will remain in the assigned room during the treatment period.
10. Visitors will be limited to those 18 years of age or older unless other instructions are noted on the precaution sheet on the patient's chart.
11. Visitors must stay behind the "safe line" marked on the floor and should remain no longer than the time specified on the form posted on the patient's door and on his chart.
12. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked if they are pregnant.
13. At the conclusion of treatment, call the RSO to:
  - A. Survey the patient and room.
  - B. Count the radiation sources to be sure that all temporary implants have been removed prior to discharging the patient.
  - C. Record a summary of the final survey results on the patient's chart.

If any permanent implants are to remain in the patient, the RSO will brief the patient on precautions for minimizing radiation exposure to others after discharge from the hospital.

14. Emergency Procedures

- A. If an implanted source becomes loose or separated from the patient, or
- B. The patient dies, or
- C. The patient requires emergency surgery, immediately call:

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Telephone (days) \_\_\_\_\_  
(nights) \_\_\_\_\_

## **RADIATION SAFETY CHECKLIST FOR TEMPORARY IMPLANT THERAPY**

### **PREFACE:**

As stated elsewhere in this application guide, patients may be released without hospitalization if the radiation levels are not a hazard to the public as determined in NRC Reg Guide 8.39, which is authorized under AAC **R12-1-717**. This guide contains procedures and action levels dependent on radionuclide being used to treat the patient's disease. The Guide is available from the Agency. The procedures provided here are for hospitalized patients.

**PATIENT:** \_\_\_\_\_ **ROOM:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

### **PREPARATION:**

- G Schedule a private room in a low traffic area.
- G Mark a visitor's "safe line" on the floor.
- G Brief the nursing staff on radiation safety measures.
- G Supply the nursing staff with personnel radiation dosimeters.

### **ADMINISTRATION:**

- G Clear the room of unneeded personnel.
- G Brief the patient on the clinical procedure.
- G Insert the implant.
- G Measure dose rates at bedside, 1 meter from bedside, "safe line", and surrounding hallways and rooms.
- G Post the room with a "Radioactive Materials" sign.

### **FOLLOW-UP:**

- G Make a radiation survey of the patient to assure that all sources have been removed.
- G Count the number of sources removed from the patient to assure that all sources have been removed.
- G Remove the "Radioactive Materials" sign.



**Patient Care:**

- \_\_\_\_\_ Wear radiation monitor when caring for patient. Leave at nursing station at the end of shift. Use same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
  - \_\_\_\_\_ If a source appears dislodged, call the attending physician and the RSO immediately.
  - \_\_\_\_\_ Omit bed bath.
  - \_\_\_\_\_ No perineal care. Pad may be changed as necessary.
  - \_\_\_\_\_ Save surgical dressings for disposal by attending physician or RSO.
  - \_\_\_\_\_ See special oral hygiene care instructions.
- 
- 

In case of emergency, or if you have a question, call:

RSO: \_\_\_\_\_ Work \_\_\_\_\_ Home \_\_\_\_\_ Pager \_\_\_\_\_  
MD: \_\_\_\_\_ Work \_\_\_\_\_ Home \_\_\_\_\_ Page \_\_\_\_\_

## ATTACHMENT N

### ITEM 24 MONITORING, CALCULATING AND CONTROLLING AIR CONCENTRATIONS

#### PREFACE:

It is assumed that the facility where radioactive gas will be used is under a dedicated air handling system. This means that the air coming into the restricted area empties directly to the outside and not into a return system. It is further understood that some nuclear medicine departments will be built into an existing facility that does not have exhaust capability. In those cases this limitation should be brought to the attention of the Agency and that the **use of aerosols instead of gases should be considered.**

#### GENERAL PROCEDURES WHEN USING A RADIOACTIVE GAS:

1. Noble gases such as Xenon in the air present an external source of radiation exposure that must be calculated. Many commercially available dosimeters and survey instruments are not capable of accurately measuring worker doses from immersion in noble gases.
2. If you will collect spent gas in a shielded trap with an effluent air contamination monitor and will follow the monitor manufacturer's instructions for checking its accuracy and constancy, initial the appropriate statement on the signature page of this attachment.
3. If you will collect spent gas in a shielded trap and will follow the model procedure shown below for checking trap effluent, initial the appropriate statement on the signature page of this attachment.
4. If you are not monitoring trap effluent or if you exhaust spent gas to the atmosphere, you must estimate worker dose by calculation. If you will follow the model procedures below for calculating worker dose from noble gases, initial the appropriate statement on the signature page of these model procedures.
5. If none of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information. Initial the appropriate statement on the signature page of this attachment.
6. If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information. Initial the appropriate statement on the signature page of this attachment.
7. Where appropriate, attach copies of calculations performed.

