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.

II. FILING AN APPLICATION

To apply for a license complete Form ARRA-1M. 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

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[1] 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 <u>any</u> 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**

<u>Item 6:</u> 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.**

[1]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)**
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^2; 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[2]). 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.

[2]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[3] 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 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.

[3]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.[4]

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.)

[4]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 piblic 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-2 for restricted areas and 5,000 dpm/100cm-2 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[6] 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 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 posses, 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 and copy 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