**I. MODEL PROCEDURE AND WORK SHEET FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF RADIOACTIVE GASES IN WORK AREAS (Restricted Area):**

1. Collect the following data:

Estimated number of studies per week (N): \_\_\_\_\_

Activity to be administered per study, in microcuries (Y): \_\_\_\_\_

Estimated activity lost to the work areas per study (assume 20 %) (f): \_\_\_\_\_

Measured airflow supply by each vent in the imaging room (if different during heating and cooling seasons, use the lesser value): (S): \_\_\_\_\_

Measured airflow exhaust by each vent in the imaging room (exhaust should be vented and not recirculated within the facility)(E): \_\_\_\_\_

Maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are  $1 \times 10^{-4}$  microcuries/ml in restricted areas and  $5 \times 10^{-7}$  microcuries/ml in unrestricted areas (See Schedule B Article 4). (C): \_\_\_\_\_

2. Perform the following calculations:

Sum all exhaust rates and all supply rates. For negative pressure, the exhaust rate must be larger than the supply rate, in milliliters (R=E-S): \_\_\_\_\_

Estimate the average concentration in restricted areas. \_\_\_\_\_

Total activity released to the restricted area:(A=Y x N x f): \_\_\_\_\_

Average concentration: (A / V):  
(V = Air volume of room in ml) \_\_\_\_\_

The total activity released to an unrestricted (activity used each week multiplied by the estimated fractional loss per study) divided by the total air exhausted (sum of all exhaust rates multiplied by the length of the work week) must be less than the applicable maximum permissible value for a restricted area.(See Schedule B, Article 4)

If the concentration is greater than the applicable maximum permissible value for a restricted area, plan for fewer studies and do the calculation again; and you may use the following example problem and table to determine your allowable patient workload by comparing required airflow and release amounts.

3. **EXAMPLE PROBLEM:**

A nuclear medicine lab plans to use 10 mCi Xe-133 per patient and will perform a maximum of 10 studies per week. What ventilation rate is required to ensure compliance?

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Maximum activity lost per week:

$$A = \frac{10 \text{ mCi}}{\text{patient}} \times \frac{10 \text{ patients}}{\text{week}} \times \frac{1 \times 10^3 \text{ microcurie}}{\text{millicurie}} \times 0.20$$

$$A = \frac{2 \times 10^4 \text{ millicurie}}{\text{week}} \times \frac{1}{1 \times 10^{-5} \frac{\text{microcurie}}{\text{ml}}}$$

$$A = 2.0 \times 10^9 \frac{\text{ml}}{\text{week}}$$

The required ventilation rate is

$$\frac{2.0 \times 10^9 \frac{\text{ml}}{\text{week}}}{40 \frac{\text{hr}}{\text{week}}} \div \frac{1.7 \times 10^6 \frac{\text{ml}}{\text{hr}}}{\frac{\text{cubic feet}}{\text{minute}}} = 30 \frac{\text{cubic feet}}{\text{minute}}$$

The answer shows that, in order to meet the requirements of AAC R12-1-408 the imaging room (RESTRICTED AREA) must have a ventilation rate of at least 30 cubic feet/min with no return of the contaminated air. Where practical, the ventilation rate should be greater than that shown necessary by the calculations. **Consider every alternative in order to maintain the air concentration of Xe-133 as low as reasonably achievable.**

The following table gives some examples of the amount of Xe-133 that can be released per week without exceeding the permissible levels for Xe-133 in restricted areas.

<u>Ventilation Rate</u> <u>(ft<sup>3</sup>/min)</u>	<u>Maximum Xe-133 Released</u> <u>per 40-Hour Week (mCi)</u>
100	67.9
500	339.7
1000	679.4

## II. MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION (Unrestricted Area):

1. Collect the following:

Activity released to unrestricted area in one year in microcuries (A): \_\_\_\_\_

Total volume of air exhausted over one year in milliliters ("on" time x airflow rate) (V): \_\_\_\_\_

2. Calculate the average concentration:  $C = A/V$ : \_\_\_\_\_
3. C must be less than or equal to the applicable maximum permissible value for an unrestricted area. If this is not the case, plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area. (See Schedule B, Article 4).

### 4. EXAMPLE PROBLEM:

A nuclear medicine lab plans to use 10 mCi per patient and will perform a maximum of 10 studies per week. A fume hood is available for disposal of Xe-133 and has a measured airflow of 168 ft/min with an opening of 8 square feet. What is the average concentration of Xe-133 at the point of release from the fume hood exhaust? (NOTE: All xenon that has been released, e.g., collection bags, filters, must be considered.)

$$A = \frac{10 \text{ patients}}{\text{week}} \times \frac{10 \text{ mCi}}{\text{patient}} \times \frac{10^3 \text{ microcurie}}{\text{mCi}} \times \frac{52 \text{ weeks}}{\text{yr}}$$

$$A = 5.2 \times 10^6 \text{ microcurie/yr}$$

$$V = \frac{168 \text{ ft}}{\text{Min}} \times 8 \text{ ft}^2 \times \frac{1.49 \times 10^{10} \text{ ml/yr}}{\text{cubic feet/min}}$$

$$V = 2.0 \times 10^{13} \text{ ml/yr}$$

$$C = \frac{5.2 \times 10^{16} \text{ microcurie/yr}}{2.0 \times 10^{13} \text{ ml/yr}}$$

$$C = 2.6 \times 10^{-7} \text{ microcurie/ml}$$

The following table gives some examples of the amount of Xe-133 that can be released per week without exceeding an average concentration of  $5 \times 10^{-7}$  microcurie/ml.

Exhaust Rate ( $\text{ft}^3/\text{min}$ )	Average Release of Xe-133 per week (mCi)
100	8.6
500	42.8
1000	85.6
1500	128.4

**III. MODEL PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT:**

Charcoal traps can significantly reduce air contamination. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

1. If the trap effluent is monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions and keep a record of the checks.
2. If you do not monitor the trap effluent, check it on receipt and either once each month or after every 10 patient studies, whichever comes first. Collect the effluent from the trap during one patient study in a plastic bag and then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble gas, and comparing its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.
3. The RSO will establish an action level based on cpm or a multiple of background cpm. If you measure a significant increase in the bag cpm, the trap is breaking down and must be replaced.
4. Follow the trap manufacturer's instructions for replacing the trap.

**IV. MODEL PROCEDURE FOR PUBLIC DOSE FROM AIRBORNE EFFLUENT:**

1. Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value of Table II of Schedule B to Article 4.
2. If you are not directly venting gases to the atmosphere, initial the appropriate statement on the signature page of this attachment.
3. If you are going to vent gases to the atmosphere, you must estimate effluent concentrations by calculation. If you will follow the model procedure shown in Section II above, initial the appropriate statement on the signature page of this attachment.
4. If neither of the above apply, you may develop your own procedure for review. If so, you should consider all the above information.

**V. EMERGENCY PROCEDURES AND SPILLED GAS CLEARANCE TIME:**

Should there occur an accidental release of Xenon-133 into either the imaging room or the hot lab, the nuclear medicine technologists would immediately remove themselves and the patient, if feasible or applicable, from the imaging room or hot lab. The room will remain vacant until such a time as the ventilation would dilute the concentration of released Xenon-133 to levels below the MPC for restricted areas, i.e.,  $1 \times 10^{-4}$  microcuries/ml.

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the calculations described below, should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

If you will calculate spilled gas clearance times according to the model procedure below, initial the appropriate statement on the signature page of these model procedures. If you develop your own procedure, you should consider all the above information.

**VI. MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME:**

- 1. Collect the following data:

Highest activity of gas in a single container, in microcuries: A: \_\_\_\_\_

Sum of airflow supply from each vent in the room, in ml/min (if different during heating and cooling seasons, use the lesser value): S: \_\_\_\_\_

The total room air exhaust determined by measuring, in ml/min, the airflow to each exhaust vent in the room. (The exhaust should be vented and not recirculated within the facility.) This may be either the normal air exhaust or a specially installed gas exhaust system: Q: \_\_\_\_\_

C, the maximum permissible air concentrations (MPC) in restricted and unrestricted areas. For Xenon-133, the MPC values are  $1 \times 10^{-4}$  microcuries/ml in restricted areas and  $5 \times 10^{-7}$  microcuries/ml in unrestricted areas. For other gases, see Schedule B to Article 4. C: \_\_\_\_\_

The volume of the room in ml: V: \_\_\_\_\_

- 2. For each room calculate the following: \_\_\_\_\_

Determine the net airflow in the room (Q - S). The value must be positive to ensure the room is at negative pressure. \_\_\_\_\_

The evacuation time is calculated by:  $t = ((-V)/Q) \times \ln(C \times (V/A))$  \_\_\_\_\_

**INITIAL ALL STATEMENTS WHICH APPLY TO THE FACILITY  
AND SIGN AND DATE FORM AT BOTTOM.**

**PREFACE:**

If you plan to use aerosols, note the following:

- Aerosol should not be collected in an unshielded trap,
- An air contamination monitor should be used with reusable traps,
- And the manufacturer's instructions for checking for accuracy and constancy should be followed. Initial the appropriate statements on this page, otherwise initial the appropriate statements for use of noble gases.

**WORKER DOSE FROM NOBLE GASES:**

- Noble gas will be collected in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions.
- Noble gas will be collected in a shielded container and will establish and implement the model procedure for checking trap effluent published in Section III of these model procedures.
- The model procedure listed in Section I for calculating worker dose from noble gases will be followed.
- A procedure for monitoring worker dose due to submersion in noble gases that has been developed and is appended.

**WORKER DOSE FROM AEROSOLS:**

- Spent aerosol will be collected in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions.
- Our procedures are attached for Agency review.
- Aerosols will not be used at this facility.

**AIRBORNE EFFLUENT:**

- Aerosols and gases will not be vented directly to the atmosphere and therefore no effluent estimation is necessary.
- A procedure for monitoring airborne effluent concentration is attached.

**SPILED GAS CLEARANCE TIME:**

- Spilled gas clearance times will be calculated according to the model procedure listed in Section V.
- A procedure has been developed for calculating spilled gas clearance times that is appended. procedures attached.
- If need be, doses will be calculated in accordance with R12-1-409.

---

**SIGNATURE**

---

**DATE**



## ATTACHMENT O

### ITEM 27 PERSONNEL DOSIMETRY AND BIOASSAY PROGRAMS

#### I. PERSONNEL DOSIMETRY PROGRAM:

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This review will conform to the suggestions contained in Regulatory Guides 8.7 and 8.34. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or TLD.
2. All individuals who are occupationally exposed to radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly or quarterly basis.
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons and could exceed 10% of the applicable limit set forth in A.A.C. R12-1-408 and R12-1-414, will be issued appropriate personnel dosimetry that will be processed by a contract service.
4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for those patients.
5. Other individuals who are exposed to radiation on an occasional basis, such as security who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.
6. When monitoring pursuant to R12-1-419(A) and (B) the licensee is required to demonstrate compliance with dose limits by summing external and internal doses (R12-1-409). Records of the summed dose shall be recorded on Form Z (attached) or other clear and legible record.
7. Individuals that are allowed to enter a restricted area and are likely to receive, in one year, an occupational dose requiring monitoring will have their histories of occupational doses for the current year determined. **At a minimum, an attempt will be made to obtain a new employee's exposure history for the current year to ensure the annual limit is not exceeded. All new employees will be asked to provide** the records of lifetime cumulative occupational radiation doses. Record of exposure history will be maintained on Form Y (attached) or other clear and legible record. Planned special exposures will require documented exposure histories in accordance with R12-1-413.
8. **Bioassays will be conducted on individuals that may be exposed internally to radioactive material. The bioassays will be conducted at intervals and with equipment that will detect 10% of the levels of the radionuclide's listed in Appendix B of Article 4. Attached are the bioassay procedures and a listing of equipment that will be used in conducting the bioassays.** Attachment O-1 contains further details of the bioassay program that will be employed.

**II. PERSONNEL DOSIMETRY INFORMATION:**

Provide the following information:

1. Dosimetry Supplier: \_\_\_\_\_
2. Type: \_\_\_\_\_ Film \_\_\_\_\_ TLD  
 \_\_\_\_\_ Beta-Gamma \_\_\_\_\_ Beta-Gamma, Neutron  
 \_\_\_\_\_ Whole Body \_\_\_\_\_ Ring \_\_\_\_\_ Wrist
3. Exchange Frequency:  
 Whole Body: \_\_\_\_\_ Ring: \_\_\_\_\_ Wrist: \_\_\_\_\_
4. Results Reviewed by:  
 \_\_\_\_\_
5. Records maintained by:  
 \_\_\_\_\_
6. Individual responsible for overexposure reports:  
 \_\_\_\_\_
7. A. \_\_\_\_\_ Model procedure for monitoring personnel external exposure will be followed.  
 B. \_\_\_\_\_ Equivalent procedures attached

**III. BIOASSAY PROGRAM:**

Initial applicable statements and provide required information:

1. \_\_\_\_\_ A bioassay program will be performed in accordance with A.A.C. R12-1-419(D).
  - A. This rule states that an individual participates in a radioiodine bioassay if the individual:
    1. Is likely to receive an annual intake in excess 0.1 of the Annual Limits of Intake (ALI) specified in Table 1, Columns 1 and 2 of Appendix B in 12 A.A.C.1, Article 4;
    2. Is a minor or declared pregnant woman likely to receive an annual committed effective dose equivalent in excess of 50 mRem, or
    3. Has been involved in a spill, an incident, or other occurrence during which radioiodine may have been taken into the body either by inhalation, ingestion, or by absorption through the skin or a wound.
  - B. If personnel are involved directly with a radioiodine therapy, each Individual who handles radioiodine stock solutions, or is involved in iodinations, and meets, as a minimum, any one of the three criteria in Part A above, must participate in a bioassay soon after the exposure to radioiodine. It is currently acceptable to do an I-131bioassay up to four weeks following the exposure and 12 weeks following the exposure to I-125. Obtain Agency approval, however, if you decide to do the bioassay at periods greater than 6 to 72 hours following exposure.

- C. For any individual whose cumulative annual intake is likely to exceed 0.1 ALI, a dosimetric determination based on the results of the bioassay perform under Part B must be performed. To assist in determining the total dose equivalent for the individual, add the obtained dose information to the committed dose equivalent information for the exposed individual. For the exposed individual whose bioassay exceeds 0.25 ALI, restrict the exposed individual from further radioiodine exposure until a bioassay indicates the individual’s exposure has dropped below 0.1 ALI.
- D. For bioassays exceeding 0.1 ALI, investigate the circumstances surrounding the exposed individual=s uptake. Records of the investigation and all bioassay measurements must be maintained as part of the licensee=s personnel dosimetry records and must be available for inspection by the Agency.

Reference: ARRA Reg Guide 8.20.

- 2  Bioassay will be performed in-house. Procedures are attached indicating personnel to perform bioassay, instrumentation to be used, calibration standard used, sample dose calculations, sample records and individual to maintain records.
- 3  Bioassay will be performed by outside firm. The firm used will be:  


---

License No.: \_\_\_\_\_
- 4  No bioassay program required by this facility.

**IV. SUMMATION OF DOSE WILL BE CALCULATED IN ACCORDANCE WITH R12-1-409:**

\_\_\_\_\_  
**SIGNATURE**

\_\_\_\_\_  
**DATE**

## ATTACHMENT P

### ITEM 28 SEALED SOURCE LEAK TEST PROGRAM

#### PROCEDURE:

1. **At a minimum all leak tests will be conducted in accordance with R12-1-417.** Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
  - A. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
  - B. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source, etc.) take the wipe near the radiation port and on the activating mechanism.
  - C. If you are testing radium sources at the same time you are testing other sealed sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the adsorbent samples as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.
4. The samples will be analyzed as follows:
  - A. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
  - B. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.
  - C. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
  - D. Record the wipe sample counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
  - E. Continue the same analysis procedure for all wipe samples.
  - F. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it a source distributed under an NRC or Agreement State license, the Agency must be notified.

- G. Sign and date the list of sources, data, and calculation.
- H. Example sealed source leak test program

Initial applicable statements and provide the required information:

1. \_\_\_\_\_ Leak tests will be performed by outside consultant. The consultant used will be: \_\_\_\_\_ License Number: \_\_\_\_\_
2. \_\_\_\_\_ Leak tests will be performed by the licensee and analyzed by outside consultant.
  - A. Individual(s) who will perform leak test are: \_\_\_\_\_  
\_\_\_\_\_
  - B. Leak test kit to be used: \_\_\_\_\_  
\_\_\_\_\_
3. Tests will be analyzed by: \_\_\_\_\_  
License Number: \_\_\_\_\_
4. \_\_\_\_\_ Licensee will perform and analyze own leak tests in accordance with the procedures outlined in Attachment P.
5. \_\_\_\_\_ Licensee will perform and analyze own leak tests in accordance with equivalent procedures attached.
  - A. Individual(s) who will perform leak test are: \_\_\_\_\_  
\_\_\_\_\_
6. Leak test kit to be used: \_\_\_\_\_
7. Counting instrument: \_\_\_\_\_
8. Counting standard: Isotope: \_\_\_\_\_ Activity: \_\_\_\_\_
9. Sample calculation:

\_\_\_\_\_  
**SIGNATURE**

\_\_\_\_\_  
**DATE**

**ATTACHMENT Q**

**ITEM 30  
"ALARA" PROGRAM**

**PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE  
AT MEDICAL INSTITUTIONS "AS LOW AS REASONABLE ACHIEVABLE"**

---

**(LICENSEE NAME)**

---

**(DATE)**

**A. Management Commitment.**

1. In accordance with AAC R12-1-407, management of this (medical facility, hospital, etc.) commits to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Officer (RSO) and a Radiation Safety Committee (RSC) if appropriate for the scope of the program.
2. An annual review of the radiation safety program, including ALARA considerations will be performed. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.
3. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. It will be demonstrated if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
4. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

**B. Radiation Safety Officer or Radiation Safety Committee (depending on scope of the program).**

1. Review of Proposed Users and Uses
  - a. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
  - b. When considering a new use of radioactive material, the RSC will review the efforts of the applicant to maintain exposure ALARA.
  - c. The RSO/RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

2. Review of ALARA Program
  - a. The RSO/RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
  - b. The RSO/RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded (see Section 6 for a discussion of investigational levels).<sup>1</sup>

**NOTE:** <sup>1</sup>The investigational levels in this program are not new dose limits but, as noted in ICRP Report No. 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify investigations.

**TABLE 1**  
**INVESTIGATIONAL LEVELS**

		Investigational Levels mrems per calendar quarter	
		<u>Level I</u>	<u>Level II</u>
1.	Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625
3.	Skin of whole body	750	2250

\* Not normally applicable to medical use operations except those using significant quantities of beta-emitting isotopes.

- c. The RSO/RSC will evaluate the program's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized user, and workers as well as those of management.

### C. Authorized Users.

1. New Methods of Use Involving Potential Radiation Exposures.
  - a. The authorized user will consult with the RSO or RSC during the planning stage before using radioactive materials for new uses.
  - b. The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. This may be enhanced by using trial runs.
2. Authorized User's Responsibility to Supervised Individuals.
  - a. The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
  - b. The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

**D. Individuals Who Receive Occupational Radiation Exposure.**

1. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.
2. Workers will know what recourses are available if they feel that ALARA is not being promoted on the job.

**E. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Exposures.**

This institution hereby establishes investigational levels for occupational external radiation dose which, when exceeded, will initiate review or investigation by the RSO or RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on Form Z "Occupational Exposure Record For A Monitoring Period", or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in Table 1:

1. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

2. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, review each such dose in comparison with those of others performing similar tasks as in index of ALARA program quality and will record the review in the Committee minutes.

3. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's Form Z or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

4. Reestablishment of Investigational Levels to levels above that listed in Table 1.

In cases where a worker's or a group of worker's doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for a new investigational level will be documented.

The RSO/RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

**F. Signature of Certifying Official.\***

I hereby certify that this institution has implemented the ALARA Program set forth above.

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**SIGNATURE**

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**NAME (PRINT OR TYPE)**

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**TITLE**

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\* The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

## ATTACHMENT R

### MOBILE NUCLEAR MEDICINE CONSIDERATIONS

- A. Provide a description of the program so the Agency can determine the scope of the operation.
- B. Provide a description of the coach/trailer that will be used for the service.
- C. Will radioactive material be used/received in the client's facility?
- D. Describe the responsibilities of the RSO and authorized users. How will they interface with the activities occurring at the mobile site(s).
- E. Describe how radioactive material will be transported, including transport records and security measures. A transport record shall be available in reach of the driver at all times while driving to a job-site.
- F. A MOU (memorandum-of-understanding) is required between the service provider and the client. Provide a copy for each site for which service will be provided. Each service location will be listed on the license, as well as the hub location if appropriate.
- G. Commit to notifying the Agency by facsimile on a weekly basis of the job-sites that will be serviced. Changes in schedule must be provided to the Agency as soon as a change is noted.
- H. Provide a description of considerations that have been addressed in conjunction with the use of PET radionuclides. Of special concern is shielding and waste disposal.
- I. Consideration must be given to instrumentation operation following the transport of afterloading devices. What procedures will be followed?
- J. At a minimum the requirements in **R12-1-718** will be met when conduction mobile nuclear medicine procedures.

**For additional guidance concerning mobile nuclear medicine, see Appendix V in NRC Nureg 1556, available from the Agency.**

**ATTACHMENT S**

**ITEM 32  
LEGAL STRUCTURE OF THE APPLICANT**

8. **LEGAL STRUCTURE OF APPLICANT**

An Individual       A Partnership       A Limited Liability Corporation       A Corporation   
 An Unincorporated Association       City/County/State Government

A Partnership

Please provide the name and address of each individual or legal entity owning a partnership interest in the applicant.

Please state the percentage ownership of the applicant partnership held by each of the individuals or legal entities listed above.

A Limited Liability Corporation

Memberships

Ownerships

A Corporation

**STOCK OF APPLICANT CORPORATION**

# AUTHORIZED SHARES TOTAL SUBSCRIBERS	# ISSUED SHARES	# SUBSCRIBED SHARES	TOTAL STOCKHOLDERS

Is the applicant corporation directly or indirectly controlled by another corporation or other legal entity?

If "yes" give name and address of other corporation or legal entity and describe how such control exists and the extent of control.

For all entities, please identify the State, District, or Territory under the laws of which the applicant is organized. Include the name and address of any Arizona agent for the applicant.

9. The applicant or any official executing this application on behalf of the applicant certifies that this application has been prepared in accordance with Arizona Administrative Code, Title 12, Chapter 1, and all information contained on this form, including any supplements and attachments, is true and correct to the best of his or her knowledge and belief.

DATE

APPLICANT (ITEM 1)

BY (TITLE)

\_\_\_\_\_

## ATTACHMENT T

### SHIELDING CONSIDERATIONS FOR A PET FACILITY

#### I. RADIATION PROTECTION GOALS:

The radiation protection goal for members of the public, established by the Nuclear Regulatory Commission and mirrored by state regulations in agreement states, is to limit exposure to insure that no individual will receive more than 100 mrem/year (1 mSv/year) total effective dose equivalent from the licensed operation.<sup>6</sup> On a weekly basis, this means controlling dose to the level of 2 mrem. This is approximately 30% of the mean effective dose rate from natural background radiation in the United States. There is an additional requirement that the dose rate in areas accessible to members of the public not exceed 2 mrem in any given hour (.02 mSv/hour). Institutional staff members whose assigned duties do not involve exposure to radiation sources are considered to be members of the public.

Radiation workers are limited to receiving 5000 mrem (50 mSv) total effective dose equivalent per year.<sup>7</sup> In addition, there are dose limits to individual organs (50 rem or 500 mSv per year), extremities and the skin (50 rem or 500 mSv per year), and the lens of the eye (15 rem or 150 mSv per year). The dose to the fetus of a radiation worker who declares herself to be pregnant is limited to no more than 500 mrem (5 mSv) in the course of the pregnancy as a consequence of occupational exposure to the mother.<sup>8</sup> Operationally, this last requirement is usually implemented by a monthly limitation of 50 mrem (0.5 mSv) to the fetus.

In addition to the specific limitations outlined above, each licensee has an obligation to conduct operations so as to maintain doses to both radiation workers and to members of the public as low as reasonably achievable (ALARA).

#### II. SHIELDING CONSIDERATIONS:

Lead and concrete are the most likely materials to be used for area shielding in the PET facility. The attenuation factor necessary for shielding is likely to be no more than 10, but the high penetration of 511 keV photons can require a significant thickness of either material.

**TABLE I**

**Comparison of half value layers for different shielding materials at 511 keV under narrow beam conditions.**

Material	Half-Value layer at 511 keV
(density in [g/cm <sup>3</sup> ])	Narrow Beam Conditions[mm]
Lead (11.4 g/cm <sup>3</sup> )	3.98
Concrete (2.35 g/cm <sup>3</sup> )	34
Concrete (1.84 g/cm <sup>3</sup> )	43

The photon energy of a positron emitter is quite different from technetium-99m. The energy is 511 keV with two photons per atom disintegration. It is very obvious that safety for personnel and members of the public must be evaluated differently than a typical nuclear medicine department that uses technetium-99m and other less hazardous radionuclides.

TABLE II

## DECAY PARAMETERS FOR SOME COMMONLY USED RADIONUCLIDES

<u>Radionuclide:</u>	<u>Half-life</u>	<u>Gamma Ray Constant</u>
Tc-99m	6 hours	1.41 R/hr per mCi at 1 cm
Tl-201	74 hours	1.01
I-131	8.05 days	3.24
F-18	109.7 min.	6.95
Rb-82	1.25 min.	7.78
Ge-68	288 days	6.62 (calibration/reference source)

**NOTE:** In some cases where layering of different barrier materials are found in a shield, a build-up model should be used.

### III. SOURCE TERMS:

The sources that must be considered in the shielding plan are the doses themselves prior to injections, calibration sources that are stored on the premises, the patient after injection, the transmission sources in the scanner and the scatter and leakage radiation from the CT scanner if PET/CT is used.

### IV. SHIELDING CALCULATIONS:

Shielding calculations can conveniently be done either in a spreadsheet or with a mathematical modeling package. In outline, the sequence of steps proceeds just as in any other shielding problem:

- Obtain a scale drawing of the facility.
- Determine the expected workloads of the facility in terms of number of patients examined per day, isotope activity used per patient, and CT workload (total mAs and kVp) per patient.
- Determine the occupancies of areas within the facility and in adjacent, uncontrolled areas. Include consideration of occupancies above and below the facility in multifloor buildings. Use occupancy factors for uncontrolled areas, just as in x-ray calculations.
- Determine the location and initial activities of all isotopic sources to be considered in the calculation and the amount of time the source will be present. This includes the injected patient as a source.
- For both  $^{18}\text{F}$  (half-life=110 min) and  $^{68}\text{Ge}$  (half-life=288 days) sources, the activities must be integrated over the appropriate time periods to obtain the total dose delivered by the source.
- Calculate the total dose from all sources at test points established at the principal work areas and at points in uncontrolled areas using the source strengths, source locations, workload factors, gamma-ray dose constants, and the inverse square law. When CT scatter is included, the data from NCRP Report No. 49 should be recast into barrier transmission for these calculations. Either Spreadsheets or mathematical modeling packages can accommodate anisotropic sources in these calculations. If the calculated doses meet the protection criteria outline above, no shielding is required.
- If the protection criteria are not met, add shielding materials to barriers until they are. Be sure to consider occupied areas above and below the PET facility.

In some cases, no shielding may be required or only shadow shields in the hot lab and injection areas may be needed. In other cases, more comprehensive shielding may be necessary. PET/CT suites will require, at a minimum, the shielding (including leaded control room windows) appropriate for the CT section of the scanner.

**V. SPECIAL EQUIPMENT:**

Vendors are providing specialized equipment to reduce exposure to operating personnel in the PET center and to improve instrument performance in the higher radiation background found in the hot lab. This equipment includes:

- Dose calibrators with thick lead shielding to reduce operator exposure during the dose assay,
- Well counters with external shields to reduce background from stored doses, sources in the scanners, and calibration sources,
- Tungsten syringe shields to reduce finger dose during injection,
- Remotely actuated syringes that keep the syringe totally enclosed in a shield while the operator delivers the dose by pushing on an extension rod,
- Extra thick L-Block table-top shields (5 cm of lead compared to 1.2 cm of lead in standard nuclear medicine applications) (note that such shields may weigh 250 kg compared to 60 kg for standard nuclear medicine models), and
- Syringe carriers and sharps containers with extra shielding.

**VI. RELEASE OF RADIOACTIVE PATIENTS:**

The short half-life of  $^{18}\text{F}$  limits the dose that members of the public are likely to receive after release of the patient from the PET facility. The federal regulations governing the release of radioactive patients, 10CFR35.75<sup>23</sup>, provide for the release of individuals if it is unlikely other members of the public will be exposed to more than 5 mSv (0.5 rem) as a consequence of this action. If other individuals are likely to be exposed to more than 1 mSv (0.1 rem), then the released patient must be provided with written instructions for conduct. Instructions are also required if the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem).

**VII. CONCLUSION:**

PET facilities present somewhat different design requirements than conventional nuclear medicine departments and are more likely to require additional radiation shielding. By use of appropriated design and by maintaining good operating practices, radiation doses to staff and the public can be kept to acceptable limits.

If it is felt that additional information is needed, the Agency has many sources for additional information concerning PET Nuclear medicine. Please note that in most cases the shielding calculations may require a physicist's input. Lastly it is important to remember that most shielding requirements can be minimized by a functional layout of the nuclear medicine department and minimal sharing of exterior walls and the ceiling. A safe rule-of-thumb is 1/4 inch of lead in the affected walls surrounding the staging room and scanning room, if distances to unrestricted areas can not be maximized.

**ATTACHMENT U**

**INCREASED CONTROLS**

**I. INTRODUCTION:**

The Nuclear Regulatory Commission (NRC) has instructed all Agreement States to initiate Increased Control programs for licensees wishing to possess the quantities of radionuclides of concern listed in the Table 1 below. The Agency is authorized under §30-654(B)(13) to regulate licensees in Arizona under the federal increased control standards. At this time there are no rules incorporating the federal standards. Example uses that require increased control programs include: teletherapy, blood irradiators, and the gamma knife.

**II. RADIONUCLIDES OF CONCERN:**

**TABLE I  
RADIONUCLIDES OF CONCERN**

<b>Radionuclide</b>	<b>Quantity of Concern<sup>1</sup> (TBq)</b>	<b>Quantity of Concern<sup>2</sup> (Ci)</b>
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above <sup>3</sup> .....	( <sup>4</sup> )	.....

<sup>1</sup>The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

<sup>2</sup>The primary values used for compliance with this Order are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

<sup>3</sup>Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

<sup>4</sup>If several radionuclides are aggregated, the sum of the ratios of the activity of each source, 1 of radionuclide, n, A(i,n) to the quantity of concern for radionuclide n, Q(n), listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) (quantity of concern for radionuclide B)] + etc..... >1.

### III. BASIC ELEMENTS OF AN INCREASED CONTROL PROGRAM:

The following areas must be discussed in a description of the applicants. Increased Controls program. The program will be inspected by the Agency before licensed operations are allowed to begin.

1. How is access to the radiation sources controlled?
  - A. At the office location
  - B. In the field
2. Will unescorted access to the sources be allowed?
3. How is trustworthy and reliability determined, including employees and vendors?
4. How will radiation sources be monitored? Include detection, assessing, and responding to unauthorized access to the stored sources.
5. Will you be able to provide immediate response to all situations?
6. Has a response arrangement been made with the local law enforcement agency?
7. Is Agency notification included in the response plan?
8. Describe the records management system for documenting all program actions.
9. Describe the control plan for interfacing with third party carriers and vendors.
10. How are carriers and vendors meeting their obligations for ensuring increased controls?
11. Will increased control shipments be made outside of normal licensed activities?
12. If applicable, describe the two independent physical barriers that will prevent unauthorized removal of radioactive material during transport to and from job-sites.
13. If applicable, can the vehicle be disabled during transport? If so, describe.
14. An applicant must commit to keeping records of the increased control program for three years. Included are employee trustworthy and reliability, carrier information, and shipment information.
15. The applicant must commit to protecting sensitive information. How will this requirement be accomplished? Will the applicant limit access to certain person? Describe the limitations.
16. **Individuals having access to the radioactive material must be fingerprinted. Please describe your plan in your Increased Controls program.**

As a reminder, the application for license will not be approved until an adequate increased control program has been demonstrated to the Agency.

### IV. ADDITIONAL INFORMATION:

The Agency's licensing person has additional information on preparing an adequate Increased Control program. Should there be additional questions contact this person or see the following:

1. Using "Google" access the NRC web-site by entering NRC "increased control."
2. For additional regulatory information see the December 1, 2005, *Federal Register* (Vol. 70, No.230, pages 72128-72132).